Title of research study: Improving Medication Adherence using an Adaptive mHealth Intervention in Adolescents with Asthma

Key Information:

Investigator:
[Insert name of the Site principal investigator]
Contact Info:
[insert site details of who to contact]
Funding: *National Institute of Health – National Health, Lung, and Blood Institute*

You are being asked to take part in a research study. Participation is completely voluntary. The purpose of this research is to test an mHealth intervention (Asthma Ctrl) designed to help teens with asthma.

If you agree to participate today, you will be asked to participate in a 12-month study of Asthma Ctrl. You will complete questionnaires today and then once a month. You will be randomly assigned at two timepoints to use either an asthma management app, Asthma Ctrl, or Asthma Ctrl+. All three components have been designed to help you manage your asthma.

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.

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.

Reason for the study:

The main reason for this research study is to learn more about how well an intervention program delivered using technology works to help improve your medication adherence (how often you take your medicine) and your asthma symptoms. We are asking you to be in this study because you have been diagnosed with asthma, are currently taking an inhaled controller medication, and are between the ages of 12 and 18 years. We plan to enroll up to 405 patients in this study from Cincinnati Children's Hospital Medical Center (CCHMC) or Childrens Hospital of Colorado (CHCO).

Procedures:

We expect that you will be in this research study for 12 months. You will be asked to complete an initial study visit and 12 study visits that occur monthly via phone. The first visit is in person or over the phone in which you will complete questionnaires and set up

electronic adherence monitoring devices. The first visit will take about 30 to 45 minutes and the remaining visits will each take about 10 to 15 minutes. More detailed information about the study procedures can be found under ***"Detailed Procedures."***

Risks to Participate:

This is a minimal risk study, meaning we do not foresee anything bad happening to you during the study. You may feel uncomfortable answering some of the study questionnaires, but you can refuse to answer them at any time.

As with any research there may be other risks that we do not know about yet.

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved adherence to your asthma medication and improved communication about managing asthma treatments. In addition, the information that researchers hope to learn from this study could allow health care providers and those diagnosed with asthma to have a better understanding of inhaler adherence and treatment management.

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:

There is no cost to you for participating in this research study. We are only asking for your time and participation. There is no cost for the FindAir sensors (caps), however, data charges may apply when using your own phone or device. In addition, you will continue to be responsible for the usual costs of your medical care.

Payment:

[NOTE: sites may use their own local compensation practice or ClinCard as described below].

You will receive $410 for your time and effort associated with participation in this research study. The table below shows how much you will be paid for completion of each study visit. Payment will be given in the form of a reloadable debit card (ClinCard) for which you will receive a handout explaining how to use the card. Each family will receive one ClinCard and compensation will be loaded once after each study visit is completed.

Timepoint	Payment Amount
Baseline Visit	$50
Month 1	$20
Month 2	$25
Month 3	$30
Month 4	$35
Month 5	$50
Months 6-11	$25
Final Visit	$50

You (your child) will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you (your child) a handout that will explain how to use the card. Because you (your child) are being paid for your participation, (Insert Name of Institution) is required by the Internal Revenue Service (IRS) to collect and use your (your child's) 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 (Insert Name of Institution) 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.

If I have Questions or would like to know about:

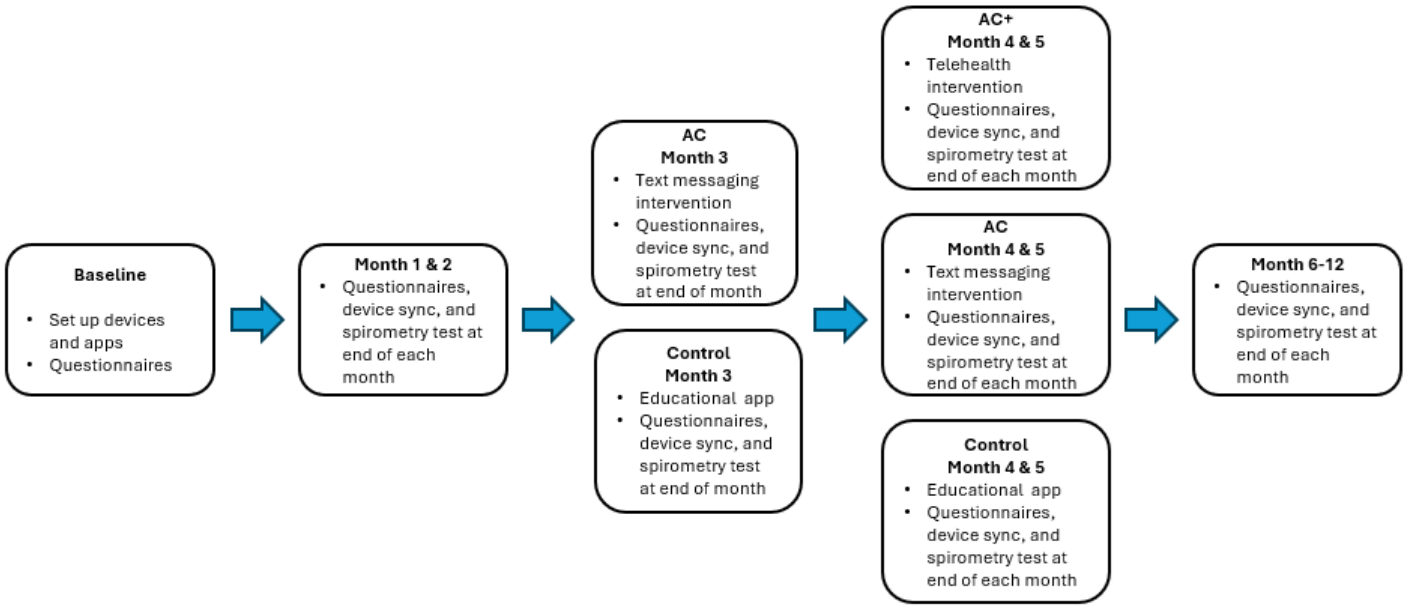
What…	**You can call …**	**At …**
• General study questions • Emergencies • Research-related injuries • Any research concerns or complaints	**Site PI Name**	Phone: xxx-xxx-xxxx
• Emergencies • Research-related injuries • Any research concerns or complaints	**Site Lead Study Coordinator**	Phone: xxx-xxx-xxxx

• Your child's rights as a research participant	**Cincinnati Children's Hospital 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 Sites can add their IRB phone number but CCHMC IRB number must remain

Total number of participants:
We expect about _____ people here will be in this research study out of _____ people in the entire study nationally.

Detailed Procedures:

At the first visit, you will fill out a series of questionnaires and you will receive two trackers that will go on top of your daily and rescue inhaler. The tracker connects to the app and records how many times you use your inhaler. Study staff will be able to see how often you are taking your medication through this app. You will also be given a mobile spirometer to assess your lung function, which you will be asked to use during the monthly visits over the phone. During the third visit, you will also be "randomized" to either the Control group OR the Asthma Ctrl group. You may be excluded from the study at this time due to adherence results. During the fourth visit, those in the Asthma Ctrl group will be re-randomized to either remain in the Asthma Ctrl group or be in the Asthma Ctrl + group. These three groups are described below. Randomization means that you will be put into a study group completely by chance, like flipping a coin. You will have an equal chance of being in each condition.



Intervention Assignments:

The control, Asthma Ctrl, and Asthma Ctrl + groups will have phone calls with the study coordinator once a month to complete questionnaires and a spirometry test.

Control: The treatment as usual condition includes twelve study visits over the phone with the study coordinator. During your third month in the study, you will complete two questionnaires over the phone and begin using an app with educational materials and medication strategies. This visit will take about 10 to 15 minutes. You will be asked to use this app on your own throughout the next three months of the study. For the remainder of the study, you will have 10, 10–15-minute long visits to complete questionnaire and spirometry tests. During visit six, study staff will call you to get your feedback on the app and have you fill out additional questionnaires.

Asthma Ctrl: The Asthma Ctrl treatment condition includes twelve study visits over the phone with the study coordinator. During your third study visit, you will complete two questionnaires over the phone and begin the text messaging intervention, where a study team member will send you brief personalized text messages 1-2 times a week to help you set goals related to your asthma and improve your adherence. You will also receive access to your adherence data during this visit. During the fourth study visit, you will be re-randomized to either the AC or AC+ group. If you remain in the AC group, you will continue to receive these personalized text messages for the following two months. For the remainder of the study, you will have 9, 10–15-minute long visits to complete questionnaire and spirometry tests. During visit six, study staff will call you to get your feedback on the app and have you fill out additional questionnaires.

Asthma Ctrl +: The Asthma Ctrl+ treatment condition includes twelve study visits over the phone with the study coordinator. During your third study visit, you will complete

two questionnaires over the phone and begin the text messaging intervention, where a study team member will send you brief personalized text messages 1-2 times a week to help you set goals related to your asthma and improve your adherence. You will also receive access to your adherence data during this visit. During the fourth study visit, you will be re-randomized to either the AC or AC+ group. If you are randomized to the AC+ group, you will be asked to complete four 20–30-minute sessions every two weeks via video conference focused on problem solving to improve your adherence with a trained clinician. For the remainder of the study, you will have 9, 10–15-minute long visits to complete questionnaire and spirometry tests. During visit six, study staff will call you to get your feedback on the app and have you fill out additional questionnaires.

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you.

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 abuse of device privileges (see cell phone contract).

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

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research studies 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.

Health data provided by the participant, specifically asthma control and spirometry data, will be used for research purposes only and will not be shared with a medical provider nor will medical advice be provided based on the data.

Data collected from the sensor caps on your inhalers include the time, date, and approximate location of inhaler medication use. Location is determined using latitude/longitude data collected from your smartphone should those smartphone permissions be enabled.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and /or data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution or for-profit company.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration 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. In addition, FindAir has a legal obligation to maintain records regarding complaints and incidents related to their device which includes both the sensor and the application. If you have a complaint or there is an incident related to your device, FindAir may collect identifiable information regarding the complaint or incident for their records. This information can include your name, contact information, device ID, and information related to the complaint or incident.

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

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH
[INSERT SITE HIPAA LANGUAGE]

SIGNATURES

The research team has discussed this study with you and answered all 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