

Study Title: Improving pediatric COVID-19 vaccine uptake using an mHealth tool: a randomized, controlled trial

Site Investigator: <insert name & title>

Institution: <Insert local institution name>

Sponsor: ISPCTN DCOC

Support: NIH

Key Information

Improving pediatric COVID-19 vaccine uptake using an mHealth tool: a randomized, controlled trial

We are asking if you want to volunteer for a research study to learn how parents want to get information about COVID-19 vaccines for their children. The research study uses a mobile device application (app) on your phone or tablet. The COVID-19 vaccine protects against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), commonly called COVID-19.

Please ask the site research team if you have any questions about anything in this form. If you have questions later, contact the person in charge of the study. Their contact information is at the end of this form.

What will happen if I join the study?

If you join the study, you will be asked to download and use a free mobile study app that will either give information about the COVID-19 vaccine or about children's health in general. The study will last 24 weeks. During the first 8 of the 24 weeks, you will receive app notifications once or twice a week that will take a few seconds to a few minutes to read and respond to. During the last 16 of the 24 weeks you will receive one monthly notification. We will ask you to complete a total of four surveys during the study. This should take about 10 minutes to finish each survey.

Do I have to join this study?

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decided not to join. If you decide to take part in the study, it should be because you want to volunteer.

What do I need to know to decide if I should join this study?

People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to join this study.

Main reasons to join the study

- You might learn new information about the COVID-19 vaccine or children's health in general.
- The results of this study could help determine how best to share child health information with parents in the future.

Main reasons not to join the study

- There is a risk that someone could find out that you are in the study. The study team will know how often you use this app but will not see any other information about how you use your phone or the web. We will do everything we can to protect your privacy and the privacy of your study information.
- You may view and answer questions about the COVID-19 pandemic that may cause some emotional stress or anxiety related to the pandemic and/or COVID-19 vaccination.

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Other consideration:

- The app could recommend the COVID-19 vaccine while it is still available under the US Food and Drug Administration (FDA) emergency use authorization (EUA) rather than FDA approval.
- You will see guidelines that are the same as the most current recommendations from the Centers for Disease Control and Prevention (CDC). These guidelines could change, and we will immediately revise these guidelines in the app.

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the site research or study teams if you decide that you do not want to be in the study. Remember, it is okay to say no. You can still get your medical care from *[local clinic]* if you are not in the study.

<Insert local Institution name>

Informed Consent Form

- We are asking you to be in a research study. You do not have to join the study.**
- You can still get your medical care from <Insert clinic name> even if you are not in the study.**
- Take as much time as you need to read this form and decide what is right for you.**

When we say “you” and “your” we are talking about the person who takes part in the research and/or their child/children.

1. Why are you asking me to be in this research study?

- We want to learn if a mobile app is a good way to help parents make decisions about vaccinating their children against COVID-19.
- We are looking for parents/caregivers with children that:
 - are at least 6 months of age and less than the age of majority (18 years in most states), and
 - are eligible for COVID-19 vaccination, and
 - have not received the COVID-19 vaccination.
- We will ask about 892 people and their children from across the US to be part of the study.
- Your child is not required to receive the vaccine as part of the study.

2. What do I do if I don't understand something?

- This form may have words that you do not understand. If you would like, a site research team member will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.
- If you decide to take part in the study, it should be because you want to volunteer.

3. What will happen if I say yes, I want to be in this study?

- a. We will ask you to complete a survey that will ask for your name and contact information; and for your child's name, race/ethnicity, sex, primary care doctor, and birthday.

Next, we will randomly put you in one of two groups with different kinds of health information. The chance of being in either group is like the chances of getting either heads or tails when you flip a coin.

For both apps:

- You will see guidelines that are the same as the most current recommendations from the Centers for Disease Control and Prevention (CDC). These guidelines could change, and we will immediately revise these guidelines in the app.
- The app could recommend the COVID-19 vaccine while it is still available under the US Food and Drug Administration (FDA) emergency use authorization (EUA) rather than FDA approval.
- Both apps are free. You do not have to pay for them.

b. After you are placed in a group, we will send you an email with a link and instructions for downloading the study app and registering on the study app. If you need technical assistance, one of the team members will be happy to contact you and help you. Registration should only take a few minutes.

c. If you did not complete the registration for study app within one week, we will contact you via telephone, email, or video conference to confirm the completion of app registration.

d. After you register on the app, we will email you a survey with questions about the COVID-19 vaccine and about your household. This should take about 10 minutes to finish.

e. Once a week, for the first 8 weeks, we will send you notifications through the app that ask you to read and/or interact with information in the app. Then, we will send you 1 notification per month for 2 months.

f. It will only take a few minutes to read and interact with the information. Every time you open and use the app, the activity will be recorded and tracked. The app will not record anything else that you do on your device or about what happens on your device.

g. At the end of the first 8 weeks, we will email you a survey with few questions about how easy the app was to use, whether your contact information has changed, and whether anyone in your family received a COVID-19 vaccine. If your child has received the vaccine, we will ask you to upload a picture of your child's vaccination card to the survey. These questions should only take a few minutes.

h. At the end of the 16 weeks, we will send you a survey that asks you If your child has received the COVID-19 vaccine and to upload a picture of your child's vaccination card. We will also ask you a few other questions about the COVID-19 vaccine and your household.

i. At the end of 24 weeks, we will send you a final survey to ask you to send us a picture of your child's vaccination card.

j. If we do not receive a picture of your child's vaccination card, we will look at your child's medical record or the state immunization registry to see if your child has received the COVID-19 vaccine. We will record if your child has or has not received a COVID-19 vaccination. We will not record any other information about your child from the medical

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record or vaccination registry. To access your child's information on the state vaccination registry, we may need to ask you for <insert site specific information needed (examples DOB, SSN, name or others>. We will not keep this information and will only use it to access your child's COVID-19 vaccination information on the state registry.

- k. If you change or lose your phone or change operating system, please contact the research team for help.
- l. As soon as the study is completed, the application on your phone will be deactivated.

4. How long will I be in this study?

- You will be in the study for 24 weeks.

5. What if I say no, I do not want to be in this study?

- Nothing bad will happen if you choose not to participate.
- You can still get medical care at <insert local institution name or clinic name>.

6. What happens if I say yes but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at <insert local institution name or clinic name>.
- If you decide to stop being in the study, please contact, <insert research coordinator name and contact information>.

7. Will it cost me anything to be in the study?

- The study will not cost you anything.

8. Will you pay me for being in the study?

- You will receive \$20.00 when you complete the first survey (described in 3d), \$20.00 when you complete the second survey (described in 3g), \$20.00 when you complete the third survey (described in 3h), and \$20.00 when you complete the last survey at the end of the study (described in 3i). The total compensation that you may receive is \$80.00. <insert site specific modality of payment>.
- If you change your mind and decide not to be part of the study, you will only be paid for the parts of the study you complete.
- If you get more than \$600 in one year (January-December) from <insert local institution name>, we may send you a tax form if the law requires it.

9. Will being in this study help me and my child in any way?

- You might learn new information about the COVID-19 vaccine or about children's general health.

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- The information the study team collects might help families in the future.

10. What are the risks of being in this study?

- There is a risk that someone could find out that you are in the study. The study team will know how often you use this app but will not see any other information about how you use your phone, tablet, or the internet. We will do everything we can to protect your and your child privacy.
- You may view and answer questions about the COVID-19 pandemic that may cause some emotional stress or anxiety related to the pandemic and/or the COVID-19 vaccination.

11. What are the alternatives to being in this study?

- You do not have to be in this study. Nothing about your medical care will change if you choose not to be in the study.

12. Can I be taken out of the study even if I want to continue?

- Yes, you will be taken out of the study if:
 - The site research team or the overall study team decide it is not in your best interest to continue.
 - the study is stopped for any reason.

13. What information will you collect about me and my child in the study?

- This information is described in detail in question 3. We will collect your contact information, thoughts about COVID-19 vaccines, your household's COVID-19 infection situation, if your child received the COVID-19 vaccine, and personal characteristics like age, race/ethnicity, and what kind of community you live in.

14. Who will see this information? How will you keep it private?

- The site research team will know your name and have access to your and your child's information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will send your information to the lead study team for the IDeA States Pediatric Clinical Trials Network (ISPCTN) (study sponsor) at the University of Arkansas for Medical Science (UAMS). This information may include protected health information, such as birth date.
- We will take your name off study information that we collect during the study. We will give this information a code so that no one can identify you. Only the study team will be able to link your identity to the code.
- When we share the results of the study, we will not include your name or anything else that could identify you.

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- There are people who make sure the study runs the right way. These people may see information that identifies you. They are:
 - National Institutes of Health (NIH)
 - ISPCTN Data Coordinating and Operations Center (DCOC)
 - OHRP (Office for Human Research Protections), a federal agency
 - Members of the UAMS Institutional Review Board (IRB) and other institutional oversight offices
 - Study monitor
 - Members of the <insert local institution name> IRB
 - Overall study Principal Investigator (PI)
 - <site Investigator name>

Only the investigator and people who make sure we do research the right way, like the UAMS IRB and the federal Office for Human Research Protections, will be able to see the study information and other information listed above. The authorization to use this health information does not expire.

We think everyone involved with research understands how important it is to keep your/your child health information private but people outside of <insert Local Institution Name> may not have to follow the same laws <insert Local Institution Name> follows to protect your/your child health information.

If you would like to withdraw your permission to use this information, you must send a letter with the name of the project and telling us not to use your study information to: (Study contact and mailing address).

15. Where and how long will you keep my information?

- Your information will be labeled with a code, and we will limit access to the code. We will only allow people who must have access to see your information.
- Only the site study team will be able to link research information to you.

16. If I stop being in the study, what will happen to my information collected in the study?

- We will not be able to take your information out of the study after it has started.

17. Will you use my information from the study for anything else, including future research?

- Yes. The NIH funds this study, and its policies require us to make all de-identified information available to the public. Because other researchers cannot connect this information to you, they can use this information for future research without getting additional consent from you.

18. Will you tell me the results of the study?

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- We will not contact you individually about what we find. However, we will publish the results in an academic journal and provide a summary of the results for our participants on a study website. (What we publish will not include anything that can identify you.)

19. What will happen if new information comes up about the study?

- We will tell you if we learn anything that may change your mind about being in the study. We will contact you by call, letter, email, text, or visit.

20. Where can I find more information about this clinical trial?

- A description of this study will be available on <http://www.clinicaltrials.gov>, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time.

21. What do I do if I have questions?

- Please call the head researcher of the study <site investigator name and title> at <telephone number> if you
 - have any questions about this study
 - feel you have been injured in any way by being in this study
- You can also call the office at UAMS that supervises research if you cannot reach the study team, have questions about your rights as a research participant, or want to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 during normal work hours.

22. If you agree to be part of this study:

- We will consider this your verbal/unwritten consent to use the information collected about you and your child for the research described above.
- You know that joining this study is voluntary.
- Someone has talked to you about the information in this form and has answered all of your questions.

23. I know that

- I can stop being in any and/or all parts of the study at any time and nothing bad will happen to me.
- I can still get medical care at <clinic name> no matter what I decide.
- I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- I do not give up any of my legal rights by participating in this study.

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**Documentation of Verbal Consent to Take Part in this Research Study and Authorization
to Use and Disclose Health Information for This Research Study**

Name of participant (please print first and last name of adult participant)

Print Child's 01 first and last name

Print Child's 02 first and last name

Print Child's 03 first and last name

The person who provided consent confirmed that all of the participant's questions were answered and the participant agreed to participate in this research study.

The participant confirmed that they are legally authorized to consent to share their child's health information.

Printed name (person obtaining consent)

Signature (person obtaining consent)

Date