STUDY INFORMED CONSENT

Therapist Education and Massage for Parent Infant-Outcomes (TEMPO)

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University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study
and
Consent to Participate in a Research Study
Adult Participants [PARENT]
Consent Form Version Date: 19Feb2020
IRB Study # 19-0282
Title of Study: Therapist Education and Massage for Parent-Infant Outcomes
Principal Investigator: Dana McCarty
Principal Investigator Department: Allied Health - Physical Therapy
Principal Investigator Phone number: (919) 843-8696
Principal Investigator Email Address: dana_mccarty@med.unc.edu
Funding Source and/or Sponsor: NIH National Center for Complementary and Integrative Health (NCCIH)

CONCISE SUMMARY

The purpose of this research study is to see if a Therapist Education and Massage Program is feasible and acceptable for parents of extremely preterm infants in the Neonatal Critical Care Center (NCCC) at UNC Children's Hospital. This study expands physical and occupational therapy standard of care by setting up parent education sessions on a weekly basis and teaching infant massage to parents. The therapist will also follow yours and your baby's progress after hospital discharge at two Special Infant Care follow-up appointments.

Possible risks for your infant are minimal and include 1) changes in heart rate, stress, discomfort, during massage, 2) a skin reaction as a result of Aquaphor during the massage session and 3) loss of confidentiality if emails are seen by other persons than the parent, or if data from the medical record is seen by others.

Possible benefits for your infant include 1) improved weight gain, sleep, and ability to stay calm as a result of infant massage and 2) improved bonding and interaction with you, the parent.

If you are interested in learning more about this study, please continue reading below.

What are some general things you and your child should know about research studies?
You are being asked to allow your child to take part in a research study. To join the study is voluntary. You may decide to not allow your child to participate, or you may withdraw your permission for your child to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving

the study before it is done will not affect your or your child's relationship with the researcher, the health care provider, or the University of North Carolina-Chapel Hill. If your child is a patient with an illness, your child does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you and your child understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn if Therapist Education and Massage for Parent-Infant Outcomes (TEMPO) program is feasible in the Neonatal Critical Care Unit and if it is acceptable to parents. We will interview parents who performed the intervention to get feedback on the TEMPO program so that we can use that information to improve the program in the future.

Your child is being asked to be in the study because he/she was born extremely preterm, or less than 28 weeks gestation. You are being asked to participate in this study because you are the biological parent of an extremely preterm infant.

Are there any reasons your child should not be in this study?

Your child should not be in this study if he/she is more than 4 weeks old, or has genetic/chromosomal abnormality, congenital neurological or musculoskeletal disorder.

How many people will take part in this study?

There will be approximately 40 infants and 40 parents in this research study. (Secondary biological parents will also have the opportunity to participate in certain aspects of the research study if they choose, with the possibility of up to an additional 40 parents.)

How long will your child's part in this study last?

Your baby will be in this study throughout hospitalization and after discharge until he/she comes for the follow-up visit at 12 months corrected age, or approximately 15 months old. Each in-person contact will last 15-45 minutes.

What will happen if you and your child take part in the study?

If you and your infant take part in this research, you will be asked to participate in a Therapist Education and Massage for Parent-Infant Outcomes (TEMPO) Program for you and your infant. During your infant's hospital stay, your participation in this study will involve the following:

- Introductory educational session with the therapist
- Weekly therapy sessions in-person or via video chat
- At least 2 infant massage sessions where the therapist teaches you massage your infant
- Discharge educational session with the therapist

After your infant discharges from the hospital, your participation in the study will involve:

- Receiving emails from the therapist every other week
- Receiving one phone call from the therapist about one month after discharge. During this phone call, we will also conduct a brief interview to see how therapy activities and massage have been going at home. You will be asked if we can audio record the interview so that we may review it as part of our data collection. If you do not give permission for audio recording, we will ask if we may take notes about your responses during the interview. The phone call should last no more than 10-15 minutes.
- Continuing to try therapy activities and massage at home (goal of at least 2-3x/week)
- Attending 2 therapy sessions at your infant's Special Infant Care Clinic follow-up appointments. These therapy sessions will take place during standard follow-up appointments for your infant, so they will not require any additional visits to the hospital. One of these visits will include a one-on-one massage review session with the therapist.

Immediately before and after the massage education session, we would like to collect a saliva sample from you and your infant using a cotton swab to swipe the inside of the cheek. We will use this saliva to measure cortisol levels. Because cortisol is an indicator of stress, we are looking for ways that massage may impact stress level. The results of this test will be recorded in the medical chart and the specimen will be disposed of.

At four points during the study (twice during your child's hospitalization, and twice at follow-up appointments), you will be asked to complete various surveys that attempt to summarize your feelings of depression, anxiety, and sense of parenting competence. It will take about 20 minutes to complete these surveys.

At the 12-month follow-up visit, you will be asked to complete a questionnaire about your baby's temperament, and the therapist will complete a gross motor assessment with your child called the Bayley Scales of Infant Development-III.

We will also conduct a short interview with you at the follow-up appointments to get feedback on the TEMPO program so that we can use that information to improve the program in the future. When we conduct these interviews, we will ask to audio record it so that we may review it as part of our data collection. If you do not give permission for audio recording, we will ask if we may take notes about your responses during the interview. When you receive the emails from the therapist every other week, you will be asked to click on a link to report how often you've tried therapy interventions and massage with your baby at home.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to **your child** from being in this study may be:

- Improved weight gain, sleep, and ability to stay calm as a result of infant massage
- Improved bonding and interaction with you, the parent

The benefits **to you** from being in this study may be:

- Becoming more comfortable touching, holding, and playing with your infant from a very young age during hospitalization
- Feeling confident in your ability to read your infant's body language and needs as they change during hospitalization
- Increasing opportunities to bond with your infant
- Learning how to perform infant massage with your infant which has many benefits for you (like reducing stress and depression) and for your infant (like gaining weight and staying calm)
- Developing a strong relationship with the therapy team in the NCCC and receiving weekly updates about your infant's motor progress
- Continuing to receive therapist tips about infant development after discharge home
- Having the opportunity to reflect on your own emotions and sense of parent competence the first year of your preterm infant's life

What are the possible risks or discomforts involved from being in this study?

The possible risks to **your child** taking part in this research are:

- Infant change in heart rate, stress, discomfort during massage
- Skin rash as a result of Aquaphor during the massage session.
- Loss of confidentiality if emails are seen by other persons than the parent, or if data from the medical record is seen by others.

These risks will be minimized in the following ways:

- Your child will be constantly monitored for safety throughout all therapy sessions by the therapist and bedside nurse.
- The therapist will provide the parent with feedback and instruction about how to adjust intervention to reduce these risks.
- A small area of your child's skin will be tested for any possible negative reaction prior to the massage session.
- The study protocol includes rigorous efforts to protect patient confidentiality. The research team will stay small to prevent proliferation of information.

The possible risks **to you** in taking part in this research are:

- Inconvenience or stress from weekly meetings with therapist and/or completion of questionnaires
- Psychological distress when learning about your child's preterm development
- Possibility of breach of confidentiality through email management server iContact (online software external to UNC-CH) used for sending bi-weekly therapist emails

These risks will be minimized in the following ways:

- With the exception of 4 sessions during hospitalization, you will have the option of video chat to decrease the burden of coordinating your schedule with the daytime therapist.
- Questionnaires will be recorded on an iPad to reduce time
- The therapists and many support staff at the NCCC are well-prepared to help you work through the challenges of and questions about preterm infant development during and after your child's hospitalization and beyond.
- Identifiable information shared with iContact will be limited to your first name and email address.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

How will information about you and your child be protected?

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your child's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Study data will be securely stored. There will be a password protected internet database only accessible to the researchers. All research subjects will be assigned a study number. The list that links your name and your child's name to a study number will be kept separately in a secure research office. The signed consent forms will be kept separate from the research data.

Any identifiable data that is collected from you and your child will be recorded using the study number. The investigators will take appropriate care to protect the confidentiality of your private information. However, there is a slight chance that others could learn information about you from this study.

You and your child's information may be used in publications or presentations. However, the information will not include any personal information that will allow your child to be identified.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

By signing this informed consent document, you agree that some of the information generated by your child participating in this study and/or a copy of the consent form may be included in your child's medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to your child. This will allow the doctors caring for your child to know what study medications or tests they may be receiving as a part of the study and know how to take care of them if they have other health problems or needs during the study. Additionally, the information may be shared with their medical insurance plan if the research services provided are billed to insurance.

What will happen if your child is injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call Dr. McCarty at 919-123-5142. She will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before you and your child's part in the study is complete?
You can withdraw yourself and your child from this study at any time, without penalty. The investigators also have the right to stop yours and your child's participation at any time. This could be because your child has had an unexpected reaction, or because the entire study has been stopped.

Will you and your child receive anything for being in this study?
The participating parent will receive a $50 gift card per participating child at the first follow-up visit after completing the massage review session with the therapist.

Will it cost you anything for you and your child to be in this study?
It will not cost anything extra to be in this study. However, you will be billed for your child's routine medical and therapy care. All tests, visits or procedures other than what is done for this study will be related to medical care that is part of the usual care for your child's condition. These would be suggested even if you decided not to allow your child to be in the research study. Here are some examples of routine medical and therapy care that may be performed within this study:

- Physical and Occupational Therapy Evaluation and Treatment
- Bayley Scales of Infant Development-III gross motor assessment at follow-up

Who is sponsoring this study?
This research is funded by the National Center for Complimentary and Integrative Health (NCCIH) which is part of the National Institutes of Health (NIH). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you or your child has questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form**.**

A description of this clinical trial will be available on 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 if there are questions about you and your child's rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

IRB Study # 19-0282
Title of Study: Therapist Education and Massage for Parent-Infant Outcomes
Principal Investigator: Dana McCarty

AUDIO RECORDING

At three points during the study, a member of the study team will interview you about your experience with TEMPO. One of these interviews will take place over the phone about 1 month after hospital discharge, and the other two will take place during follow-up appointments. The audio will be recorded using a portable digital recorder, and audio files will be saved on a password protected server until after transcription. After the study period ends, the audio files will be destroyed. If you choose not to be audio recorded, the study team will ask to take written notes on your responses. You may ask for audio recording to be turned off at any point.

Check the box that best matches your choice:

_____ Ok to audio record me during the study

_____ NOT Ok to audio record me during the study.

SALIVA SAMPLE/BUCCAL (cheek) SWAB

_____ **I MAY** have a saliva sample/buccal (cheek) swab for
My Initials the TEMPO study.

_____ **I MAY NOT** have a saliva sample/buccal (cheek) swab
My Initials for the TEMPO study.

SALIVA SAMPLE/BUCCAL (cheek) SWAB

_____ **My child MAY** have a saliva sample/buccal (cheek) swab for
Parent Initials the TEMPO study.

_____ **My child MAY NOT** have a saliva sample/buccal (cheek) swab
Parent Initials for the TEMPO study.

PATERNAL PARENT CONSENT

The TEMPO program includes voluntary and optional secondary parent participation (paternal) to incorporate an additional perspective on the TEMPO program, and assess the acceptability and feasibility of paternal participation in the program. Before approaching the secondary parent about whether they would like to consent to participate, your permission is required as they would be given permission to share in participation in all parental education activities in which you are the primary parent.

SECONDARY PARENT (PATERNAL) PARTICIPATION PERMISSION

_____ **I GIVE PERMISSION** for my child's paternal parent to be approached for
My Initials consent.

_____ **I DO NOT GIVE PERMISSION** for my child's paternal parent to be
My Initials approached for consent.

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Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

Parent's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____
Printed Name of Research Participant (child)

_____ _____
Signature of Parent Date

_____
Printed Name of Parent

_____ _____
Signature of Research Team Member Obtaining Permission Date

_____
Printed Name of Research Team Member Obtaining Permission