eACT: Epilepsy Adherence in Children and Technology

NCT03817229

Umbrella Informed Consent Form, Version 7

Approved by CCHMC IRB 3/15/2023

Title of research study: Epilepsy Adherence in Children and Technology (eACT)

Investigator:
XXXX

Contact Info:
XXXXX

Funding: **National Institute of Health: R01 NR017794**

Key Information:

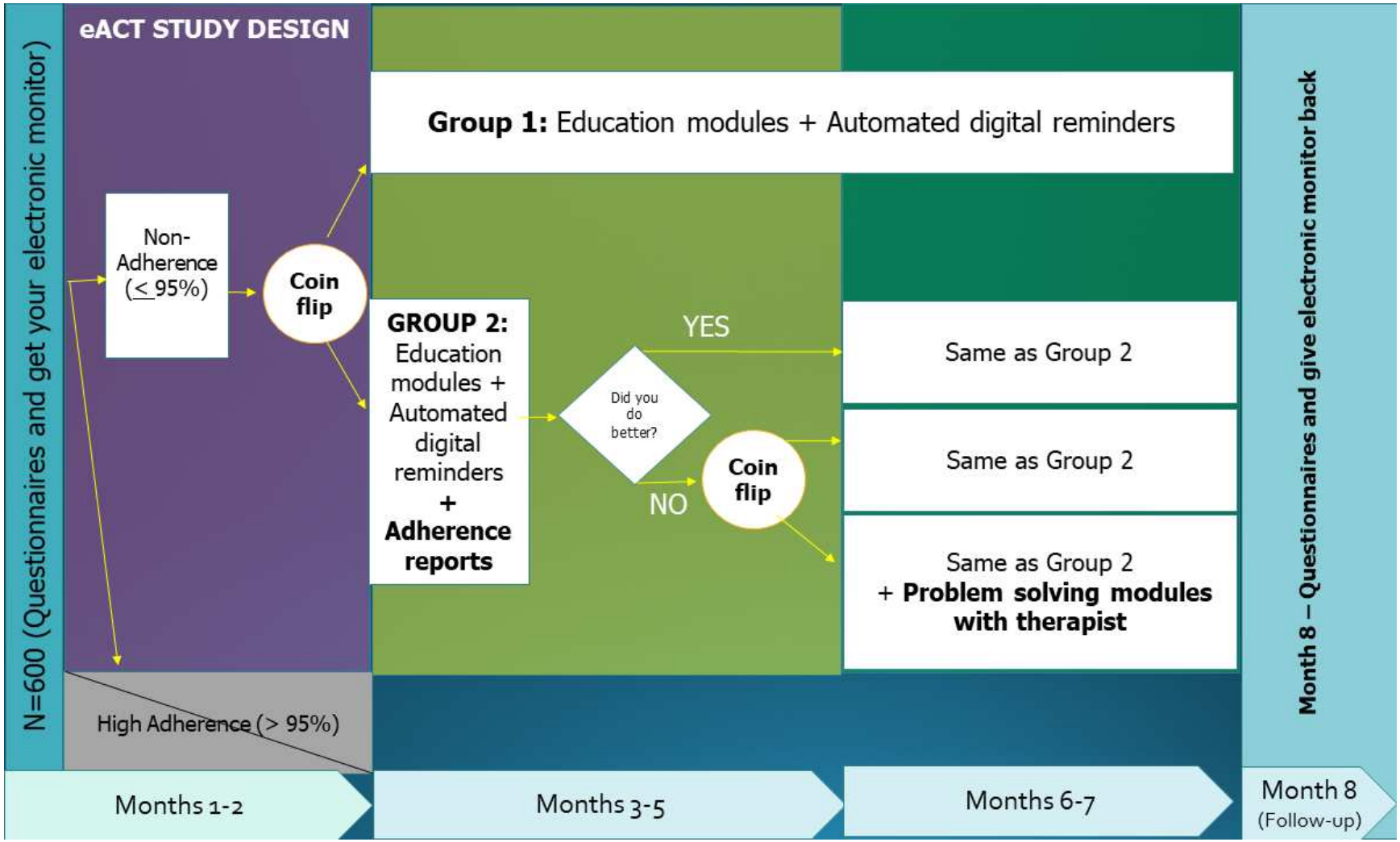
The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

The goal of this study is to help children with epilepsy take their epilepsy medicine more consistently. Our research and clinical work has showed us that taking medicines everyday can be difficult, especially when things get in the way, like forgetting, difficulty managing medicine and life, or children refusing to take their medicine. Our study will use mobile health ("mhealth") technology (e.g., cell phone, tablet, or computer) to teach caregivers different ways to overcome the challenges that make taking epilepsy medicine difficult. Most of this study will take place using mHealth, so you will not need to come to the hospital for study visits.

Our goal is to recruit 600 children (2-12 years of age) and their caregivers for this study across four epilepsy sites in the country. We will use electronic monitors to see how your child takes his/her medicine for the first two months of the study. For families with adherence rates above 95%, they will not need any intervention and will stop the study at that time. For families who have adherence below 95%, they will be randomized to one of two groups: Group 1 or Group 2. This occurs with the flip of a coin.

If you are randomized, we will teach you several different strategies to help you learn more about epilepsy, treatment, and taking medicine. These strategies include education about epilepsy, daily reminders, feedback on how you child takes his/her medicine weekly, and problem-solving skills. Not everyone will get all the different strategies because we want to see which strategies work the best. You will receive these strategies for a total of 5 months. After 5 months, we will stop sending reminders and providing adherence reports to you. We will simply ask you to complete questionnaires one time electronically and keep using your adherence monitors for another month. The attached figure shows you how participants will go through the entire study.

Combined Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.


eACT STUDY DESIGN
N=600 (Questionnaires and get your electronic monitor)
Group 1: Education modules + Automated digital reminders
Non-Adherence (≤ 95%)
Coin flip
GROUP 2: Education modules + Automated digital reminders + Adherence reports
Did you do better?
YES
NO
Coin flip
Same as Group 2
Same as Group 2
Same as Group 2 + Problem solving modules with therapist
High Adherence (> 95%)
Month 8 – Questionnaires and give electronic monitor back
Months 1-2
Months 3-5
Months 6-7
Month 8 (Follow-up)

Reason for the study:

The main reason for this research study is to help children with epilepsy take their anti-seizure medicine more consistently. Problems with medication adherence (i.e., taking medication consistently as prescribed by your child's doctor) are common in children with epilepsy and we need to better understand the strategies that are most helpful for families to overcome difficulties with adherence. Our study will help us to learn more about how mobile health technology (mHealth) can be used to improve adherence and teach caregivers strategies to give epilepsy medicine on a regular basis. We are asking you, as a caregiver, to be in this research because your child has been diagnosed with epilepsy, is between the ages of 2-12, and is being prescribed anti-seizure medicine.

Procedures:

You will be asked to complete a number of questionnaires about your and your child's background and how you and your family manage your child's epilepsy medicine. You will complete these online and we will send a link to your email address (or text your cell phone, if needed) with the questionnaires. We will also review your child's medical record to gather information about your child's epilepsy diagnosis and treatment plan. At enrollment, you will be given an electronic monitor (e.g., pillbox, pill bottle) to track your child's medication adherence. You will use this monitor for two months.

Based on the information gathered from the adherence electronic monitor, you will either 1) end the study or 2) be assigned to one of the two groups. Group 1 will receive education micro-learning sessions and reminders from their electronic monitor. You will be given a link and username/password to access the 4-5 education mini-sessions. These will take approximately 5-8 minutes to watch and you can view them when it is convenient for you. You will choose what type of reminders you want when you enroll in the study and these will also be turned on when you are assigned to one of the groups. Group 2 will receive the same as Group 1 and additional strategies, such as individualized adherence reports and possibly a problem-solving module with two mHealth therapy-guided sessions. The individualized adherence reports will be sent to you via push notifications on your cellular phone; thus, we will need your cell phone number to send these. The intervention part of the study is 5 months. Throughout the study, you will continue to give your child their medications as prescribed.

After the intervention phase, you will complete questionnaires again electronically one more time immediately following the intervention. Again, we will sent you a link to the questionnaires to your email address (or text you the link, if needed).

- You will be compensated every time you fill out study questionnaires. At the end of the study, you will be asked to return the electronic monitor used for this study.

- We expect you to be in the study for up to 8 months altogether. The first two months are only to monitor how your child takes his/her epilepsy medicine. The next 5 months are the intervention, and the following 1 month is the follow-up period.
- All research procedures are not part of routine clinical care.
- You will be asked to complete questionnaires at 2 different time points.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:

There are minimal risks to participants in this study. All questionnaires have been used in research without any reported negative effects. You can refuse to answer questions for any reason. More detailed information about the risk can be found under ***"(Detailed Risks)"***

Benefits to Participate:

There are no known benefits to you for taking part in this research. However, it is possible that you will learn more about epilepsy, its treatments and ways to manage epilepsy medicine. The information that the researchers learn from this study will allow health care professionals to have a better understanding of how we can improve medication adherence and disease management for children with epilepsy in the future.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. Your alternative to participating in this research study is to not participate.

Cost to Participate:

Aside from your time, there are no costs for participating in this research study. You will be responsible for the usual costs of your child's medical care, but you will not be charged any additional costs for study participation.

Payment:

If you agree to take part in this research study, we will pay you up to $85 for your time and effort. You will complete questionnaires two times in the study and receive increasing payments for each visit (Baseline=$20 and Post-intervention=$25). If you use your electronic monitor throughout the study and return it at the end of the study, you will receive an additional $40. You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, (your site XXXX) is required

by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the (your site XXXX) business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	XXXXX	Phone: XXXX
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**XXXXX**	Phone: XXXXX
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: XXXXX

Total number of participants:

We expect about 150 people here will be in this research study, out of 600 people in the entire study nationally. Cincinnati Children's Hospital Medical Center (CCHMC) is the Primary Site for the study, and data from other sites will be shared with minimal identifying information.

Detailed Procedures:

- If you decide to participate, you will be asked to complete study questionnaires via REDcap, a secure web-based interface at two different time points altogether. You will also be asked to keep your child's medication in a bottle or pillbox for the duration of the study.

- After 2 months of using the bottle or pillbox, and depending on how many doses of medication your child has missed, you will either be done with the study or you will be placed into one of two treatment groups. You will continue to give your child their epileipsy medicine as usual.
- Which treatment option you get will be chosen by chance, like flipping a coin. You will have an equal chance of receiving each treatment. Neither you nor the study doctor will choose what treatment you get.
    - Group 1 will get 4-5 education mini-sessions and reminders to give epilepsy medicine. You will choose which type of reminder you want, such as emails, text alerts, or the electronic monitor beeping or lighting up.
    - Group 2 will receive the same thing as Group 1 but will also get adherence reports about how they are doing with taking medicine each Monday. These will be sent via push notification to your cellular phone and you will receive them weekly. This part of the intervention will last 3 months in total.
- After 3 months and depending on how you are doing, you will either stick with the same intervention for 2 more months or be assigned to one more strategy to help with managing epilepsy medicine for 2 more months. This strategy includes learning about problem-solving strategies and having two virtual meetings with a therapist. Neither you nor the study doctor will choose what treatment you get.
- After you have completed the total 5 month intervention period, you will be asked to complete questionnaires via REDCap, a secure web-based interface, one more time (Month 8 of the study). You will be compensated each time you complete questionnaires.
- At the completion of the study, you will be asked to return the electronic bottle or pillbox you were given at the beginning of the study. If you use this monitor throughout the study, you will be compensated additional money.

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you or affect your child's care in any way.

If you decide to leave the research, contact the investigator so that the investigator can document you are no longer interested in participating in the study, and arrangements can be made for you to return the electronic pillbox or bottle given to you at the beginning of the study.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include: the study doctor determines that it is in your child's medical best interest, the study ended early for any reason, or new information becomes available.

If you withdraw your permission to use and share your PHI, you would be withdrawing from participation in the research study. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

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

Detailed Risks:

LESS COMMON, LESS SERIOUS
• Psychological risk: Discomfort filling out questionnaires (infrequent)
• Privacy risks: Loss of confidentiality (rare)
• Unknown or unforeseen risks associated with study participation

If any of the procedures that cause you to feel uncomfortable in any way, you will be encouraged to discontinue. The PI will meet with you to discuss your concerns, and if appropriate, assist in making clinical referrals.

Another risk may be loss of confidentiality. Please see the section of this consent form entitled Privacy to learn steps that will be taken to reduce the risk of loss of confidentiality.

Finally, there may be unknown or unforeseen risks associated with study participation.

Privacy:

Efforts will be made to 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. Participation and results of research tests/procedures will be included in your medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. To communicate study related information across sites, our team will be using Trello, a task management system that is frequently used by research teams. No identifying information will be entered into the Trello system; however, we will be tracking

participants through the study procedures using their anonymous study ID. We will also store some information in REDCap, a secure web-based interface supported by the CCHMC Division of Biomedical Informatics. REDCap is in compliance with HIPAA and designed to protect PHI in the electronic transfer and storage of study data and information. We will be using a Wordpress portal for the education and problem-solving modules. These will only include your anonymous study ID; you will be given a unique ID and password to access this system. Additionally, we will use your address, which is considered personal health information, to categorize the type of area you live in, like urban or rural. Finally, for the adherence reports, we will be using a service developed at CCHMC to provide the reports. This server will include your cell phone number so we can send you push notifications for the reports but no other identifying information will be in the portal.

Cincinnati Children's Hospital Medical Center, the Primary Investigator and Co-Investigators collaborating on the study will take the following precautionary measures to protect you and your child's privacy and confidentiality and/or your child's medical records. All participants' data will remain strictly confidential, as all information is coded with a unique number, rather than you or your child's name or other identifying information. These files are stored in password-protected computer files or on password protected servers at CCHMC. All study documents will be stored in a locked cabinet in the PI's secure lab area and only research staff working on the project will have access to these secured files.

There are some limits to confidentiality for the research study. If a participant (child and caregiver) reveals intent to harm themselves or others or actual harm (e.g., abuse, neglect, suicidal behaviors), we must disclose this information to ensure your and your child's safety.

In addition, because the intervention is mHealth, we will need some identifying information (i.e., cell phone number, email address) to send you questionnaires and/or provide you strategies for the intervention (e.g., modules, feedback reports, telehealth). We will also use your home address to categorize the area you live. We will make every effort to keep these confidential but cannot guarantee that they will be.

The sponsor, monitors, auditors, and the IRB, will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
(your sites XXX) will need to use and share your PHI as part of this study. This PHI will come from:

- Your hospital medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications, time of diagnosis, demographics, including your address

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?
People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study.

Will your child's other medical care be impacted?
By signing this document, you / your child agree to participate in this research study and give permission to (your site XXX) and Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent Date

_____ _____
Signature of Parent or Legally Authorized Representative* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent Date