Cover Page

Official Title of Study: A Pilot Feasibility Trial of a Tailored Intervention to Improve Adherence in Adolescents and Young Adults with Cancer

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Title of Research Study: A Tailored Intervention to Improve Adherence in Adolescents and Young Adults with Cancer (IRB #2020-0904)

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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.

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.

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. 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.

REASON FOR THE STUDY

The main reason for this research study is to test two different types of programs designed to help make it easier for adolescents and young adults with cancer to take their medication every day and see if they are feasible (able to be done), acceptable, and easy to use. We are asking for your help in testing out these two programs. We are inviting you to take part in this research study because you are 15-24 years old and are taking medication as part of your cancer treatment regimen.

PROCEDURES

This study has two parts. The first part lasts about 4 weeks and includes taking your medication from an electronic pill bottle. If your adherence rate is 95% or higher during these 4 weeks, you are already reaching the adherence target without any help, so you will be done with the study after this part.

If your adherence rate is below 95%, you will continue on to the second part of the study where we will see if one of two different programs can help make taking your medication easier. The second part lasts about 13 weeks and includes 8 contacts with your coach and completing 2 sets of surveys. If you participate in all parts of the study, the study will last about 17 weeks. We will schedule all of your meetings with your coach at a time that works for you and you can complete the surveys on your smartphone or computer at a time that works for you. A member of our team will also look at your medical record to get some information.

More detailed information about the study procedures can be found under **"DETAILED PROCEDURES."**

RISKS TO PARTICIPATE

You may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you.

- More detailed information about the risks of this study can be found under **"DETAILED RISKS"**

BENEFITS TO PARTICIPATE

We cannot promise any benefits to you or others from your taking part in this research. However, we hope that these programs will help make it easier to take your medication each day. When we finish this study, we hope that we will know more about how make it easier for other adolescents and young adults with cancer to take their medication. This may help other adolescents and young adults later on.

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.

COSTS TO PARTICIPATE
There are no costs for participating in this research study. You 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, you may earn up to $150 for your time and effort. If you just do Part 1, you may earn up to $30. The table shows how much you will earn for each part of the study.

	Part 1				Part 2												
Week	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**
Surveys					$20												$20
Use Pill Bottle	$5 for each week you use it and upload your data + $10 when you bring back your bottle																
Coach Contacts						$15 when you complete all 8 sessions											

You will be paid for this study with 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, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay you. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your SSN or TIN. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your 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:

Questions about…	You can call …	At …
• Emergencies • Research-related injuries • Any research concerns or complaints	**Meghan E. McGrady, PhD**	(513) 803-8044
• Emergencies • Research-related injuries • General study questions, any research concerns or complaints	**Cincinnati Children's Hospital Lead Study Contact**	(513) 803-0906
• Your 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.	(513) 636-8039

TOTAL NUMBER OF PARTICIPANTS
We expect about 40 people to complete 1 of these 2 programs as part of this study. We expect that this will include about 10-15 people from Cincinnati Children's.

DETAILED PROCEDURES
This study has two parts. If you qualify and decide you want to be in the study, you will start with Part 1.

Part 1: For this study, we are focused on people who sometimes miss doses and don't have any problems using the electronic pill bottle to store their medication. To help us figure out what it is like for you to use an electronic pill bottle, at the beginning of the study, Cincinnati Children's will give you an electronic pill bottle to store your medication. You will be asked to use this pill bottle for 4 weeks. You will also be asked to download an app to your phone that you will use to send the Cincinnati Children's study team information from your electronic pill bottle. You will be asked to use this app to send the Cincinnati Children's team information from your pill bottle each week. If you do not have a phone, you may receive one from Cincinnati Children's to use while you are in this study. At the end of 4 weeks, the Cincinnati Children's study team will look at how you are doing taking your medication. If your adherence rate is 95% or higher, you are already reaching the adherence target without any help, so you will be done with the study.

If your adherence rate is below 95%, you will continue to Part 2 of the study where we will see if one of two different programs can help make taking your medication easier.

Part 2: Part 2 includes 3 different study tasks
1. Electronic pill bottle: You will be asked to keep using the electronic pill bottle to store your medication for the whole time that you are in the study. Each week, you will be asked to use the app to send the Cincinnati Children's study team information from your pill bottle.

2. Surveys: At the beginning of week 5, you will be asked to fill out some surveys about you and what it is like to take your medication. You will complete another set of surveys at the end of the study. It should not take more than 30-45 minutes to complete these surveys. These surveys can be completed on a website on your computer or smartphone at a time that is convenient for you. The Cincinnati Children's study team will let you know it is time to complete these surveys and will be able to help you if you have any questions about the surveys.

3. Program participation: After you have finished your first set of surveys, you will be given 1 of 2 programs (the Feedback Program or the Tailored Program). Which program you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what program you get. You will have an equal chance of being given each program. In both programs, you will be assigned to work with a coach from Cincinnati Children's.

The first program is called the Feedback Program. In this Program, your coach will send you 1 text message a week. This text message will include some information about how you have been doing taking your medication and people you can talk to if you have any questions.

The second program is called the Tailored Program. In this Program, you will meet with your coach every other week for 8 weeks for a total of 4 meetings. These meetings will occur via a video call and will take about 30-45 minutes. During these meetings, you will work with your coach to come up with a plan to help make it easier to take your medication. The Cincinnati Children's study team will audio record these sessions so we can track the topics your coach talks about with you. During weeks when you are not meeting, your coach will check in with a text message to see how things are going.

The table below summarizes the things you may be asked to do.

	Part 1				Part 2												
Week	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**
Surveys					X												X
Use Pill Bottle	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Coach Contacts						X	X	X	X	X	X	X	X				

CHANGE OF MIND/STUDY WITHDRAWAL
You can leave the research at any time; it will not be held against you. If you decide to leave the research, please contact the Principal Investigator (Dr. McGrady) so that they can document you are no longer interested in participating in the study. The Cincinnati Children's study team will ask you to explain the extent of your withdrawal. For example, you may choose to stop participating in the Feedback Program or Tailored Program but still complete the surveys and use the pill bottle. The Cincinnati Children's study team will also ask if we can still collect data from your routine medical care. If you agree, this data will be handled the same as the research data.

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

DETAILED RISKS
You may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you. You do not need to answer any questions that you do not wish to answer. You can choose to end any study procedure at any time. If you become very upset while talking with your coach, we can end that session. We will also offer to have you speak with someone about how you are feeling. If Dr. McGrady makes a referral for follow-up counseling for you as a result of this study, you will be responsible for that cost. You will continue to be responsible for the usual costs of your medical care.

There may be other risks that we do not know about yet.

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. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

After this study is over, we will save a copy of the dataset in a secure folder on the Cincinnati Children's server. If information that could identify you is removed, this dataset could be stored and used for future research or shared with another investigator for future research studies without your additional informed consent.

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.

Cincinnati Children's Hospital Medical Center, the Primary Investigator, and Co-Investigators collaborating on the study will take multiple precautionary measures to protect your privacy and confidentiality and your medical records. First, the audio recording of the sessions will be destroyed after we write down what was said in the conversation. Second, all data will remain strictly confidential and all information will be coded with a unique number, rather than your name or other identifying information. Cincinnati Children's will keep a password-protected computer file on their secure local server that includes information about you (i.e., name, age, diagnosis) and how to contact you (i.e., email address, phone number). Cincinnati Children's will share this information with the Cincinnati Children's team via a secure email so that the Cincinnati Children's team can contact you and get you started on the study procedures. All other study data (i.e., audio recordings, survey responses, adherence data) will be stored in password-protected computer files or on password protected servers at Cincinnati Children's. All hard copies of study documents will be stored in a locked cabinet in Dr. McGrady'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, if your medical provider is concerned about your treatment progress and believes that viewing your adherence data could help to inform clinical care, we

are asking for your permission to share your adherence data with them. This is an optional part of the larger study. No other data will be shared with your medical provider.

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?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children's 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
- Reports and notes from clinical and research observations

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 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.

While you/your child are participating in this research study you may not be able to access some of your/your child's health information that is related to the study. Any request for this information can be fulfilled once the study is completed.

CONSENT FOR RELEASE OF ADHERENCE DATA

Please read the statements below and indicate your choice with your initials.

____ I **do not give my permission** for the research team to share my electronic pill bottle data with my provider should my provider request these data

____ I **give my permission** for the research team to share my electronic pill bottle data with my provider should my provider request these data

_____
Name of Provider(s) with whom we can share your electronic pill bottle data

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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