Digital Intervention (MiVacunaLA 2.0) to Promote COVID-19 Vaccine Acceptance Among Hispanic Children: Community-Based Randomized Controlled Trial

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Abstract

Background: During the early rollout of the children's COVID-19 vaccine in the United States, there were racial and ethnic vaccination rate disparities. In the Los Angeles area, Hispanic children were less likely to be COVID-19 vaccinated in comparison to non-Hispanic White children. Factors associated with lower vaccination rates among Hispanic children were misinformation and distrust on vaccine safety. Community-partnered research is a powerful tool for building community trust, countering the longstanding history of marginalization in minoritized communities, and developing community-informed approaches to improve health outcomes among vulnerable populations.

Objective: We conducted a community-based randomized controlled trial (RCT) of a digital intervention to increase COVID-19 vaccine uptake among Hispanic children. The mobile-phone delivered digital intervention was designed in collaboration with community organizations, and linguistically- and culturally-tailored to meet the informational needs of Hispanic parents and caregivers. The intervention focused on families with unvaccinated children 5 to 11 years old, but was offered to families with any unvaccinated children 17 years or younger.

Methods: We used a Difference-In-Difference (DID) model with an Intention to Treat (ITT) approach. The primary outcome was self-reported COVID-19 vaccine uptake among household children. Secondary outcomes included COVID-19 vaccine knowledge, vaccine trust, and measures of participant engagement. We conducted a sensitivity analysis using Treatment On the Treated (TOT) approach.

Results: Two hundred fifty-four participants completed the baseline survey. Participants were on average 34 years old and had an average of 2 minors in the household, with 62.2% of households reporting children ages 5-11 years old. Most participants (81.5%) reported English as their primary language, 73.6% were born in the U.S, and 77.2% completed some college or more. We found a statistically significant difference of 13.3% points (95% CI 17.6%, 38.9%; P<.05) in self-reported vaccine uptake between intervention and control groups among parents/caregivers of Hispanic children 5 to 11 years old. We also found a statistically significant difference of 14.3% points (95% CI .0%-23.7%; P<.01) between intervention and control groups in trust of the governmental approval process for the children's COVID-19 vaccine. Most participants reported the weekly digital videos and educational information were “very” or “extremely” useful (8% and 89%, respectively). We also found 53% of participants clicked thru on a provided link inviting them to make a COVID-19 vaccination appointment.

Conclusions: This RCT study demonstrates that a culturally tailored, community-based, mobile phone delivered vaccine educational intervention can effectively increase COVID-19 vaccine uptake and trust in governmental vaccine processes among Hispanic children. These findings highlight the potential of community-informed digital strategies, similar to MVLA 2.0, to enhance vaccine trust and uptake. These strategies offer a promising approach for addressing pediatric vaccination gaps across diverse communities, suggesting broader applicability and scalability in public health efforts. Clinical Trial: MiVacunaLA was registered in the NIH Clinical Trials (NCT05234372) on February 8th, 2022 at https://clinicaltrials.gov/study/NCT05234372. MiVacunaLA 2.0 RCT was approved by UCLA IRB Board (#21-000857). We also registered MiVacunaLA 2.0 RCT in the American Economic Association (AEA) RCT Registry (AEARCTR-0011339).

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Title: Digital Intervention (MiVacunaLA 2.0) to Promote COVID-19 Vaccine Acceptance Among Hispanic Children: Community-Based Randomized Controlled Trial

Abstract

Background: Early in the United States children's COVID-19 rollout, racial and ethnic vaccination rate disparities were evident. Based on COVID-19 communication literature and qualitative interviews with Hispanic parents, we developed a mobile-phone delivered digital intervention delivered to address factors associated with low vaccine confidence.

Objective: We conducted a community-based randomized controlled trial of a digital intervention called MiVacunaLA/MyShotLA to increase COVID-19 vaccine uptake among Hispanic children. The fully automated digital intervention was designed in collaboration with community organizations and linguistically- and culturally- tailored to meet informational needs of Hispanic caregivers. The intervention focused on families with unvaccinated children 5-11 years old but was offered to families with any unvaccinated children 17 years or younger.

Methods: Participants were recruited with community organization partners and trained parent ambassadors via an open online screener. The 4-week intervention consisted of three text messages with culturally- and linguistically- tailored educational information weekly. Intervention materials were delivered digitally through a closed online platform. Study team members were blinded. We used a Difference-In-Difference (DID) model with an Intention to Treat (ITT) approach. The primary outcome was self-reported COVID-19 vaccine uptake among household children questionnaires. Secondary outcomes included COVID-19 vaccine knowledge, vaccine trust questionnaires, and measures of participant engagement. We conducted a sensitivity analysis using Treatment On the Treated (TOT) approach.

Results: Two hundred fifty-four participants completed the baseline survey (128 control; 126 intervention). The average participant age was 34 years with an average of 2 minors in the household, and among households, 62.2% reporting having children ages 5-11 years old. Most participants (81.5%) reported English as their primary language. We found a statistically significant difference of 13.3% points (95% CI 0.3%, 26.4%; *P*<.05) in self-reported vaccine uptake between intervention and control groups among caregivers of Hispanic children 5-11 years old. We also found a statistically significant 14.3%-point difference (95% CI .0%-23.7%; *P*<.01) between intervention and control groups in trust of governmental approval processes for the children's COVID-19 vaccine. Most participants reported the weekly digital videos and educational information were "very" (8%) or "extremely" (89%) useful.

Conclusions: MiVacunaLA demonstrates that a culturally tailored, community-based, mobile phone delivered vaccine educational intervention can increase COVID-19 vaccine uptake among Hispanic children and improve caregivers' trust in governmental vaccine processes. MiVacunaLA is innovative in its integration of community informed design with a fully automated, mobile-phone-centric format, and builds on prior literature by prospectively evaluating a culturally tailored, text message-linked web curriculum in a community setting. Findings provide evidence that scalable, low-cost, digital strategies can measurably improve trust and uptake in a population facing persistent vaccination gaps. Real-world implications include the portability and adaptability of this approach across diverse communities and settings to support timely, community-engaged vaccination efforts for broader applicability and scalability in public health.

Trial Registration: MiVacunaLA was registered at ClinicalTrials.gov (NCT05234372) on February 8, 2022. Recruitment for MVLA 2.0 began in June 2022. This study was approved by the University of California, Los Angeles (UCLA) Institutional Review Board (#21-000857).

Keywords: COVID-19 vaccines, digital education, Latino children, health equity

Introduction

Background

During initial rollout of the COVID-19 vaccine for children ages 5 to 11 years old in the United States, children identifying as part of a racial and ethnic minority group were underrepresented among first dose recipients [1-5]. This was due, in part, to poor access to accurate information, concerns about vaccine safety and efficacy, exposure to dis/misinformation, and lack of trust in governmental vaccine processes [5-8]. Studies show parental and caregiver acceptance of COVID-19 vaccination for their children is positively associated with beliefs about vaccination benefits [9]. Improving parental and caregiver acceptance is a key public health focus given the trends in childhood vaccine uptake after the COVID-19 pandemic.

Following the pandemic, vaccination rates among U.S. kindergartners across other childhood vaccinations declined compared to prior years [10, 11]. Meanwhile, the United States has seen the resurgence of previously eliminated or highly controlled vaccine preventable diseases, such as measles-mumps-rubella (MMR) [12, 13]. While pre-pandemic vaccination rate disparities existed among subgroups [14], these trends were further exacerbated by the pandemic [15]. As such, novel interventions are needed to effectively combat misinformation, rebuild trust in vaccination benefits and safety, and engage under-vaccinated communities.

In the early stages of the COVID-19 vaccine rollout, leveraging community-engaged strategies aided in promoting vaccine confidence and addressing barriers such as language accessibility, addressing dis/misinformation, and building trust in vaccination among the Hispanic population [16, 17]. Incorporating community voices and perspectives into vaccine promotion and distribution strategies can have more meaningful impact with community members as opposed to traditional communication methods [18, 19]. Digital interventions have also increased uptake of other vaccines, such as human papillomavirus (HPV) vaccination, suggesting that community-based digital interventions might be particularly effective at increasing vaccine confidence and uptake to address recent declines in children vaccination rates [20, 21]. However, few randomized controlled trial (RCT) studies exist on the use of community-based digital interventions to improve COVID-19 vaccination rates among Hispanic children. Testing and identifying such interventions can yield critical public health and primary care approaches and lessons for responding to both current vaccine uptake disparities and future public health emergencies.

Study Objectives

This manuscript describes efforts to increase COVID-19 vaccination rates among Hispanic children ages 5-11 years old in the Los Angeles County area through a community-informed culturally and linguistically appropriate RCT. We evaluated the efficacy of a digital intervention, called MiVacunaLA/MyShotLA (MVLA) 2.0, for parents or caregivers of Hispanic children to increase COVID-19 vaccination uptake for children. We also evaluated the intervention's efficacy in increasing knowledge of COVID-19 vaccines as well as trust in the governmental approval process for the vaccine.

Methods

Intervention Content and Approach

MVLA 2.0 builds on MVLA 1.0, which was created in response to the U.S. Food and Drug Administration (FDA) approved COVID-19 vaccines for children 12-17 years old and COVID-19 communication literature [22]. The MVLA 1.0 design and implementation are described in detail elsewhere [22]. Briefly, MVLA 1.0 used a community-partnered approach to develop and distribute COVID-19 vaccine education via text messages, emails, and brief videos multiple times a week for 4 weeks. MVLA 2.0, the focus of this manuscript, began recruitment between June and August of 2022, with the intervention implemented between August and November 2022.

For MVLA 2.0, we updated and refined the digital materials to focus on vaccination of 5–11-year-olds based on parental and community partner feedback. We conducted focus groups with parents and caregivers of children between the ages of 5-11 years from MVLA 1.0 to tailor MVLA 2.0 for the 5–11-year-old age group. Detailed focus group results are reported in a separate manuscript [23] and revealed the need to adapt the intervention's educational content to address emerging COVID-19 vaccine concerns specific to children, as well as myths and misinformation [23]. Next, we collaborated with community-based organizations to conduct community sessions with parent advocates from these organizations. Participants suggested several new features to MVLA that included: 1) infographics to visually summarize weekly content, 2) voiceovers in English and Spanish of text to address literacy needs, 3) a discussion board where participants could post questions about the vaccine and have a physician respond, and 4) parent testimonials from those who had vaccinated their children. In addition, community partners identified the need for new content to address questions about emerging COVID strains. These suggestions were all incorporated into the MVLA 2.0 intervention.

For the MVLA 2.0 intervention, participants received three text messages or emails per week (Monday, Wednesday, and Thursday) inviting them to complete a specific activity. On Mondays, participants were invited to watch a relevant informational video for that week. On Wednesdays, participants were invited to visit the platform to read additional relevant educational information. On Thursdays, participants received a summary infographic of the week's material. Figures A1 and A2 (Multimedia Appendix) provide examples of the infographics we used for week 3 (English and Spanish), and Table A1 (Multimedia Appendix) provides an outline of the intervention material and activities.

To deliver MVLA 2.0, we utilized the digital infrastructure of the Understanding America Study (UAS) platform. We created a participant-only website to provide access to weekly study content. The online platform for MVLA 2.0 included all study information, a discussion board, and downloadable infographics summarizing each week's COVID-19 topic. Participants could select their preferred language (English or Spanish) to engage with the website and all study material. Please refer to Table A2 (Multimedia Appendix) for a detailed description of the MVLA 2.0 intervention topics.

Community Engagement, Recruitment, Timeline, and Other Intervention Logistics

We applied community-partnered research methods throughout the study. Recruitment involved community organization leads and a group of Parent Ambassadors— parents who completed MVLA 1.0 and expressed interest in continuing to raise awareness by aiding with recruitment for MVLA 2.0. Recruitment was conducted through public school serving organizations located in East and South Los Angeles, communities with a high proportion of Hispanic families and disproportionately lower COVID-19 vaccination rates in children and youth based on Los Angeles County Department of Public Health Data [24]. We recruited using word-of-mouth and community partner social media sites to share the project flyer within their networks. The following organizations supported recruitment efforts by sharing our study flyer: Best Start LA, Coalition for Humane Immigrant Rights of Los Angeles (CHIRLA), Communities in School, Families in School, Inner City Struggle, Great Public Schools Now, KIPP Public Charter Schools, Latino Equality Alliance (LEA), Mexican American Legal Defense and Education Fund (MALDEF), Mexican American Opportunity Foundation (MAOF), Nuestra Voz (Our Voice), and YMCA of Metropolitan

Los Angeles.

We planned to start recruitment when vaccines for children ages 5 to 11 were newly released. Therefore, we tailored the intervention to address informational needs of Hispanic parents/caregivers of children in this age group. While the intervention information was relevant across all age groups, recruitment and intervention materials focused on households with children ages 5 to 11 years as we anticipated the greatest impact among this age group. COVID-19 vaccines for children younger than 5 years old were released in June of 2022, so we updated intervention content to reflect up-to-date vaccine approval for the younger group (see Figures A1 and A2).

We recruited parents and caregivers of Hispanic minors under 18 years old who had access to a computer or cell phone to receive the intervention (inclusion criteria) via an online access open screener. Recruitment efforts were targeted to reach families with unvaccinated children 5 to 11 years old but also allowed interested families with at least one child under 18 years old to participate in the intervention. While recruitment was focused among Los Angeles County parents, participants were not excluded if they resided in other neighboring areas or were from other racial/ethnic groups (no exclusion criteria).

We ended recruitment two weeks prior to starting the intervention to allow time to randomize all participants and enter their information for receiving text messages and emails into the digital platform. Figure A3 (Multimedia Appendix) shows the intervention implementation timeline. Participants first filled out an online screening survey to determine eligibility. Qualifying participants received a text message and email inviting them to participate and directing them to the electronic consent. Upon consenting, participants were directed to the baseline survey. We did not establish specific eligibility criteria for sites or for individuals delivering the intervention, as the intervention was delivered digitally.

We used separate block randomization for cohorts, conducted by one UAS staff using STATA. Randomized participants received MVLA 2.0 either at month 1 (intervention) or at month 2 (control). We used a 1:1 allocation ratio for randomization to the intervention and control groups. All participants completed a baseline and a 1-month follow-up survey. In the first month, the intervention group received educational material for 4 weeks while the control group received a biweekly message reminding them of the number of days left until the beginning of month 2 when they were scheduled to start MiVacunaLA. After the intervention group completed the 4-week educational intervention, we sent all participants reminders twice a week for 2 weeks to complete the 1-month follow-up survey. The control group received the intervention after all groups completed the follow up survey.

All intervention materials were delivered digitally. Participants completed the intervention activities in order. If a participant did not complete an intervention activity by the end of the week, they still received content for the following week. However, when participants attempted to access the next activity, they were prompted to first complete the missed activity. Participants had the flexibility to complete all intervention activities by the end of the month, with an additional 1-week grace period before the 1-month follow-up survey became available. Once the survey was available, participants could not complete additional intervention activities.

Ethical Considerations

MiVacunaLA 2.0 was registered and approved by University of California, Los Angeles (UCLA) Institutional Review Board (#21-000857). Participants completed an online informed consent in their preferred language. Consent information was also available to participants as a PDF on the intervention platform for their reference. Participants' contact information was collected in the screening survey. A study Principal Investigator (PI) worked with UAS staff to create identifiers so that all data downloaded from the UAS platform, and subsequently used in data analysis, was de-identified. Thus, no identification of individual participants in any images of the manuscript or supplementary material is possible. Only one PI and one UAS staff member had access to participant identifiers, which were password protected in an encrypted file, as well as access to pre-trial randomization information. Study team members were blinded. After randomization, intervention and control participants started the intervention immediately (intervention arm) or in two months (wait-list control arm). Participants received a USD $40 gift card sent electronically after completing all intervention activities.

Given this was a behavioral intervention and no concomitant care was provided during the intervention, there was minimal risk, and we did not collect data regarding harms. There were no significant changes to the trial after commencement or interim analysis during the data collection phase. We added information about COVID-19 vaccines for children 6 months to 4 years old being FDA approved to the material during the design phase. During consent, participants were informed that they could decline participation at any time and could opt-out of any intervention activity they did not feel comfortable completing. In addition to the detailed information provided on the curriculum and digital approach, those interested in accessing all the educational materials and survey documents to replicate this RCT may contact the corresponding author.

Primary Outcomes

The primary outcome was self-reported vaccinating of household children in three age groups based on COVID-19 vaccine availability pre-and post-intervention. The age groups used were: 1) 6 months to 4 years, 2) 5 to 11 years, and 3) 12 to 17 years. The primary outcome was analyzed at the household level with at least one child in the specified age groups. The baseline survey asked for vaccination status for all household children. When participants confirmed a specific child's vaccination, only the status of the household's remaining non-vaccinated children were queried in the follow-up survey. We imputed the same vaccination status for the household expressed at baseline and the 1-month follow-up survey. For those with missing data, we assumed that if a household vaccinated one child in a specific age group, then the household's children in that same age group were vaccinated at follow-up.

Table A3 (Multimedia Appendix) shows the vaccination status of qualifying households with children by age groups at baseline and follow-up for all participants, regardless of loss to follow up. For those participants not completing the follow-up survey, we assumed an unchanged vaccination status provided from baseline.

Secondary Outcomes

Secondary outcomes included perceived change in COVID-19 vaccine knowledge and trust from baseline and follow-up. For vaccine knowledge, we asked participants to indicate whether the following statement was true or false: "After being fully vaccinated with the COVID-19 vaccine, your chances of being hospitalized or dying from COVID-19 are reduced at least by 90 percent if you contract the virus". We coded the variable as equal to 1 if participants answered true, and zero if they answered false or unsure. Second, we asked participants, "How would you rate your knowledge about the COVID-19 vaccine?" This variable was coded equal to 1 if participants answered adequate or superior knowledge, and equal to zero if the answer was basic, minimal, or no knowledge.

We measured vaccine trust via two separate questions: "How much do you trust the governmental approval process to ensure the COVID-19 vaccine is safe for a) the public b) children?" We coded this variable as equal to 1 for those who answered they trust government fully, mostly, or somewhat, and equal to zero if they answered they do not trust the government for each question. We also measured participant engagement with the intervention regardless of the study arm. This analysis included all participants (intervention and wait-list control groups together) who interacted with the material on the digital platform and completed at least one activity. At the end of each week, we collected information on the perceived usefulness of the weekly video and in-platform information and participants' familiarity with the information. We also tracked participants' in-platform click-thru rates of a link to the Los Angeles County Department of Public Health appointment portal for COVID-19 vaccination; whether participants downloaded infographics to share; and whether participants utilized audio files for written information and infographics sent midweek.

Statistical Analysis

We evaluated efficacy using an Intention To Treat (ITT) approach. For the ITT analysis, we imputed the vaccination status for those who did not complete the follow-up survey with the same value entered at baseline. This conservative approach assumes no behavioral change among participants who were lost to follow up. We used the same approach for the secondary outcomes.

We used a Treatment On the Treated (TOT) approach as a sensitivity analysis. For the TOT analysis, we only included participants who completed the follow-up survey, and whose vaccination status was reported at follow-up. We used a Difference-In-Difference (DID) model estimation for ITT and TOT approaches. Please refer to Table A4 (Multimedia Appendix) for a description of the DID model specification used for the statistical analysis.

To fit these models, we used a generalized linear model, using maximum likelihood estimation, with a binomial distribution and an identity link function to fit vaccination status as the dependent variable, with main fixed effects for both month (0=baseline, 1=follow-up) and intervention arm (0=control, 1=intervention), and an interaction term between month and intervention. The interaction term, defined specifically as Month x Intervention, represents the primary variable of interest and reflects the DID in the outcome variable. The models also accounted for repeated measures within the same household and utilized an unstructured correlation structure.

We ran Little's Missing Completely at Random (MCAR) test to evaluate whether our data was missing completely at random. Subsequently, for the TOT analysis, we evaluated whether statistically significant differences exist between those who completed follow-up surveys and those who did not. We then modeled the TOT data using estimated weights based on significantly different characteristics between the two groups. This approach was used to help ensure we were not overestimating efficacy based on the characteristics of those who completed follow-up surveys. We estimated a Probit model where we regressed the attrition related variable on those statistically significant variables between the two groups and created weights inverting these probabilities to estimate the intervention's efficacy on COVID-19 vaccine uptake among household children within a specific age group. This RCT was reported using the CONSORT 2025 (Consolidated Standards of Reporting Trials) checklist.

Results

Demographic Characteristics for Overall, Control, and Intervention Samples

Figure 1 presents the CONSORT diagram flow for the intervention. Based on screening survey completion and study criteria, we invited 512 qualifying participants. Among those, 310 people (60.5%) consented to participate, completed the baseline survey, and were randomized to intervention or control groups. From those who consented and completed the initial baseline survey, we excluded 56 participants who reported no household minors in their baseline responses, which conflicted with their screener responses. Of the remaining 254 parents and caregivers in the baseline sample (126 and 128 participants in intervention and control groups, respectively), we had 216 participants who completed the 1-month follow-up survey (99 and 117 participants in intervention and control groups, respectively) with a retention rate of 85%. We had 17% missing data for the primary outcome, or vaccine uptake. Of those, we imputed N=37, for a total analytical sample of N=247 (see Table 2). We had 4% missing data for secondary outcomes, or vaccine knowledge and trust. Our total analytic sample for secondary outcomes was N=243 (see Table 3).

Table 1 provides baseline demographic characteristics for the full sample and for control and intervention groups separately. The sample includes 254 participants with a household minor recruited at baseline. Most participants were Hispanic (93%) and completed the intervention in English (81%). Most participants had some college education or more (77%), were employed (79%), and over half (59%) had an annual household income greater than $50,000. Just over half had children aged 5 to 11 years (62%), and about one-third had children aged 12 to 17 years (36%). The average age of parents/caregivers was 34 years old and the average number of children in the household was 2. We evaluated whether differences in participant characteristics between study arms were statistically significant using a t-test.

Table 1. Baseline demographic characteristics by overall, control, and intervention samples

Characteristic	Overall (N=254)[a]	Control (N=128)	Intervention (N=126)	p-value[b]
Age of parent, mean (SD)[c]	33.8 (6.3)	33.7 (6.2)	33.9 (6.4)	0.6777
Number of minors in household, mean (SD)	1.7 (0.8)	1.7 (0.9)	1.6 (0.7)	0.8239
Language, n (%)				
English	207 (81.5)	102 (79.7)	105 (83.3)	0.4544
Spanish	47 (18.5)	26 (20.3)	21 (16.7)	
Parent COVID-19 vaccination status, n (%)				
Vaccinated	95 (37.4)	51 (39.8)	44 (34.9)	
Not vaccinated	155 (61.0)	76 (59.4)	79 (62.7)	0.3125
Unsure/Missing	4 (1.6)	1 (0.8)	3 (2.4)	
Ethnicity, n (%)				
Not Hispanic/Spanish origin or Missing	24 (9.4)	11 (8.6)	13 (10.3)	0.8942

Mexican/Mexican American/Chicano	152 (59.8)	79 (61.7)	73 (57.9)	
Other Hispanic/Spanish origin[d]	78 (30.7)	38 (29.7)	40 (31.8)	
Born in the United States, n (%)				
Yes	187 (73.6)	99 (77.3)	88 (69.8)	
No	52 (20.5)	25 (19.5)	27 (21.4)	0.1763
Prefer not to respond/Did not respond	15 (5.9)	4 (3.1)	11 (8.7)	
Highest education attained, n (%)				
Some high school or less	22 (8.7)	11 (8.6)	11 (8.7)	
High school graduate/GED	30 (11.8)	15 (11.7)	15 (11.9)	
Some college or more	196 (77.2)	100 (78.1)	96 (76.2)	0.9915
Missing	6 (2.4)	2 (1.6)	4 (3.2)	
Employment status, n (%)				
Employed	202 (79.5)	107 (83.6)	95 (75.4)	
Unemployed	8 (3.2)	3 (2.3)	5 (4.0)	0.1041
Other[e]	44 (17.3)	18 (14.1)	26 (20.6)	
Household income, n (%)				

< $25,000	51 (20.1)	23 (18.0)	28 (22.2)	
$25,000 - $49,000	46 (18.1)	25 (19.5)	21 (16.7)	0.6350
> $50,000	150 (59.1)	77 (60.2)	73 (57.9)	
Missing	7 (2.8)	3 (2.3)	4 (3.2)	
Health insurance status, n (%)				
Insured[f]	227 (89.4)	115 (89.8)	112 (88.9)	0.2362
Not insured/Don't know	27 (10.6)	13 (10.2)	14 (11.1)	
Marital status, n (%)				
Currently Married	203 (79.9)	105 (82.0)	98 (77.8)	
Widowed/Divorced/Separated	20 (7.9)	9 (7.0)	11 (8.7)	0.4035
Never Married	20 (7.9)	8 (6.3)	12 (9.5)	
Other[g]	11 (4.3)	6 (4.7)	5 (4.0)	
Type of household, n (%)				
Married with Children	207(81.5)	107 (83.6)	100 (79.4)	
Single/Married Without Children	7 (2.8)	2 (1.6)	5 (4.0)	0.6133
Single with Children	16 (6.3)	9 (7.0)	7 (5.6)	

Other[h]	24 (9.4)	10 (7.8)	14 (11.1)	
Any minors in household under 6 months, n (%)				
Yes[i]	8 (3.1)	5 (3.9)	3 (2.4)	0.7222
Any minors in household 6 months-4 years, n (%)				
Yes[i]	105 (41.3)	51 (39.8)	54 (42.9)	0.6258
Any minors in household 5-11 years, n (%)				
Yes[i]	158 (62.2)	87 (68.0)	71 (56.4)	0.0562
Any minors in household 12-17 years, n (%)				
Yes[i]	92 (36.2)	44 (34.4)	48 (38.1)	0.5374

[a] Excludes n=56 who reported no minors in their household at baseline.
[b] p-value from chi-square tests (or Fisher's exact tests, when appropriate) for categorical variables and Wilcoxon tests for continuous variables.
[c] Control group: N=125 parents had non-missing age; intervention group: N=117 had non-missing age.
[d] Includes: Puerto Rican, Cuban, multiple ethnicities, and "Other"
[e] Includes: Housekeeper, Retired, Disabled, Temporary Employment, Student, and "Other"
[f] Includes: Government insurance, insurance through the VA, private insurance, Medicare
[g] Includes: Missing, cohabitation (common law marriage)
[h] Includes: Don't know, Prefer not to respond, Missing, and "Other"
[i] All other participants indicated "No"

There were no statistically significant differences between intervention and control groups in demographic characteristics. Table A3 shows more intervention versus control households indicated at least one minor 5 to 11 years old in their household (22.5% versus 19.5%) was vaccinated at baseline, while fewer intervention versus control households reported having at least one minor vaccinated at baseline in other age groups (5.6% versus 13.7% for minors 6 months to 4 years; 27.1% versus 34.1% for minors 12 to 17 years old).

Table A5 (Multimedia Appendix) shows demographic characteristics at baseline for those completing the follow-up survey (85%) and those who did not (15%). Most significant demographic characteristics were associated with follow-up survey completion. Those who completed the follow-up survey were more likely to be unvaccinated, Hispanic, employed, U.S. born, currently married or cohabitating, younger, with a smaller number of children at baseline. They were also more likely to have higher educational attainment and a household income greater than $50,000. See discussion on Table A5 about weights considered for TOT estimation related to significant differences between follow-up completers and non-completers.

DID Model with ITT Approach

Estimates from the DID model using the ITT approach for the primary outcomes related to vaccination are shown in Table 2 for households with children in each age group individually and all together. Table 2 shows vaccination status estimates for control and intervention groups at baseline and at follow-up in the regression analysis setting, alongside estimates of the difference within and between groups at pre- and post-intervention. The control and intervention groups had overall baseline vaccination rates of 25.7% and 15.7%, respectively. At follow-up overall vaccination rates were 44.2% and 48.4%, respectively, among these groups. The estimate of interest in Table 2 is the DID estimate shown as “difference.” We found a statistically significant difference between intervention and control groups of 13.3% points (95% CI 0.3%, 26.4%; *P*<.05) among children 5-11 years old in change from pre- to post-intervention. We do not find a significant DID for other age groups. Given ITT as the conservative estimate of intervention efficacy, we concluded the intervention had a positive effect on COVID-19 vaccine uptake among the primary target group for this intervention, children 5-11 years old.

Table 2. DID regression estimates for primary outcomes with ITT approach: vaccination status (N=247)[a]

	Baseline	1-month follow-up	Change Δ (95% CI)	P
6 months-4 years[b], (%)				
Control	13.8%	31.4%	17.6% (7.0%, 28.2%)	0.0011
Intervention	5.5%	27.8%	22.3% (11.1%, 33.5%)	<.0001
Difference			4.7% (-10.7%, 20.1%)	0.5521
5-11 years[b], (%)				
Control	19.5%	34.5%	14.9% (7.5%, 22.4%)	<.0001

Intervention	22.4%	50.7%	28.3% (17.6%, 38.9%)	<.0001
Difference			13.3% (0.3%, 26.4%)	0.0448
12-17 years[b], (%)				
Control	34.1%	50.0%	15.9% (5.1%, 26.7%)	0.0039
Intervention	27.1%	47.9%	20.8% (9.3%, 32.3%)	0.0004
Difference			4.9% (-10.9%, 20.7%)	0.5406
All ages[b], (%)				
Control	26.6%	43.6%	16.9% (10.3%, 23.6%)	<.0001
Intervention	21.9%	46.3%	24.4% (16.8%, 32.1%)	<.0001
Difference			7.5% (-2.6%, 17.7%)	0.1468

[a] Simple (unadjusted) difference-in-differences of vaccination of minors in household. Rates of vaccination are among those participants who indicated having at least 1 minor in the household within that age range and assumes that anyone missing a 1-month follow-up had minors that remained unvaccinated. For those who reported a minor was vaccinated at baseline (and thus were not asked the vaccination questing at 1-month), we imputed the "yes" value to the 1-month follow-up given that question is not asked again at follow-up for this group. Model estimated using a generalized linear model and maximum likelihood estimates.
[b] Sample sizes for each age group are: N=105 households for 6 months-4 years; N=158 households for 5 to 11 years; N=92 households for 12-17 years.

Estimates of the DID model with the ITT approach for secondary outcomes related to vaccine knowledge and trust are shown in Table 3. We found a statistically significant difference between intervention and control group of 14.3% points (95% CI 5.0%-23.7%; *P*<.01) pre-intervention to post-intervention for trust of governmental approval process to ensure COVID-19 vaccine is safe for children. We do not find significant effects of the intervention on other secondary outcomes.

Table 3. DID regression estimates for secondary outcomes with ITT approach: vaccine knowledge and trust (N=243)[a]

	Baseline	1-Month Follow-up	Change Δ (95% CI)	P
…chances of being hospitalized or dying from COVID-19…[b]				
Control	52.9%	65.1%	12.2% (3.6%-20.8%)	0.0055
Intervention	50.0%	65.1%	15.0% (5.9%-24.1%)	0.0013
Difference			2.8% (-9.8%-15.4%)	0.6614
…rate knowledge about COVID-19 vaccine…[c]				
Control	25.2%	43.1%	17.9% (8.9%-26.9%)	0.0001
Intervention	30.8%	56.7%	25.8% (15.9%-35.8%)	<.0001
Difference			8.0% (-5.5%-21.4%)	0.2458
…trust governmental approval process… for public…[d]				
Control	81.3%	89.4%	8.1% (1.9%-14.3%)	0.0103
Intervention	74.2%	90.0%	15.8% (9.3%-22.4%)	<.0001
Difference			7.7% (-1.3%-16.7%)	0.0939
…trust governmental approval process… for children…[d]				
Control	78.9%	85.4%	6.5% (0.7%-12.4%)	0.0293

Intervention	66.7%	87.5%	20.8% (13.6%-28.1%)	<.0001
Difference			14.3% (5.0%-23.7%)	0.0026

[a] Simple (unadjusted) difference-in-differences of knowledge and trust. Rates are among those participants who indicated having at least 1 minor in the household and assumes that anyone missing a 1-month follow-up did not change in their trust and knowledge from baseline. Model estimated using a generalized linear model and maximum likelihood estimates.
[b] Variable coded equal to 1 if true, equal to zero if false/unsure.
[c] Variable coded equal to 1 if adequate/superior knowledge, equal to zero if no/minimal/basic knowledge.
[d] Variable coded equal to 1 if fully/mostly/somewhat trust, equal to zero if do not trust.

Participant Engagement

Table A6 (Multimedia Appendix) shows most participants (84 to 89%) found the video (provided on Monday) and educational information (provided on Wednesday) very/extremely useful. Materials in weeks 1 and 4 had the highest percentages of participants expressing material was very or extremely useful (89%). When asked about familiarity with that week's provided information, about half of participants responded they were very/extremely familiar (41% to 53%), with week 1 information showing the lowest percentage of participants responding being very/extremely familiar with information (41%).

Table A7 (Multimedia Appendix) summarizes participant engagement data. More than half of participants clicked the specific link for making a COVID-19 vaccination appointment each week (47% to 58%). Among those who completed that week's activity, 89% to 90% of participants clicked to download the summary infographic to save/share. A large share of participants listened to the audio files from the written information sent on Wednesdays (66%) and the summary infographic sent on Thursdays (54%).

Sensitivity Analysis

A TOT sensitivity analysis with DID model estimation was used. Table A8 (Multimedia Appendix) presents estimates from the DID model for the primary vaccination outcome, both for individual age groups and collectively. The analysis revealed an 18.6 percentage point difference (95% CL) in vaccination uptake for children ages 5-11 years in the intervention group compared to controls (p=0.02), and a 12.1 percentage point increase when considering all age groups (p=0.04). Little's MCAR test found evidence that data was not MCAR (p<.01). Weighted estimates from the DID model, which account for statistically significant differences between participants who completed the follow-up survey and those who did not, are provided in Table A9 (Multimedia Appendix). These weighted TOT estimates for children ages 5-11 years and the overall sample closely align with the unweighted estimated, showing increases of 20.1 percentage points (of p=0.01) and 12.2 percentage points (p=0.04), respectively.

Similarly, TOT analyses of secondary outcomes related to vaccine knowledge and trust (Tables A10 and A11, Multimedia Appendix) are consistent with the ITT results. Specifically, we found a larger increase in trust in the governmental approval process for children post-intervention, with TOT unweighted and weighted estimates showing differences of 18.8 and 20.1 percentage points (p=0.01), respectively. Additionally, these tables indicate a significant difference of 10.8 and 10.6 percentage points (p=0.05) in government approval processes for the public for unweighted and weighted TOT analyses. Detailed estimates using the TOT approach with DID model are in Tables A8 to A11.

Discussion

In this study, we examined whether a community-based digital intervention could increase COVID-19 vaccination rates and trust in the governmental approval process to ensure vaccine safety in children ages 5-11 years. MVLA 2.0 significantly increased COVID-19 vaccine uptake in children ages 5-11 years and trust in the COVID-19 vaccine governmental approval processes for children. The MVLA 2.0 digital intervention demonstrated a comparable effect on vaccine uptake as compared to the magnitude of effect observed in another such COVID-19 specific digital intervention [25], which found an adjusted absolute difference of 11.9 [95% CL, 4.5-19.3] percentage points in their 1-week intervention conducting during emergency room visits. Electronic Health Record (EHR) approaches typically used in broader immunization efforts have demonstrated effect sizes between 4.2% (adjusted) to 7% (P=0.05) [26, 27]. These findings offer new insights into the role of community-informed and culturally tailored digital strategies, such as MVLA 2.0, in increasing trust in vaccines and improving vaccination rates. Furthermore, this digital intervention demonstrated the potential for scaling across diverse communities to address other pediatric vaccination gaps.

MVLA 2.0 intervention impact appears to reflect a combination of delivery, cultural tailoring, and user-centered design. Although we cannot rule out selection or reporting bias as contributors to the observed effects, interviews from MVLA 1.0 participants suggest several components were likely impactful [23]. These included digitally accessible text-messaging delivering a web-based curriculum, with written educational content and videos reinforcing weekly material content over time. We also incorporated culturally tailored, real-time feedback to address parental concerns about COVID-19 vaccinations in 5–11-year-olds and counter misinformation, disinformation, and myths prevalent in the

Hispanic community. Finally, we applied user-centered design features such as a discussion board and voice-overs for written content to enhance engagement, accessibility, and adherence.

While some progress for COVID-19 vaccination was made during the pandemic within the Hispanic community, trends in overall vaccinations remain low. Further, national estimates on intent to get a COVD-19 vaccine among Hispanic groups have dropped from 18.6% to 11.4% between September 2024 and January 2025, [28]. Perhaps more concerning, is post-pandemic decline in uptake of other childhood vaccines [2]. In California, where this intervention was conducted, statewide estimates on unvaccinated Hispanics identified have increased nearly 5% in the four-month period between end of September 2024 (15.7%) and end of January 2025 (19.2%) alone [28]. A January 2025 article received media coverage over its analysis of 2019-2022 vaccination data showing an overall decline in MMR and DTaP vaccination rates across 11 states and, more worrisome, that three of those states had MMR statewide rates below herd immunity and broadly vulnerable to an outbreak [29]. Just weeks after this data was published, also widely reported, Texas experienced its largest measles outbreak in three decades with the first U.S. mortality from measles in a decade, and the first pediatric mortality in two decades [30].

Additionally, there are concerns many of the impediments to COVID vaccination are similarly involved with the more recent downward trends in vaccination elsewhere, and some initial evidence to suggest these concerns may be warranted [31]. Because the MVLA 2.0 intervention was designed to be digital and culturally tailored, this model may have the potential for scaling across diverse communities to address other pediatric vaccination gaps. Future research is needed to explore the use of digital culturally tailored interventions such as MVLA 2.0 more broadly, as a cost-effective strategy to improve vaccination rates and reduce disparities in under-vaccination for children.

Both intervention and control groups showed an increase in knowledge post intervention. Although the magnitude of this increase was not significantly different between groups for most outcomes, this study showed a significant intervention effect for increasing trust regarding the governmental approval process of the COVID-19 vaccine for children. A recent systematic review reported that health concerns, vaccine attributes, and mistrust were primary divers of COVID-19 vaccine hesitancy, whereas trust and confidence, community and social factors, and demographics and identity were key factors associated with vaccine uptake [32]. Taken at the aggregate, these broader trends in vaccine hesitancy and the associated underlying causes reinforce the need for additional research into broad-based, easily disseminated multi-factorial approaches to improve vaccine confidence.

Approaches like the mobile-phone centric format used in MVLA 2.0, may help promote vaccine acceptance, especially given the near-ubiquity of cellphone and smartphone ownership. According to the Pew Research Center, 98% of Americans own some kind of cellphone, and 91% some kind of smartphone. The penetration of ownership/type of usage is relatively high regardless of income (95% and 84% respectively those making under $30,000/yr) or ethnicity (97%/87% Black, 99%/93% Hispanic) and even age (94%/79% for those over 65) [33]. Further, considerable support can be found in the literature for adopting digital, mobile-based interventions to change health behaviors including immunization among adolescents [34], influenza vaccination among pediatric Hispanic patients in low-income urban areas [35], increasing HPV vaccine uptake among underserved high-risk populations [36], as well as culturally specific vaccine education to combat misinformation and improve vaccination behaviors [35, 37-45]. Prior studies have recognized the ease of implementation as a benefit of mobile phone-delivered text-based interventions [35, 37-52].

Study Limitations and Suggested Future Work

This study has some limitations. We used self-reported vaccination status, which is subject to over or under reporting. Parents may have over-reported vaccination due to social desirability bias, particularly after participating in a pro-vaccine educational intervention. The lack of objective verification through medical records or vaccination databases tempers confidence in the primary findings. However, the target population for this intervention may be less likely to provide official records due to concerns with immigration and documentation status. Thus, building trust to ensure the collection of official vaccination records for future digital vaccine acceptance interventions is key.

Lower baseline vaccination rates in the intervention group may overestimate efficacy. Due to a 15% attrition rate and systematic differences between completers and non-completers, the ITT analysis may be compromised, despite attempts to adjust for these differences using weighting in the TOT analysis. The assumption that vaccinating one child in an age group translates to all children in that household being vaccinated for those with missing data could lead to inflated effect sizes. In this study, individual children in a household did not have unique IDs and therefore we were unable to link responses between baseline and follow up. Thus, future work should aim to analyze vaccination uptake at the individual level. Furthermore, confidence intervals in our results were wide in relation to our primary (vaccination status of children 5 to 11 years old) and secondary outcome (trust in the government process for the approval of COVID-19 vaccines for children). This variability may suggest that estimates of intervention effect lack precision, likely explained by the small sample size. Thus, future studies warrant a larger sample size to provide a more precise estimate of the efficacy of a digital intervention on vaccine uptake and trust.

While a strength of this study included utilizing a community-based approach to recruit populations typically “under-represented” in research, this also may limit the generalizability of our findings. We recruited primarily among participants already engaged with community organizations and willing to participate in vaccine research, which could create selection bias. This population could differ systematically from the broader Hispanic community in terms of health engagement, technology access, and baseline vaccine attitudes. Second, most participants completed the intervention in English so results may not generalize to households who prefer to communicate in Spanish. Interestingly, when MVLA 1.0 79% of participants completed the intervention in Spanish [22]. This shift in language predominance might be explained by differences in the community partner organizations engaged in MVLA 2.0 and the populations they serve. Third, there may have been a bias in participants willing to be screened for eligibility to participate. Future digital intervention studies should work closely with community organizations to incorporate a screening method where the community organization can confirm participants are affiliated with their organization to improve recruitment tracking.

Future directions for vaccine interventions should emphasize the development of culturally tailored community-based digital strategies to build trust in vaccines. This includes actively engaging with community leaders and advocates to ensure interventions are relevant and resonate with the target population. Addressing misinformation could involve using mobile platforms to provide accurate, accessible information and counteract false narratives in the same modality in which they are being disseminated. Additionally, improving vaccination behaviors might be achieved by integrating behavioral insights to identify and overcome specific barriers to vaccination within the community. Scaling these strategies to diverse populations is critical to address the challenge of decreasing vaccination rates.

Conclusions

The findings from this RCT evaluating MVLA 2.0, a culturally tailored, community-based, mobile-phone-delivered intervention, demonstrate increased parental trust in the governmental process and higher COVID-19 vaccine uptake among Hispanic children. This study is innovative in combining community-informed content, real-time culturally tailored feedback, and a fully automated, mobile phone–centric delivery model. It adds to existing literature by prospectively testing a culturally tailored digital curriculum in a community setting and showing improvements in both uptake and trust. These findings provide rigorous evidence that scalable, low-cost digital strategies can address vaccine confidence and uptake in populations with persistent gaps. Real-world implications include the portability and adaptability of this approach across diverse communities and settings—urban or rural—and its feasibility and potential for broader applicability and scalability to support public health vaccination campaigns.

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Data Availability

The datasets generated and analyzed during this study are not publicly available to protect patient confidentiality. De-identified data, study protocol and statistical analysis plan may be accessed upon request to the corresponding author and Institutional Review Board approval.

Author Contributions

Conceptualization LB, YCL; methodology LB, AK, RLC, EA, BW, MM, YCL ; software LB, AK, BW, MM, YCL; validation LB, AK, RD, KN, YCL; writing—original draft preparation LB, AK, RD, DM, RLC, EA, BW, MM, KN, YCL; writing—review and editing LB, AK, RD, DM, RLC, EA, BW, MM, KN, YCL; visualization LB, AK, YCL; supervision LB, YCL; project administration LB, DM, BW, MM, YCL; funding acquisition LB, RD, RLC, EA, KN, YCL. All authors have read and agreed to the published version of the manuscript.

We certify that no artificial intelligence (AI) tools, were used in the writing, editing, or preparation of any portion of this manuscript. All content, including text, figures, and tables was created by the authors without the use of AI.

Conflict of Interest

None declared.

Abbreviations

DID: Difference in Difference

HPV: Human Papillomavirus

ITT: Intention to Treat

MCAR: Missing Completely at Random

MMR: Measles-mumps-rubella

MVLA: MiVacunaLA/MyShotLA

PI: Principal Investigator

RCT: Randomized Controlled Trial

TOT: Treatment on the Treated

UAS: Understanding America Survey

UCLA: University of California, Los Angeles

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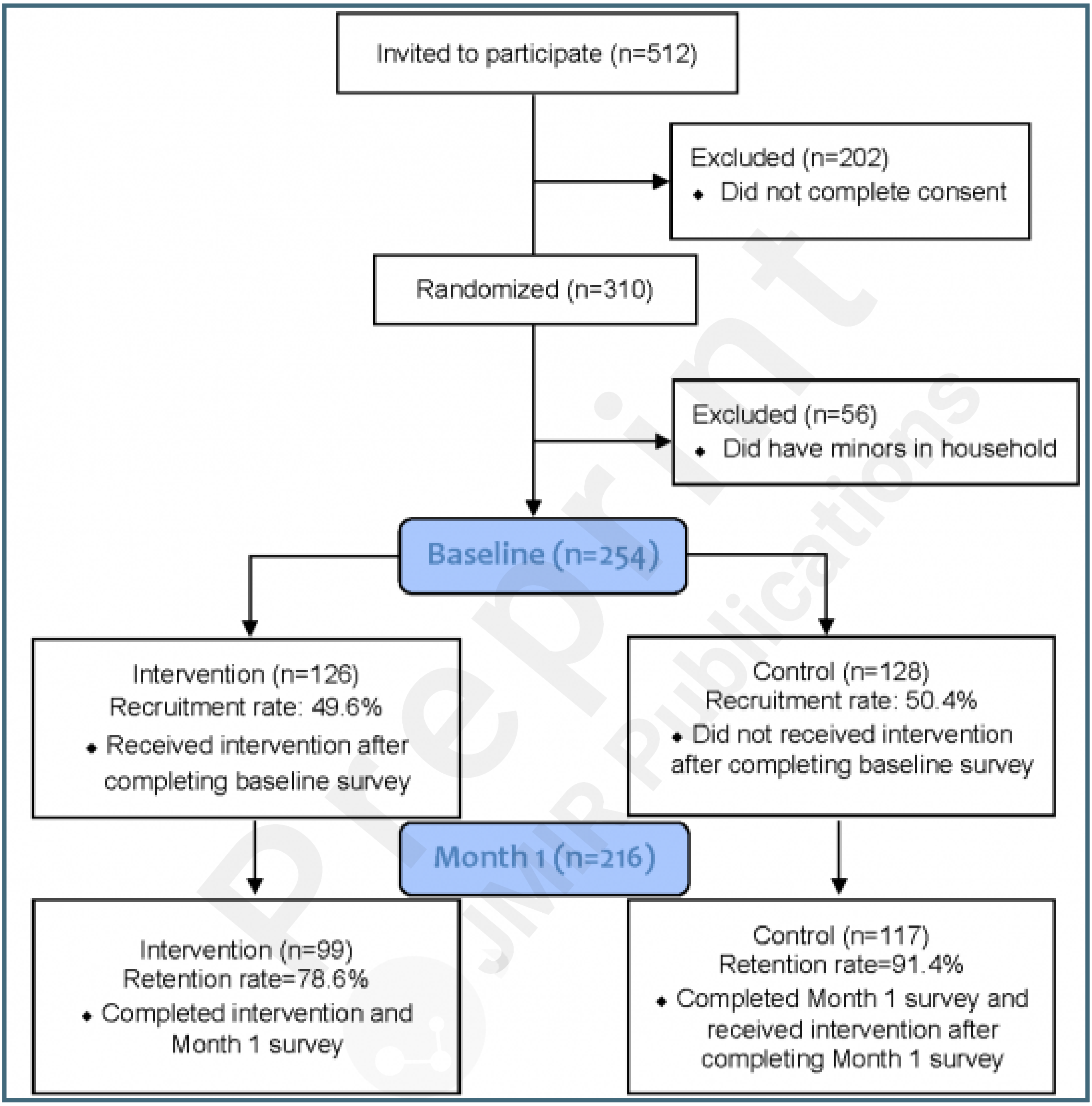
Supplementary Files

Figures

Flow of the participants in MiVacunaLA 2.0 randomized controlled trial.



Multimedia Appendixes

Supplementary figures and tables.
URL: http://asset.jmir.pub/assets/55ccd01340d590173132755fff80acd9.pdf

CONSORT (or other) checklists

CONSORT 2025 Checklist.
URL: http://asset.jmir.pub/assets/80b40aeb7faa396902fa0e6064229a69.pdf

CONSORT E-HEALTH CHECKLIST.
URL: http://asset.jmir.pub/assets/d9cf15b74ebaa635d280fa3f8654284c.pdf