

RE-PACT: Respiratory Exacerbation Plans for Action and Care Transitions for Children with Severe CP

NCT05292365
3/10/2022

**University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research**

Study Title for Participants: RE-PACT Study (Aim 2)
Formal Study Title: RE-PACT: Respiratory Exacerbation Plans for Action and Care Transitions for Children with Severe CP
Lead Researcher: Ryan Coller, MD
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Institution: University of Wisconsin – Madison

Key Information

The information in this section is to help you decide whether to be a part of this study. You can find more detailed information later in this form.

Why are researchers doing this study?

Cerebral Palsy (CP) is the most common motor disability in US children, and respiratory illness is the number one cause of hospitalization in children with severe CP. Since respiratory illnesses first emerge at home, families are the first in line to help manage their children's care. Increasing communication between primary caregivers and medical care teams may help prevent hospitalization.

We invite you to take part in this research study because you are a primary caregiver of a child with CP who receives specialty respiratory care/treatment.

What will I need to do in this study?

At the start of the study, you will be randomly assigned (like flipping a coin) to be part of the “intervention” group or the “control” group. You will have a 50/50 chance of being assigned to each group, and will be told which group you are in.

If you are part of the intervention group, you will meet with a clinical member (nurse practitioner or physician) of the Pediatric Complex Care Program (PCCP) team to create a “respiratory action plan” you can follow if your child becomes ill during the 6-month trial. Each week, you will be asked to respond to a text message about your child’s current health. The clinical team member will monitor these text messages and get in touch if you seem concerned about your child’s health. Each month, you will also be asked to complete an online survey about your child’s health and caregiving experiences. You will continue to receive your usual care and coordination assistance from the Pediatric Complex Care Program.

If you are assigned to the control group, you will continue to receive your usual care and coordination assistance from the Pediatric Complex Care Program and will be asked to complete a survey about r child’s health and caregiving experiences at the beginning and end of the 6-month study.

You can find more detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
<ul style="list-style-type: none"> • Willing to reply to a weekly text message inquiring about your confidence in your child's current health. • Willing to participate in the study for 6 months. • Interested in meeting with a nurse practitioner monthly to learn more about how to care for your child when they are ill (if assigned to the intervention group) 	<ul style="list-style-type: none"> • Are not interested in receiving additional support regarding your child's respiratory health. (We understand that some families feel they have enough assistance and don't want for more input or visits.) • Do not have time to participate in study activities (completing surveys, responding to weekly text messages, attending monthly sessions with the nurse practitioner).

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will continue to receive all your usual services from the Pediatric Complex Care Program. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study as well as a description about what you will be asked to do during the study.

At the first visit, called the enrollment visit, you will read and discuss this consent form and have your questions answered about the study. You may take as much time as you need to decide whether to participate. If you decide to join the study, you will sign the consent form and receive a copy for your records. Next, you will also be asked to complete an online survey about your child's health and caregiving experiences. The survey takes about 10 minutes to complete. Then the study staff will randomly assign you to a study group (*intervention group or control group*) and give you instructions on the next steps in your study participation (see below). Depending on your preference, the enrollment visit can take place in-person (at a clinic visit) or remotely in a WebEx teleconference. The visit should last about 45 minutes.

If you are assigned to the *intervention group*, a second meeting (in-person, by phone or WebEx) will be scheduled within the first month of your enrollment. At this visit, you will meet with a clinical member (nurse practitioner or physician) of the PCCP team to create a written "respiratory action plan." This plan will outline things you can do when your child is at risk for experiencing a worsening of respiratory symptoms (problems such as difficulty breathing, noisy breathing or shortness of breath) and who and when to call for clinical advice. The action plan(s) you create with the study team will contain the same, standard clinical care guidelines provided by your child's respiratory team. If your child already has a similar plan, you can include those steps in the study respiratory action plan. The clinical team member

will send you the action plan by mail (and MyChart if requested) and encourage you to refer to the plan when needed. The plan will give you instructions on what to try first, when to consult with your child's providers, and when to go to the hospital. Your child may have more than one action plan if needed. You will also be given instructions on how to contact the clinical team member during the study if you have questions or concerns about the plan or your child's health. This meeting will last about 20 minutes. Throughout the study, your child will continue to receive their usual care and services from the Peds Complex Care Program and AFCH Specialty Clinics.

In addition, each week you will receive a text message asking:

"How confident are you that your child can avoid an unplanned hospitalization over the next month?

Please respond on a scale from 1 (not confident) to 10 (fully confident). If your child is currently hospitalized, please respond by texting "h". Thank you!"

This message will be sent weekly for the next 6 months on a random day (Sunday – Thursday) and time (between 8AM and 9PM). You are asked to respond immediately, or as soon as you are able. You will receive up to two reminder texts if you do not respond. Responding to each text message should take less than one minute. A clinical member of the PCCP will review your responses and contact you if you indicate having low confidence to see how your child is doing and discuss any treatment recommendations. They may also communicate this information with other members of your child's clinical team to get their opinions on what to do next. These conversations should take about 10-15 minutes. When study team members discuss your child's care with other members of your child's care team (for example, specialist doctors), they will share the minimum amount of information needed to discuss your child's health and not all the details may you have shared about your opinions of the doctors or the care they have given your child. Researchers hope to determine if this type of "just-in-time" communication is beneficial to caregivers and children, and whether it prevents hospitalizations for respiratory illnesses.

Finally, each month you will be asked to complete an online survey about your child's health and caregiving experiences. The survey takes about 10 minutes to complete.

If you are assigned to the *control group*, you and your child will receive your usual care and services from the Peds Complex Care Program and AFCH Specialty Clinics. You will be contacted 6 months after your enrollment visit and asked to complete the final study survey. Like the enrollment survey, this online survey should take about 10 minutes to complete.

Following your study participation, study staff will collect information from your child's medical record (see section called **Protected health information (PHI) used in this study** for a list of information to be gathered). This information will be stored in a secure database and only authorized study personnel will have access to the data.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your or your child's health care.

Who can I talk to about this study?

If you have questions about the study, you can contact the project manager, Gemma Warner, at gwarner@pediatrics.wisc.edu or 608-263-0740. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential

research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Things you tell the researchers about your child's health
- Information currently in your child's medical records as well as information added to their medical records during the study. This information will include your child's medical history; their diagnoses; dates and reasons for clinic and emergency department visits, hospitalizations, MyChart messages, and phone calls in the past year; organ systems affected by chronic conditions, subspecialists seen in the past year, medical technologies used (such as a trach, g-tube, or baclofen pump), duration of enrollment in the Peds Complex Care Program, and respiratory treatments at time of enrollment. We will get this information from your child's electronic medical record.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

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

If you choose to leave the study, the study team will use any data collected up to that point in the study results. Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Ryan Coller, MD, at the Department of Pediatrics, 600 Highland Ave, Madison, WI 53792.

Will being in this study help me in any way?

Being in this study may help you better understand your child's health status. If you are randomized to the intervention group, the study team will share information about your child's health and your confidence about caregiving with your child's clinical providers. This may increase early detection of health crises, such as respiratory or other infections. Increased communication and care coordination may also improve your experience navigating the health system. It may also prevent emergency department visits and hospitalization.

If you are a part of the control group receiving your usual care, we do not expect participating in the study will be of benefit to you or your child. However, if the intervention in this study proves beneficial, this approach may be developed and used in the Peds Complex Care Program, which could benefit you, your child, and other families enrolled in the program.

What are the study risks?

- If you are randomized to participate in the intervention group, you may experience mild psychological discomfort in discussing parenting, personal and family matters, including challenges and demands about caring for a child with severe CP.
- The study surveys inquiry about family demographics, including parental education and household income. Answering these questions may cause discomfort. You skip any question you wish not to answer.
- The other risk of taking part in this study is that your or your child's study information could become known to someone who is not involved in performing or monitoring this study. We will take every precaution to keep your child's health information private.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will 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.

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed above for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research or share it with other researchers without additional consent from you.

This study is being conducted in collaboration with researchers at University of California-Los Angeles (UCLA) and families in their pediatric complex care program. We will share information collected in this study with UCLA researchers, first removing identifiable information to ensure the privacy of study participants.

Will information from this study go in my child's UW Hospital and Clinics medical record?

If you are assigned to the intervention group, any clinical communications with the study clinical team member will be documented in your child's medical record as they would with routine care, as well as

copy of your child's respiratory action plan. Members of the Peds Complex Care team and your other UW Health providers will be able to see these notes.

Will I receive the results of research tests?

The study surveys are only for research, not to diagnose mental health or other issues. We will not be sharing the results of these surveys with you. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

Can I be removed from the research without my agreement?

The person in charge of the research study, Ryan Coller, can remove you from the research study without your approval. This rare event could happen if:

- you lose contact with us and do not participate in any of the study's activities
- your child is no longer part of the Pediatric Complex Care Program

Will I receive anything for participating?

You will be paid \$100 following the enrollment visit and \$100 following the final survey, for a total of \$200.

Permission to communicate about the study by email

We are requesting your email address so we can send and receive study information, such as the survey link for the study surveys. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the provider or clinic you would usually contact. For urgent issues having to do with the study, please contact the lead study investigator, Ryan Coller, MD, at 608-263-9408 (office) or Gemma Warner, project manager, at 608-239-4280. We will return your call within one business day.

How many people will be in this study?

We expect about 90 families will participate in this study. 45 families will join from the Pediatric Complex Care Program in Madison, WI and 45 families will join from the Pediatric Medical Home program at UCLA.

Who is funding this study?

This research is being funded by the National Institutes of Health. **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.**

What will happen to my data after my participation ends?

We will keep your data for an indefinite period of time, meaning we have no plans of ever destroying them. Keeping data for future research is called "banking." The banked data will be kept in a secure location for use by researchers. We will use the data in future research projects about children and caregiver support. We may also use them for other types of research. The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside

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researchers may be at other universities, private companies, or other kinds of organizations. Banked data will not be shared with your health care providers or used in your treatment outside this study.

Agreement to participate in the research study

You are making a decision whether or not to have you and your child participate in this study. You do not have to sign this form. If you refuse to sign, however, you and your child cannot take part in this research study. If you sign the line below, it means that you have:

- read this consent and authorization form describing the research study procedures, risks and benefits
- had a chance to ask questions about the research study and your child's participation, and received answers to your questions
- decided to allow your child to participate in this study
- given authorization for the person's protected health information to be used and shared as described in this form

Printed name of child

Printed name of parent or
legally authorized caregiver

I am this child's parent
--- OR ---
 I am not this child's parent but
am the person legally authorized
to consent to the child's general
medical care

By checking this box and typing my name below,
I am electronically signing this consent form.

Signature of parent or
legally authorized caregiver

Date

Signature of Study Team Member Obtaining Consent

Date