Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: A protocol for care coordination and motivational interviewing for women with a recent preterm birth

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You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff.

Study Overview

You are being asked to take part in this research study because you recently had a preterm birth and you are planning to take your baby for primary care at Karabots Pediatric Care Center or Cobbs Creek.

The purpose of this study is to find out if care coordination can help with access to preventive health care and achieving desired health behaviors after a preterm birth.

Care coordination involves someone from your doctor's office working with you to develop a plan of care, make sure your questions are answered between visits, and address your individual concerns so you can get the health care you need.

If you agree to take part, your participation will last for up to six months and will involve working with a care coordinator by phone, video, or in person during that time. You may not complete all the study procedures that are listed, it may depend on which procedures are being assessed at the time you enroll. The care coordinator may provide education, care navigation, referral to services, and support for positive health behaviors (e.g. healthy diet, sleep, attending a postpartum visit) through a strategy called Motivational Interviewing. Motivational Interviewing involves talking with someone about your own values and your own motivation for change. In addition, there will be three study interviews to collect data specifically for the study.

The main risks of this study are any distress generated from working with the care coordinator.

You may benefit if the care coordinator is able to help you receive recommended preventive care or develop or continue healthy behaviors.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

What is the current standard of treatment after preterm birth?

Health care professionals recommend that women follow-up with their obstetrical team and their primary care team after preterm birth to address any potential health problems that have been identified during the pregnancy and plan for ongoing health

What are the study procedures?

- This study involves screening, care coordination, and motivational interviewing components, we may provide some parts of this program to you without providing the full intervention. You will be informed at enrollment which parts we are currently testing.
- In the first two weeks of the study the care coordinator will assess your health care needs and health behaviors by talking with you and your health care team. The care coordinator will work with you to develop a care plan. A care plan is a 1 – 2 page document that outlines recommendations and goals for your health care. The care plan helps make sure that everyone involved with your health care is on the same page.
- The care coordinator will help support your care plan by providing health care navigation, education, referrals to resources, and supporting desired positive behaviors. The care coordinator will meet with you either in-person, by phone, or by video. There is no set schedule for meeting with your care coordinator. The exact amount of contact you have with the care coordinator will depend on your individual needs.
- To support your health behaviors, the care coordinator will use Motivational Interviewing. Motivational Interviewing involves conversations about what is important to you and your motivation for health.
- You should expect to talk with your care coordinator 6 – 10 times during the next six months. Each conversation might last 10 – 30 minutes.
- The care coordinator might be the first person on your health care team to find out about a safety concern. For example, if you tell your care coordinator about severe depression, the care coordinator will work with other members of the clinical team to help connect you to emergency resources.
- In addition to working with a care coordintor, there will be three study interviews lasting approximately 15 – 30 minutes, either in-person, by phone, or by video call, to find out about your recent health care and your health behaviors. The study team will also review your medical records to gather this information.
- Some conversations with the care coordinator and some study interviews will be audiorecorded and transcribed to make sure we understand what is working well and what isn't working during this study. All recordings and transcripts will be stored at CHOP on secure computers in password-protected files.

What will be done with my data during this study?

During the study, we will collect information from your health record and from asking you to answer questions. By agreeing to participate in the study, you agree to give this information to CHOP for research purposes.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are any discomfort or embarressment caused by participating in the intervention or from completing the study interviews. You might be uncomfortable or embarrassed by talking about topics like your personal habits related to healthy eating or questions about how you have been feeling. You do not have to ansewer any questions that make you too uncomfortable.

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

Are there any benefits to taking part in this study?

You might benefit by finding it easier to get to your doctors' appointments and to develop or keep healthy habits with the support provided by this study. These benefits could improve your ongoing health. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help doctors determine how best to support women after a preterm birth.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will be asked to work with a care coordinator through telephone calls, or in-person, or video visit time additional to regular health care visits. There is no set schedule for these contacts – you and your care coordinator will decide what is best for your situation. You will also be asked to complete three study interview, each of which will take approximately 30 minutes.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP or at Penn Medicine.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What choices do you have other than this study?

If you chose not to participate in this study, you can still receive all of your regular care from your obstetrical and primary care team.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records and interviews. Information related to your medical care at CHOP will go in your medical record. This could include information about your upcoming appointments or goals for your health. For younger participants who see doctors at CHOP it might include information from primary care visits (for example, weight measurements). Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP and UPenn.
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- Employees of the company transcribing the audio recordings of conversations with the care coordinator and some study interviews;
- The National Institutes of Health who is sponsoring this research.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed three years after the study is completed.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institutes of Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Emily Gregory
The Children's Hospital of Philadelphia
Department of Pediatrics
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study. However, it is possible that participating in this study will lead you to communicate more with your health care team. This might lead them to recommend more health care visits or tests based on knowing more about your health situation. If this happens, and you chose to follow their recommendations, these visits or tests might have some costs to you (for example, costs related to transportation for visits).

Will you be paid for taking part in this study?

You will be paid $30 for completing the enrollment interview, $30 for an mid-point interview, and $60 for a final interview for your time and effort. (Each participant may be paid up to $120 total over the course of the study.)

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. Gregory at 215-419-3122. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

What will be done with my data and specimens when this study is over?

Your data will not be used for any future research after this study is complete. Your data will be stored for a period of time to ensure accurate analysis and then will be destroyed.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent. You are also authorizing the use of your health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.

Name of Subject

Signature of Subject

Date