Meds@HOME Mobile App Study

NCT05816590

10/30/2023

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: Meds@HOME Mobile App Study

Formal Study Title: ***Meds@HOME - Improving Medication Safety for Medically Complex Children with mHealth across Caregiving Networks (R18 Aim 2)***

Lead Researcher: Ryan Coller, MD, 608-263-9408, Department of Pediatrics, University Hospital and Clinics, H4/410 CSC

Institution: ***School of Medicine and Public Health, UW-Madison***

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

Researchers and parents affiliated with the Pediatric Complex Care Program at American Family Children's Hospital have developed a mobile (phone) app that allows caregivers of children with special healthcare needs to track their child's routines and medications and share the app with other individuals caring for their child. The goal of this study is to learn whether this app is helpful in promoting improved care for children with special healthcare needs, and to determine whether app use reduces medication errors. Currently, there are no tools like this to help caregivers of children with special healthcare needs, yet parents tell us there is a great need for such a tool, especially when multiple people are providing care for a child. The name of the app is Meds@HOME.

We are inviting you and your child to take part in this research study because your child with chronic conditions receives at least one medication that is considered "high-risk", meaning that side effects from the medication or even small errors in how it is given can be serious.

Throughout this consent form, when we refer to "you," we are referring to both you (the primary caregiver) and your child.

What will I need to do in this study?

If you decide to take part, you will be randomly assigned (like flipping a coin) to use the Meds@HOME app or not to use the app for 6 months. If you are assigned to use the app, you may invite other caregivers to also use it. Both groups (app users and non-app users) will be asked to fill out an online survey at the beginning and end of the trial.

We expect that you will be in this research study for 6 months.
You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
Interested in trying out a mobile app to track caregiving tasks (if you are assigned to the app group). Comfortable with not getting to try out the app (if you are assigned to the group not using the app). Willing to invite at least one other caregiver to participate in the study. Interested in contributing to scientific knowledge even though you may not benefit directly from the study.	Are not interested in being randomly assigned to a study group. Don't want to enter or track your child's care routines and medications using an app. Don't have another caregiver to invite into the study, or don't want to invite another caregiver to join the study.

Do I have to be in the study?
No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or your child's healthcare, or any services you or your child receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information
The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?
When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?
If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at:

Email address: atHOME@pediatrics.wisc.edu
Study manager: Gemma Warner, (608) 263-0740

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

ENROLLMENT VISIT

You will meet with the study staff to enroll in the study. This visit can be done remotely (using Zoom or WebEx) or in-person (at the American Family Children's Hospital or clinic). After reviewing and signing this consent form (and discussing the assent form with your child, if applicable), study staff will walk you through the following tasks:

1) Decide which other caregiver(s) you would like to invite into the study. We will ask you to invite at least one, but no more than two, secondary caregivers to participate.

2) Complete a short (5 minute) discussion on a "high-risk" medication your child is taking. We will ask you why your child takes this medication and how much, how often, and how they take the medication.

3) Randomly assign you to the app user group or the non-app user group.

4) If you are assigned to the group using the Meds@HOME app, study staff will help you download the app to your mobile device and give you a brief tutorial on how the app works. This will take about 10 minutes.

5) Finally, study staff will answer any remaining questions you may have and explain when you can expect to receive your first study stipend ($100).

6) After the visit, you will be sent a link to a 15-minute online survey asking questions about your caregiving tasks and demographic information about you and your child, such as your race, ethnicity, gender, etc.

The enrollment visit will last 30-45 minutes, depending on whether you need to download and get an introduction to the Meds@HOME app.

6 MONTH TRIAL

If you are NOT assigned to use the app, you will have no other study activities for 6 months.

If you are assigned to use the app, you will be encouraged to try it out for 6 months. Study staff will explain the general functions of the app, and you can choose which functions you'd like to use in caring for your child. The following table outlines the types of things you can do with the app.

Caregiver Profile(s)	Caregivers can enter their name, email, phone number, relationship to child, and preferred method of communication. Caregivers can also add a photo to their profile. You will decide who to invite to use the app and can deactivate a user at any time.
Child Profile	You can also create a profile for you child. At a minimum, a child's profile must include their name. Optional other fields include a photo, gender, date of birth, address, and "important things to know about me" (i.e., allergies, I'm calmed by, I'm upset by, I need assistance with, best way to communicate with me, comfort measures I prefer, and my technology).
Care Routines	The app allows you to create routines outlining what cares need to be performed and on which days and times. For example, you could create a routine for morning medication administration, listing your child's medications, amounts, and how they are to be given. Optional push notifications can be set so that users receive an alert to an upcoming routine. Only primary caregivers can create, edit, delete routines. All users can check off when a routine has been completed.
Troubleshooting Strategies	You can enter the descriptions of issues and how they should be addressed. For example, you could list your child's seizure action plan provided by their neurologist.
Inventory Reminders	The app allows you to set a notification at a specific interval reminding you to check supplies and reorder. This can help in tracking your medication stock, durable medical equipment, and other supplies.

The app is designed to help in the care of your child by providing a place to document caregiving instructions and task completion. If shared with other caregivers, it could be a useful way to communication with your child's caregivers. You will decide what parts of the app are useful to you. You can include or leave blank any feature you like. If you find that the app is not useful, you can discontinue using and still stay in the study.

Should you have questions or issues with the app, you may contact the study team for assistance.

Several days before the end of the 6 month trial of the app, study staff will notify you that your access to the app is about to be switched off. You will no longer be able to use the app after the trial.

END OF STUDY

At the end of the 6-month study period, study staff will contact you to arrange a brief (5-10 minute) phone call to discuss the "high-risk" medication your child is taking (which medication they are taking, why they are taking it, and how much, how often, and how they take the medication, . Following this call, you will be sent a link to a 15-minute online survey asking questions about your caregiving tasks. Your second study stipend ($100) will be sent.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Things entered into the Meds@HOME app (your child's profile, routines, and medications)
Things you tell the researchers about your child's health
Information currently in your child's medical records as well as information added to their medical records during the course of this study. This information could include their medical history, medications, and visits made to the hospital, emergency department and specialty clinics. We will get this information from their health care providers.

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

You can leave the research study at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you decide to withdraw from the study, please notify study staff. The data we have collected up until that point will be retained. If you decide to stop using the app, you can still complete the study by participating in the exit phone call and final survey.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Ryan Coller, MD, Department of Pediatrics, 600 Highland Avenue, Madison, WI 53792.

Will being in this study help me in any way?

Users of the app may find it helpful in caring for their child and communicating with other caregivers. If you are in the group not using the app, we do not expect you to gain any benefit from being in the study. However, even if the study does not help you directly, your participation may benefit other people in the future by helping us learn whether this app is a useful tool for caregivers of children with special healthcare needs.

What are the study risks?

You will be asked to complete interviews and surveys containing questions about you, your child and their health, and the care you provide for your child. Discussing these topics may cause you distress or embarrassment. You will be reminded that participation in study activities is completely voluntary, and you may choose to skip specific survey or interview questions without negative consequences.

If the study staff discovers improper administration or dosing of medication through a survey or interview, they will bring this issue to the attention of the lead researcher, Ryan Coller, who will contact you to discuss the finding.

If you are a part of the group using the Meds@HOME app, there are additional potential risks:

If you do not password-protect your phone, there is a small risk that the information entered into the Meds@HOME app could be seen by an unauthorized person, thus jeopardizing the confidentiality of your use of the app and its contents. You will be encouraged to use a password to keep the contents of your phone confidential during the study.

If your phone is lost or stolen, there is a risk that someone could access its contents, including the data you have entered in the app. Please contact study staff immediately if your phone is misplaced so that we can disable your Meds@HOME account. You can also set up a remote disable feature on your phone allowing you to remotely disable or remove any apps and/or data if your phone is misplaced.

You may choose to invite other caregivers to use the app. If other caregivers are utilizing this app, and they do not exercise proper confidentiality and security measures, your child's health data may be at risk for disclosure to others. Please invite other caregivers selectively and be sure to share the study information sheet with them which outlines the recommended precautions for mobile devices.

If the details of your child's medical information is entered into the app incorrectly or if a user misreads or misinterprets the information recorded in the app, it could result in care delivered to the child differently than intended by caregivers. You

are encouraged to double check your data entry and information for accuracy while using the app.

As with all mobile devices, please avoid using the app while driving as this may cause an accident.

Taking part in this research study may lead to added costs to you. This may happen if your cell phone plan caps the amount of data you can use in a given month. If you are not connected to WiFi and are using the app, your usage of data may get charged to your plan.

Finally, you may find use of the app to be inefficient, ineffective, or challenging. The study will provide access to technical support (telephone number and email address) in the event you experience technical difficulties or challenges using the app.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes the University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program and the Department of Health and Human Services.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We will potentially share information collected for this study with researchers or organizations outside UW-Madison.

Will information from this study go in my medical record?
None of the information we collect for this study will go in your medical record.

Will I receive the results of research tests?

The surveys you will complete in this study ask about symptoms of emotional distress such as depression and worry. We are using the questionnaires only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

There is a chance of discovering improper administration or dosing of medication through a survey or interview. If this happens, the study team will bring this issue to the attention of the lead researcher, Ryan Coller, who will contact you to discuss the finding.

Can I be removed from the research without my agreement?

The person in charge of the research study can remove you from the research study without your approval. This may happen if you do not follow the study rules or no longer meet the requirements to be in the study. You will not be removed from the study if you choose not to use the app.

What else do I need to know?

Will I receive anything for participating?
If you agree to take part in this research study, we will pay you $200 for your time and effort. You will be paid $100 following the enrollment visit and another $100 after study completion.

Permission to communicate about the study by email
We are requesting your email address so we can send you links to the online surveys, invitations to use the app, reminders, and to provide assistance with any app issues. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Ryan Coller, MD, lead researcher, 608-263-9408.

How many people will be in this study?
We expect 152 families will be in this research study. This will include 152 primary caregivers, 152 children, and up to 304 secondary caregivers.

Who is funding this study?

This research is being funded by the Agency for Healthcare Research and Quality, a branch of the U.S. Department of Health and Human Services.

What will happen to my data after my participation ends?
Your study data will be stored on secure computer systems maintained by the University of Wisconsin. This includes the information you enter into the app and your responses to the interviews and surveys. Only authorized study staff will have access to this data.

We plan to keep your data for an indefinite period of time, meaning we have no plans of ever destroying it. Your data will be labeled with a code number that allows only the members of this research team to identify you. Keeping data or biospecimens for future research is called “banking.” The banked data will be kept in a secure location for use by researchers. The banked data will not allow anyone, even to the members of this research team, to identify you.

We will use the data in future research projects related to the development and use of the meds@HOME app. We may also use them for other types of research. The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations. Banked data will not be shared with your health care providers or used in your treatment outside this study. Because your data do not include any information that can identify you, we cannot withdraw them from the bank once they have been added.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you and your chld cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You and your child want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form, as well as your child’s protected health information.

_____
Printed child’s name

Assent

Obtained
Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.

I am this child's parent
--- OR ---

I am not this child's parent but am the person legally authorized to consent to the child's general medical care

By checking this box and typing my name below,
I am electronically signing this consent form.

Printed caregiver's name	Signature of Signature of Caregiver (Parent or individual legally authorized to consent to the child's general medical care caregiver), date timestamp
Printed name of person obtaining consent	Signature of caregiver, date timestamp

**** You will receive a copy of this form ****