Clinical Trials Title: Behavioral Economics and Adherence in Teens (BEAT!)

NCT03958331

Date Last Modified and Approved: 2/5/2020

NIH Grant Title: Improving Drug Adherence Using mHealth and Behavioral Economics in Adolescents with Epilepsy (R21NR017633)

Title of research study: Beat!: Improving Drug Adherence Using mHealth and Behavioral Economics in Teens with Epilepsy

Investigator:
Avani C. Modi, Ph.D

Contact Info:
Avani C. Modi, Ph.D
Phone: 513-544-5017

Funding: **National Institute of Health:**
R21NR017633 - 01A1

Key Information:

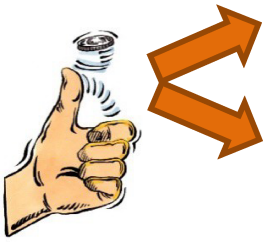
The following is a short summary of this study to help you and your teen decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having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

The goal of this study is to help teens with epilepsy take their epilepsy medicine more consistently. Our research and clinical work has showed us that taking medicines everyday can be difficult for teens, especially when things get in the way, like forgetting, difficulty managing medicine and life, or not wanting to feel different from peers. Our study will use mobile health ("mHealth") technology (e.g., cell phone, tablet, or computer) to provide reminders and give teens regular feedback about how they are doing taking their medicines. Most of this study will take place using mHealth, so you and your child will not need to come to the hospital for study visits.

Our goal is to recruit 138 teens (13-17 years of age) and their caregivers for this study across two epilepsy sites in the country. We will use electronic monitors to see how teens take their medicine during the first month of the study. Teens with adherence rates above 95% will not need any intervention and the study will stop after the one month period. Teens who have adherence below 95% will be randomized (e.g., this occurs with the flip of a coin) to one of two groups: Group 1 or Group 2.

If your child is randomized, your child will receive automated digital reminders and feedback reports about how they are doing taking their medicines. They may also receive information about how their adherence compares to other teens their age. Not every teen in the study will get all of these intervention components. Teens will receive different components of this study (e.g., adherence feedback, reminders) for a total of 5 months. After 5 months, we will stop sending reminders and providing feedback reports. Caregivers will not participate in the intervention but will be asked to complete surveys at different times during the study. You and your teen will be asked to complete a survey at the time of enrollment. After the teen completes the intervention, we will simply ask you and your child to complete questionnaires 2 more times (immediately after the intervention and 3 months later) electronically. Your child will keep using the adherence monitors for another 3 months after the intervention. The attached figure shows you how participants will go through the entire study.

<table>
<tr><td>First Week</td><td colspan="3">  Online Survey $10</td></tr>
<tr><td>Months 1</td><td>Phase 1</td><td>  
Are you meeting the goal of taking your seizure medicine as prescribed?</td><td>Yes: →

No: Move on to Phase 2</td></tr>
<tr><td>Months 2-6</td><td>Phase 2</td><td> 
We will flip a coin and you go to Group 1 or Group 2</td><td>Group 1: Reminders+ Adherence reports

Group 2:
Reminders +
Adherence reports +
Social Norms
reports</td></tr>
<tr><td>Month 7</td><td colspan="3">Online Survey $15</td></tr>
<tr><td>Month 9</td><td colspan="3">  Online Survey $20 
&
Return Pill Bottle/Tray
Use bottle/tray entire study and return it for additional $25
Up to $70 total (patients) and up to $45 total (caregivers)</td></tr>
</table>

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

Reason for the study:

The main reason for this research study is to help teens with epilepsy take their anti-seizure medicine more consistently. Problems with medication adherence (i.e., taking medication consistently as prescribed by a doctor) are common in teens with epilepsy and we need to better understand the strategies that are most helpful for teens 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 among teens. We are asking you, as a caregiver, and your teen to be in this research because your child has been

diagnosed with epilepsy, is between the ages of 13-17, is being prescribed anti-seizure medicine, and speaks English.

Procedures:

You and your child will be asked to complete a number of questionnaires about how your family manages your child's epilepsy medicine and some background information. You and your child will complete these online and we will send a link to you and your child email address (or cell phone, if needed) with the questionnaires. If you and your caregiver are unable to complete the questionnaires online, we will provide paper/pencil questionnaires for you to complete during your clinic visit. We will also review your child's medical record to gather information about your child's epilepsy diagnosis and treatment plan. At enrollment, you and your child will be given an electronic monitor (e.g., pillbox, pill bottle) to track how he/she takes his/her epilepsy medicine. You/your child will use this monitor for at least one month.

Based on the information gathered from the adherence electronic monitor, your child will either 1) end the study or 2) be assigned to one of the two groups. Teens in group 1 will receive digital reminders and feedback about how they are doing taking their epilepsy medicine. Your teen will choose what type of reminders he/she wants after enrollment in the study and these will be turned on when your child is assigned to one of the two groups. Group 2 will also receive digital reminders as well as feedback about how they are doing taking their epilepsy medicine. In addition, they will receive feedback about how they are doing compared to other teens with epilepsy (i.e., social norms feedback). The adherence reports and social norms feedback will be sent via push notifications on your teen's cellular phone and then your teen will be prompted to open a secured, encrypted link with the teen's individual adherence feedback report. Neither parents nor health care providers will receive these feedback report from the study team. The time your child will receive this intervention is 5 months. Throughout the study, your teen will continue to take their medications as prescribed and continue using the electronic monitor.

After the intervention, you and your child will complete questionnaires again electronically, or with paper/pencil questionnaires that will be mailed to your residence, two more times (immediately following intervention, and 3 months later). Again, we will send you and your child a link to the questionnaires based on the email addresses (or phone numbers) you provide us.

- You and your child 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 and your child to be in the study for up to 9 months altogether. The first month is only to monitor how your child takes his/her epilepsy medicine. The next 5 months are the intervention for the teen, and the following 3 months are the follow-up period.
- All research procedures are not part of routine clinical care.

- You and your child will be asked to complete questionnaires at 3 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. Study questionnaires have been used in research without any reported negative effects. You and your child 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 your child will learn more about 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 teens with epilepsy in the future.

Other Options:

Participation in research is completely voluntary. Your and your child's decision to participate or not to participate will not affect the care your child receives. The alternative to participating in this research study is to not participate.

Cost to Participate:

Aside from 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 and your child agree to take part in this research study, we will pay your child up to $70 and you up to $45 as compensation for your time and effort. You and your child will complete questionnaires three times in the study and receive increasing payments for each visit (Baseline=$10; Post-intervention=$15; 3-month follow-up=$25). If your child uses the electronic monitor throughout the study and returns it at the end of the study, the child will receive an additional $25. You each will receive payment for this study in the form of a reloadable debit card (ClinCard). We will give you and your child a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's Hospital Medical Center (CCHMC) is required by the Internal Revenue Service (IRS) to collect and use your child's social security number (SSN), as well as your SSN or taxpayer identification number (TIN) to track the amount of money that we pay. You and your child will need to complete a Federal W-9 form for this income tax reporting. This form also requires your child's Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your child's study chart. If you and your teen 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	Avani C. Modi, Ph.D.	Phone: 513-544-5017
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Sara Wetter** **Lauryn Urso**	Phone: 513-857-2656 304-670-7087
• 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: (513) 636-8039

Total number of participants:

Out of 138 teens in the entire study nationally, we expect about 70 teens from this hospital to participate in this research study. 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 and your child decide to participate, you and your child will be asked to complete study questionnaires via REDcap, a secure web-based interface, or using paper/pencil questionnaires either provided at your clinic visit or mailed to your residence, at three different time points altogether. You and your child will also be asked to keep your child's epilepsy medicine in a bottle or pillbox for the duration of the study.
- After 1 month of using the bottle or pillbox, and depending on how many doses of medicine your teen has missed, your teen will either be done with the study or he/she will be placed into one of two treatment groups. Teens will continue to take their epilepsy medicine as usual.

- Which treatment option your teen gets will be chosen by chance, like flipping a coin. They will have an equal chance of receiving each treatment. Neither you, your child, nor the study doctor will choose what treatment your teen gets. The intervention will last 5 months.
    - Group 1 will get digital reminders to take epilepsy medicine and adherence reports about how they are doing with taking medicine weekly. Teens will choose which type of reminder they 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 information about how they are doing taking medication compared to other teens their age (i.e., social norms feedback). These will be sent via push notification to the teen's cellular phone on a weekly basis.
- After your child has completed the total 5 month intervention period, you and your child will be asked to complete additional questionnaires via REDCap, a secure web-based interface, 2 more times (immediate after the intervention and 3 months later). Each of you will be compensated for completion of questionnaires with individual reloadable debit cards (ClinCard).
- At the completion of the study, you/your child will be asked to return the electronic bottle or pillbox that was provided at the beginning of the study. If your teen uses this monitor throughout the study, your child will be compensated additional money ($25).

Change of Mind/Study Withdrawal:

You and your child 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 or your child 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 that was provided at the beginning of the study.

The person in charge of the research study or the sponsor can remove you and your child 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 or your child withdraw permission to use and share your PHI, you and your child 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) or receiving feedback about how they are doing with taking medicine • Privacy risks: Loss of confidentiality (rare) • Unknown or unforeseen risks associated with study participation

If any of the procedures cause you or your child to feel uncomfortable in any way, you will be encouraged to discontinue. The PI will meet with you and/or your child to discuss 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 and your child's 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 child's medical record. All information within your child's 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/your child to the extent allowed by law.

We cannot promise complete privacy. Organizations that may inspect and copy your/your child's 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. For the adherence and social norms 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 and your child questionnaires and/or provide reminders/feedback reports. 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 child's 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/your child's name and other identifying information confidential.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH
To be in this research study you and your child 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?
CCHMC will need to use and share your/your child's PHI as part of this study. This PHI will come from:

- Your child's hospital medical records
- Your/your child's research records
- The study questionnaires, electronic medication monitors, and feedback reports

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

- Laboratory test results, diagnosis, and medications, time of diagnosis, demographics

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

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you and your child as part of this study
- Other individuals and organizations that need to use your/your child's 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/your child's PHI as part of the research are generally limited in how they can use your/your child's PHI. In addition, most people who receive your/your child's PHI are also required by federal privacy laws to protect your/your child's PHI. However, some people that may receive your/your child's 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 and your child may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your/your child's PHI would also include a withdrawal from participation in the research study. If you or your child wish to withdraw permission to use and share PHI you and your child 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 or your child 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 and your child's 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 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 your child, and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you and your child 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 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

STUDY TITLE: Beat!: A Clinical Trial

Avani C. Modi ***513-544-5017***
Name of Principal Investigator (study doctor) Telephone Number

INTRODUCTION

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to learn more about the best ways we can use technology to help teens with epilepsy take their epilepsy medicine on a regular basis. You are being asked to join this study because you are a teen with epilepsy, are prescribed epilepsy medicine, and speak English.

WHAT WILL HAPPEN IN THE STUDY?

If you agree to join this study, you will be asked to fill out some study questionnaires online using paper/pencil questionnaires provided during your clinic visit, and start using an electronic pillbox/pill bottle for your epilepsy medicine. Then, depending on how you are doing with taking your medicine, you may end the study or you may start using some of the technology we have created to help with taking medication more consistently.

If you continue with the study, you could get phone reminders about taking your medicine, feedback about how you are doing taking your epilepsy medicine, or information about how you are doing taking your medicine compared to other teens with epilepsy. The study team will not share this feedback and information with your parents. The study team will not share this feedback and information with your health care providers. If you qualify and decide you want to be in the study, you will continue to come to Cincinnati Children's Hospital Medical Center for your regular doctor's appointments. This study will not require extra visits to the doctor because everything will be done electronically (via email links or text messaging). The whole study will last up to 9 months.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

We do not know if being in this study will help you. We may learn something that will help other teens with epilepsy who have a hard time taking their epilepsy medicine.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

There are very small risks to participating in the study, such as feeling uncomfortable filling out online questionnaires or getting weekly feedback about taking your medicine, the questionnaires taking a long time, being uncomfortable by the feedback you get about taking medicine, or having your private information shared by accident. All information shared through the weekly feedback will be anonymous and teen identity will not be revealed. There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it. Take all the time you need to make your choice. Ask us any questions you have at any time.

SIGNATURES

After you have read this form and talked about this research with your parents and the doctors or nurses you need to decide if you want to be in this research. If you want to be in this research you should sign or write your name below.

_____	_____
Child's Assent	Date
_____	_____
Signature of Person Obtaining Assent	Date

Title of research study: Beat!: Improving Drug Adherence Using mHealth and Behavioral Economics in Teens with Epilepsy

Investigator:
Avani C. Modi, Ph.D

Contact Info:
Avani C. Modi, PhD
Phone: 513-544-5017

Funding: **National Institute of Health: R21NR017633 - 01A1**

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 teens with epilepsy take their epilepsy medicine more consistently. Our research and clinical work has showed us that taking medicines everyday can be difficult for teens, especially when things get in the way, like forgetting, difficulty managing medicine and life, or not wanting to feel different from peers. Our study will use mobile health ("mhealth") technology (e.g., cell phone, tablet, or computer) to provide reminders and give teens regular feedback about how they are doing taking their medicines. 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 138 teens (13-17 years of age) and their caregivers for this study across two epilepsy sites in the country. We will use electronic monitors to see how teens take their medicine during the first month of the study. Teens with adherence rates above 95% will not need any intervention and the study will stop after the one month period. Teens who have adherence below 95% will be randomized (e.g., this occurs with the flip of a coin) to one of two groups: Group 1 or Group 2.

If you are randomized, you will receive automated digital reminders and feedback reports about how you are doing taking your medicines. You may also receive information about how your adherence compares to other teens your age. Not every teen in the study will get all of these intervention components. You will receive different components of this study (e.g., adherence feedback, reminders) for a total of 5 months. After 5 months, we will stop sending reminders and providing feedback reports. Caregivers will not participate in the intervention but will be asked to complete surverys at different times during the study. You and your caregiver will be asked to complete a survey at the time of enrollment. After you complete the intervention, we will ask you and your caregiver to complete questionnaires 2 more times (immediately after the intervention and 3 months later) electronically. You will keep using the adherence monitors for another 3 months after the intervention. The attached figure shows you how participants will go through the entire study.

<table>
<tr><td>First Week</td><td colspan="3">Online Survey $10</td></tr>
<tr><td>Month 1</td><td>Phase 1</td><td>Are you meeting the goal of taking your seizure medicine as prescribed?</td><td>Yes: → STOP

No: Move on to Phase 2</td></tr>
<tr><td>Months 2-6</td><td>Phase 2</td><td>We will flip a coin and you go to Group 1 or Group 2</td><td>Group 1: Reminders+ Adherence reports

Group 2: Reminders + Adherence reports + Social Norms reports</td></tr>
<tr><td>Month 7</td><td colspan="3">Online Survey $15</td></tr>
<tr><td>Month 9</td><td colspan="3">Online Survey $20
&
Return Pill Bottle/Tray
Use bottle/tray entire study and return it for additional $25
Up to $70 total (patients) and up to $45 total (caregivers)</td></tr>
</table>

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Reason for the study:

The main reason for this research study is to help teens with epilepsy take their anti-seizure medicine more consistently. Problems with medication adherence (i.e., taking medication consistently as prescribed by a doctor) are common in teens with epilepsy and we need to better understand the strategies that are most helpful for teens 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 among teens. We are asking you and your caregiver to be in this research because you have been diagnosed with epilepsy, are prescribed anti-seizure medicine, and speak English.

Procedures:

You and your caregiver will be asked to complete a number of questionnaires about how you manage your epilepsy medicine and some background information. You and your caregiver will complete these online and we will send a link to you and your caregiver's email address (or cell phone, if needed) with the questionnaires. If you and your caregiver are unable to complete the questionnaires online, we will provide paper/pencil questionnaires for you to complete during your clinic visit. We will also review your medical record to gather information about your epilepsy diagnosis and treatment plan. At enrollment, you will be given an electronic monitor (e.g., pillbox, pill bottle) to track how you take your epilepsy medicine. You will use this monitor for one month.

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. If you are in group 1, you will receive digital reminders and feedback about how you are doing taking your epilepsy medicine. You will choose what type of reminders you want after enrollment in the study and these will be turned on when you are assigned to one of the two groups. If you are in group 2, you will also receive digital reminders as well as feedback about how you are doing taking your epilepsy medicine. In addition, you will receive feedback about how you are doing compared to other teens with epilepsy (i.e., social norms feedback). The adherence reports and social norms feedback will be sent via push notifications on your cellular phone and then you will be prompted to open a secured, encrypted link with the your individual adherence feedback report. Neither parents nor health care providers will receive these feedback reports from the study team. The time you will receive this intervention is 5 months. Throughout the study, you will continue to take your medications as prescribed.

After the intervention, you and your caregiver will complete questionnaires again electronically, or with paper/pencil questionnaires that will be mailed to your residence, two more times (immediately following intervention, and 3 months later). Again, we will send you and your caregiver a link to the questionnaires based on the email addresses (or phone numbers) you provide us.

- You and your caregiver 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 and your caregiver to be in the study for up to 9 months altogether. The first month is only to monitor how you take your epilepsy medicine. The next 5 months are the intervention for the teen, and the following 3 months are the follow-up period.
- All research procedures are not part of routine clinical care.

- You and your caregiver will be asked to complete questionnaires at 3 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. Study questionnaires have been used in research without any reported negative effects. You and your caregiver 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 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 teens with epilepsy in the future.

Other Options:

Participation in research is completely voluntary. Your and your caregiver's decision to participate or not to participate will not affect the care you receive. The alternative to participating in this research study is to not participate.

Cost to Participate:

Aside from time, there are no costs for participating in this research study. You and/or your caregiver will be responsible for the usual costs of your 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 $70 and your caregiver up to $45 as compensation for your time and effort. You and your caregiver will complete questionnaires three times in the study and receive increasing payments for each visit (Baseline=$10; Post-intervention=$15; 3-month follow-up=$25). If you use the electronic monitor throughout the study and returns it at the end of the study, you will receive an additional $25. You each will receive payment for this study in the form of a reloadable debit card (ClinCard). We will give you and your caregiver a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's Hospital Medical Center (CCHMC) is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN), as well as your caregiver's SSN or taxpayer identification number (TIN) to track the amount of

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

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Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	Avani C. Modi, Ph.D.	Phone: 513-544-5017
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Sara Wetter** **Lauryn Urso**	Phone: 513-857-2656 304-670-7087
• 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: (513) 636-8039

Total number of participants:

Out of 138 teens in the entire study nationally, we expect about 70 teens from this hospital to participate in this research study. 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 and your caregiver will be asked to complete study questionnaires via REDcap, a secure web-based interface, or using paper/pencil questionnaires either provided at your clinic visit or mailed to your residence, at three different time points altogether. You and your caregiver will also be asked to keep your epilepsy medicine in a bottle or pillbox for the duration of the study.

- After 1 month of using the bottle or pillbox, and depending on how many doses of medicine you have missed, you will either be done with the study or you will be placed into one of two treatment groups. You will continue to take your epileipsy medicine as usual.
- Which treatment option you gets will be chosen by chance, like flipping a coin. You will have an equal chance of receiving each treatment. Neither you, your caregiver, nor the study doctor will choose what treatment you get. The intervention will last 5 months.
    - Group 1 will get digital reminders to take epilepsy medicine and adherence reports about how they are doing with taking medicine weekly. Teens will choose which type of reminder they 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 information about how they are doing taking medication compared to other teens their age (i.e., social norms feedback). These will be sent via push notification to the teen's cellular phone on a weekly basis.
- After you have completed the total 5 month intervention period, you and your caregiver will be asked to complete additional questionnaires via REDCap, a secure web-based interface, 2 more times (immediate after the intervention and 3 months later). Each of you will be compensated for completion of questionnaires with individual reloadable debit cards (Clincard).
- At the completion of the study, you/your caregiver will be asked to return the electronic bottle or pillbox that was provided at the beginning of the study. If you use this monitor throughout the study, you will be compensated additional money ($25).

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you or affect your 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 that was provided at the beginning of the study.

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

If you withdraw 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) or receiving feedback about how you are doing with taking medicine
• Privacy risks: Loss of confidentiality (rare)
• Unknown or unforeseen risks associated with study participation

If any of the procedures cause you to feel uncomfortable in any way, you will be encouraged to discontinue. The PI will meet with you to discuss 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 and your caregiver's 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/your caregiver to the extent allowed by law.

We cannot promise complete privacy. Organizations that may inspect and copy your/your caregiver's 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. For the adherence and social norms 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 caregiver's privacy and confidentiality and/or your medical records. All participants' data will remain strictly confidential, as all information is coded with a unique number, rather than you or your caregiver'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 caregiver'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 and your caregiver questionnaires and/or provide reminders/feedback reports. 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/your caregiver's 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?
CCHMC will need to use and share your/your caregiver's PHI as part of this study. This PHI will come from:

- Your hospital medical records
- Your/your caregiver's research records
- The study questionnaires, electronic medication monitors, and feedback reports

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

- Laboratory test results, diagnosis, and medications, time of diagnosis, demographics

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/your caregiver's PHI as part of the research are generally limited in how they can use your/your caregiver's PHI. In addition, most people who receive your/your caregiver's PHI are also required by federal privacy laws to protect your/your caregiver's PHI. However, some people that may receive your/your caregiver's 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 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 or your child 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 other medical care be impacted?

By signing this document, you agree to participate in this research study and give permission to Cincinnati Children's to use and share you PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, you 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 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 Date

_____ _____
Signature of Individual Obtaining Consent Date