NCT03317977

Translating an Efficacious Illness Management Intervention for Youth with Poorly Controlled Asthma to Real World Settings

3/28/23

Parental Consent (Permission) Form

[Medical] Research Informed Consent

Title of Study: Translating an Efficacious Illness Management Intervention for Youth with Poorly Controlled Asthma to Real World Settings

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Location(s): Children's Hospital of Michigan
Wayne Children's Health Access Program

Funding Source: National Institutes of Health

When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

Purpose

You are being asked to take part in a research study to test a treatment program called REACH for Control (RFC). RFC is a treatment program for children diagnosed with moderate to severe asthma who have had two or more visits to the emergency room or hospital in 12 months. In RFC, a Community Health Worker (CHW) will work with children and their families in their own homes to find ways to improve the way they take care of asthma. CHWs are counselors who have been trained specifically to help children and families improve their health. This study is being conducted at Wayne State University, Children's Hospital of Michigan and Kid's Health Connection. The estimated number of study participants to be enrolled at Children's Hospital is about 170. **Please read this form and ask any questions you may have before agreeing to be in the study.**

Study Procedures

If you agree to take part in this research study, you and your child will be assigned randomly (like flipping a coin) to one of two groups. You will be assigned to either the RFC treatment group or the MATCH treatment group. All treatment will be provided by Community Health Workers (CHWs) or asthma educators who are employed by Kid's Health Connection (KHC), a community agency in Detroit. Treatment sessions will take by telehealth. Telehealth means that the CHW or asthma educator will meet with you and your child using an online system called Doxy.me where you can see each other and talk to each other on the Internet in real time. You can log into Doxy.me for your sessions from a smart phone, laptop, desktop computer or other device with Internet access. The CHW or asthma educator will also send handouts with information that may be helpful to you and your child to you by email.

If you and your child are assigned to RFC, you will take part in a 24 week treatment program. A CHW will work with your family to assess any barriers to asthma management and identify ways to improve

your child's asthma management. In the beginning, you and your CHW will meet twice a week. The first session of each week will focus on providing you and your child with asthma education, developing a new asthma management skill or changing the way your family interacts when taking

care of asthma. The first weekly session will last about 60 minutes. The second meeting of the week will be a brief, check-in session that will last about 15 minutes and allow the CHW to discuss your progress on health-related goals that were set earlier in the week. Toward the end of treatment, the number of sessions can be reduced to once a week. The CHW can also help develop an asthma action plan for your child in school, connect your family with resources in the community that may be helpful, and help you and your child identify a doctor to care for your child's asthma if you do not have one. RFC treatment will last six months in total.

If you are assigned to the MATCH treatment group, you and your child will take part in a six-session treatment program over six months. You will receive asthma education, assistance in finding a doctor to care for your child's asthma if you do not have one and assistance in developing a school asthma action plan.

All telehealth treatment sessions will be audiotaped. The purpose of audiotaping is to allow the CHWs' supervisor to review treatment session to be sure that the RFC and MATCH programs are being delivered correctly.

In addition to treatment sessions, you will take part in a total of four other study visits. You may choose to complete these visits either at your home with help from the researchers, on the Internet by following a link and/or over the phone. If you chose the option to complete the visit at your home with help, research staff will come to your home and provide you with a tablet computer to complete questionnaires on and will interview you over the phone while at your home. The researchers will remain in their vehicles, so that there will be no face-to-face contact. These visits will be scheduled at a time that is convenient for you and your family and should take about 90-120 minutes. The first study visit will take place when you are enrolled into the study and the follow-up visits will take place six, twelve, and eighteen months after you enroll. At each study visit, you and your child will complete interviews and questionnaires that ask about how you and your family take care of asthma, frequency of asthma symptoms and any visits to the emergency room or hospitalizations You will also receive brief telephone calls three times in between your study visits to ask you about your child's asthma health, which will each last about 15 minutes.

Your child's medical record at Children's Hospital of Michigan will be reviewed for their asthma medical history and to see how often s/he visits the emergency room or is hospitalized. If your child has received asthma treatment received at a hospital other than Children's Hospital of Michigan, you will be asked to sign a release of information form to obtain their records. In addition, your child's treatment record at KHC will be reviewed to obtain information such as how many treatment sessions you received. You will be asked to sign a release of information to allow the researchers to collect this information.

At the six month study visit, you and your child will take part in an interview about your experiences in the RFC or MATCH program. This interview will be audiotaped so that your thoughts about the program in your own words can be recorded. This interview will add about 30 minutes to the visit.

You will be in the study for a total of 18 months.

Benefits

As a participant in this research study, there may be no direct benefit for you; however, information from this study may benefit other people with asthma now or in the future. You may also benefit from improvements in how your family cares for asthma or your child's asthma health.

Risks

By taking part in this study, you may experience the following risks:

- You or your child may become tired from completing questionnaires and interviews. If you or your child become tired, you will be given a rest period or questionnaires can be read to your child. You or your child could also become upset from answering personal questions.

- Although every effort will be made to protect your confidentiality by storing your identity on password protected computers and using a secure system to conduct the telehealth visits, it is possible that unauthorized persons could gain access to your personal information.

- If at any time during the study there is concern that child abuse has possibly occurred, or you or your child report thoughts of suicide or an intention to harm someone else, the research staff must release/report that information to the appropriate authorities.

There may also be risks involved from taking part in this study that are not known to researchers at this time.

Alternatives

The only alternative is not to participate in the study. If you would like additional information regarding asthma care or other programs available in the community to improve asthma management, you may talk to the hospital staff and they can assist you or provide you with more resources.

Study Costs

Participation in this study will be of no cost to you.

You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered "standard of care" and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x-rays, scans, surgeries, routine medical care, and physician charges.

Your health insurance company may not pay for these "standard of care" charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay.

So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the study.

Compensation

For taking part in this research study, you will be paid for your time and inconvenience. You will receive $100 at each of your four study data collection visits for a total of $400. You will not be paid for completing RFC or MATCH treatment sessions.

Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. No reimbursement, compensation, or free medical care is offered by Wayne State University.

If a "research related injury" results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance. A "research related-injury" means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research.

It is important for you to follow your physician's instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

You will not be paid for any other injury- or illness-related costs, such as lost wages. You are not waiving any legal rights and are not freeing the sponsor, Principal Investigator, or hospital of any malpractice, negligence, blame or guilt by participating in this study.

If you think that you have suffered a research related injury, contact the PI right away at 313-577-1055.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for research or educational purposes, your identity will be protected or disguised. Audiotapes will be destroyed upon completion of the study

A description of this clinical trial is available on http://ClinicalTrials.gov as required by U.S. Law (trial # NCT03317977). This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study, you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

Questions

If you have any questions about this study now or in the future, you may contact Dr. Deborah Ellis or one of her research team members at the following phone number: 313-577-1055. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study, you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant / Legally authorized representative*	Date
Printed name of participant / Legally authorized representative *	Time
Signature of witness**	Date
Printed of witness**	Time
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time
Oral Assent (children age 7-12) obtained by	Date

*Remove LAR reference if you don't intend to consent participants that have or may have LAR.

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

Signature of translator	Date
Printed name of translator	Time

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HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and her research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and her research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, address (street address, city, state and zip code), elements of dates, telephone numbers, medical record number, and any unique identifying numbers or characteristics or code.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: name (or initials), address (street address, city, state and zip code), telephone numbers, and any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project
- WSU's Institutional Review Boards (IRB)
- Authorized members of WSU's workforce who may need to access your information in the performance of their duties.
- Other collaborating institutions, which include: Wayne Children's Health Access Program.
- The study Sponsor or representative, including companies it hires to provide study related services, which include: National Institutes of Health
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study, you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- ❖ By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

Signature of participant	Date
Printed name of participant	

- ❖ For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

Signature of authorized representative	Date
Printed name of authorized representative	Relationship to the participant
Signature of person obtaining Authorization	Date
Printed name of person obtaining Authorization	Time