UNIVERSITY of ROCHESTER

CONSENT FORM

Efficacy Trial of the FMF Connect Mobile Health Intervention

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This consent form describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully.

Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are a parent/caregiver of a child with a fetal alcohol spectrum disorder (FASD) or prenatal alcohol exposure (PAE).
- The purpose of this study is to test a new smartphone app called FMF Connect. The app was developed specifically for parents/caregivers of children with FASD or PAE.
- Your participation in this study will last for about three months.
- Procedures will include completing online surveys three times during the study (6 weeks apart). Some people will be randomly chosen to get the FMF Connect app at the start of the study. Everyone else will get the app 3 months later.
- There are risks from participating.
    - The most common risk is discomfort or boredom from completing surveys or communicating with other parents/caregivers in the app.
    - One of the most serious risks is a loss of confidentiality. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks with the study team if you have questions.
- You might not benefit from being in this research study. The potential benefit to you might be learning new information and strategies in the app that could help you care for your child.

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Purpose of Study

The purpose of this study is to test a new smartphone app for parents/caregivers of children with FASD. The app is called Families Moving Forward (FMF) Connect. The goal of the app is to provide parents/caregivers with useful information to help manage their children's condition and obtain peer support. We are also testing whether individualized coaching helps parents/caregivers use the app.

Description of Study Procedures

If you decide to take part in this study, the following will happen:

Screening for Eligibility

- Answer questions to see if you meet eligibility for the study.
- Complete a brief demographic survey.
- Provide information and/or records about your child's history of prenatal alcohol exposure or FASD diagnosis.

Study Surveys – All Eligible Participants

- Complete surveys online at the start of the study.
    - Surveys ask about your child's behavior, your thoughts about parenting, family needs, knowledge about FASD and advocacy, self-care, and current services.
    - Surveys may take 35-45 minutes to complete

Random Assignment to Study Group

- You will be randomly chosen to be in one of three groups:
    - Group 1: FMF Connect app + Coaching
        - This group gets the FMF Connect app at the start of the study. They also will get text-based messages in the app from a Coach. The FMF Connect Coach will help with goal setting and using the app.
    - Group 2: FMF Connect app
        - This group gets the FMF Connect app at the start of the study. They do not get individual coaching.
    - Group 3: Waitlist group
        - This group gets the FMF Connect app 3 months later when they finish the study.

Study Surveys at 6 and 12 Weeks – All Eligible Participants

- Complete a smaller number of online surveys at 6 weeks. This may take 15-20 minutes to complete.
- Complete all of the online surveys from the start of the study again at 12 weeks.

- If you are in Group 1 or 2, there will also be a survey about your thoughts on app quality.

We may communicate with you by email if you provide your email address. When you receive the app, we will send you weekly email communications as part of the app. The app includes a group chat component, called the Family Forum, which will allow you to post messages over the Internet to other parents/caregivers and trained peer moderators. Since a data connection is required to use some of the app components, possible charges from your mobile service provider can incur. By default, in order to avoid unexpected charges, the app will only access the Internet over WiFi. You will be able to enable/disable cellular data connection at any time through the app settings (wireless carrier fees may apply).

Number of Subjects
Up to 300 parents/caregivers can enroll in the study.

Duration of the Study
The duration of the study will last about 3 months.

Risks of Participation
You may feel disappointed or upset if you are not eligible for the study or do not get the group assignment you were hoping for. We designed the groups in this study to allow us to show whether the app is effective in improving outcomes for families. This type of study design is considered the “gold-standard” in research. It will be important in making the FMF Connect app more widely available for families.

When participating in the study you may feel uncomfortable or bored when completing surveys. You can always choose not to answer any questions that make you uncomfortable, take a break, or decide to stop participating.

There are additional risks you should be aware of when trying out the app. For example, you may feel uncomfortable by something another parent/caregiver posts in the app. To reduce the risk of discomfort, we will have a trained moderator who is also a parent/caregiver of a child with FASD. This moderator will create a welcoming environment for everyone and will monitor for inappropriate posts. Clear rules and expectations for posting will be provided to all parents/caregivers using the app. You can also send an email to study staff if you feel uncomfortable or have concerns. Your safety and well-being is important to us. The moderator will let us know if s/he has concerns about your or anyone’s safety based on posts in the app. You can also choose not to enter or post anything in the group chat component of the app.

There are also additional risks to privacy and confidentiality through the app. We will protect against these risks by using state-of-the art authentication and encryption algorithms between the app and the secure Cloud data storage. We will also have you set a passcode to access the app on the phone. Your personal data will be encrypted automatically whenever your phone is locked. You will select a unique username in the app. We recommend you do not include any personally identifying information when you select your username. In the Family Forum group chat feature, you will have the ability to choose how much information to share about yourself and your family. We will instruct all parents/caregivers not to share anyone else's information posted in the group chat component within or outside the app, but we can not control that. The moderator will monitor for inappropriate sharing.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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 website at any time.

Benefits of Participation

You might not benefit from being in this research study. It is possible, although not guaranteed, that you might find some of the information included in the app to help you understand your child better. You might also experience a sense of support or encouragement from other parents/caregivers.

Costs

There will be no cost to you to participate in this study.

Payments

You will get a reloadable gift card at the start of the study if you are eligible. You will be paid according to the following schedule:

Timepoint	Amount
Completing surveys at the start of the study	$40 loaded on gift card
Completing the smaller number of surveys at 6 weeks	$20 loaded on gift card
Completing surveys at 12 weeks	$40 loaded on gift card

You will not be paid for completing screening surveys or for using the app.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will treat your information in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with published results. Your code numbers and any identifying information will be kept in locked files or secure encrypted servers that only the Principal Investigators or study staff can access. Study staff respect your family's desire for privacy. If, however, concerns arise about your welfare or that of someone else in your family, a study staff member will talk with you about these concerns to make sure that any support you need is made available. Study staff may need to share information with outside authorities in the event that a study subject reports a danger to themselves or others. As professionals, study staff are required to report suspected child or elder abuse. If this occurs, they will make every effort to talk with you prior to filing a report.

Sometimes, however, researchers also need to share information that may identify you with people that work for the University, regulators, or the study sponsor. If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study staff will collect your personal information. For example:

- Research records
- Records about emails and phone calls made as part of this research
- Medical records from FASD evaluations you provide
- Records about your surveys
- Data collected within the app

Who may use and give out information about you?

- Study staff

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Seattle Children's Research Institute
- National Institute of Alcoholism and Alcohol Abuse

Why will this information be used and/or given to others?

- To do the research
- To study the results

- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Information
Because this project is being done with other researchers around the world as part of the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD), data collected in this study will be sent electronically to a central location and could be used by other researchers in CIFASD. Names will not be included in these shared data, but it will be possible to link information collected about you in this study to information collected in other studies.

Other researchers who are not part of CIFASD may request access to these data, but again, no names will be released. These other researchers will not ask for your consent to use your data in the future. Researchers may be from the University of Rochester, other universities, government agencies (like the National Institutes of Health), or private companies. Any published results from researchers on your data will not identify you. Researchers may also create new products (like new interventions) as part of their

research. If that happens, you will not share in the profits or losses in the sale of these products.

Sponsor Support
The University of Rochester is receiving payment from the National Institute of Alcohol Abuse and Alcoholism for conducting this research study.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Christie Petrenko, Ph.D. at 585-275-2991 x 241.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;

- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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Use of E-mail for Communication in Research

When using e-mail to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and the researcher should understand the following conditions, instructions and risks of e-mail use:

Conditions for e-mail use:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) E-mail communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

Instructions for e-mail use:

a) Avoid use of your employer's computer.
b) Put your name in the body of the e-mail.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your e-mail address.
e) Take precautions to preserve the confidentiality of e-mail.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Risks of e-mail use:

Sending your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

Use of Text Message Communication for Research

Text messages by mobile/cell phones are a common form of communication. The FMF Connect research study involves sending you text messages that are relevant to the research study and are limited to communications regarding scheduling and reminders for completing study surveys/interviews. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and the University of Rochester are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and the University of Rochester are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messages will only be read during regular business hours. Texts sent on nights, weekends, and holidays will not be read until the following business day.

- Text messaging should not be used for sensitive medical information, or in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says “Stop Research Text.”

- Your agreement, and any request to stop text messaging, applies to this research study only.

It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I will receive a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent (University of Rochester Research Staff)

This signed form was received on the date below and any questions have been answered. The subject has demonstrated comprehension of the information.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date

CONSENT TO RE-CONTACT

May someone from the study team, contact you in the future to see if you would like to participate in other research?

Yes No

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