Feeling and Body Investigators for Pediatric Abdominal Pain (FBI)

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DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Duke Tummy Pain Study
Principal Investigators: Dr. Nancy Zucker and Dr. Helen Egger

CONSENT FOR ASSESSMENTS AND TREATMENT

INTRODUCTION

You and your child are being asked to take part in a research study investigating a new treatment for young children ages 5-9 years old that get tummy aches. Our screening has indicated that the two of you are eligible to participate. Frequent tummy aches (also called functional abdominal pain or FAP) are one of the most common tummy problems experienced by young children. Having tummy aches can be upsetting for both the child and the parent. It can also lead to many visits to the doctor and can cause the child to miss important events like school. We want to find a way to help children with their tummy aches.

Research studies are voluntary and include only people who choose to take part. As your study doctor or the study staff discusses this consent form with you; please ask him or her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you and your child decide to take part in this research study.

The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Mental Health will sponsor this study. Part of Dr. Nancy Zucker's and Dr. Helen Egger's salaries and their staff will be paid by this grant.

WHO WILL BE OUR DOCTOR IN THIS STUDY?

If you and your child decide to participate Dr. Nancy Zucker, PhD and Dr. Helen Egger, MD will be your doctors for the study and will be in contact with your child's regular health care provider throughout the time that you are both in the study and afterwards, if needed. While participating in the study, you should continue to seek medical care for any health issues that your child might have with your child's regular health care provider.

WHY IS THIS STUDY BEING DONE?

Children with tummy aches sometimes have to miss school or other important events. Both the children and their parents may worry that something may be physically wrong with them. Yet, despite how worrisome and interfering tummy aches can be, there are currently no accepted successful treatments available for young children with tummy pain.

Led by a team of researchers from Duke University and Duke University Medical Center (DUMC), the purpose of this study is to test ways to help parents and children learn how to manage tummy aches in a fun and playful way.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 100 parent-child pairs will be asked to take part in this phase of the study. The study

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will include both boys and girls between the ages of 5-9.

WHAT IS INVOLVED IN THIS STUDY?
If you and your child agree to participate in this research study, you will be asked to sign and date this consent form.

The study involves a total of 2 lab or **assessment** sessions, 2 interviews, 2 weeks of filling out a Daily Pain Diary (for one week prior to starting the treatment sessions and for one week following your treatment sessions)10 investigational **treatment** sessions, and a 6 month follow-up survey. "Investigational" means that this is not a standard or routine way to treat tummy aches but it is being tested in this research study.

There are two types of investigational treatment being tested in this study: 1) a child-focused therapy; and 2) a parent-focused therapy. You will be randomly assigned to receive one type of treatment or the other, as if we were flipping a coin

1. Come to a welcome meeting. We'll go over all of the study paperwork at this meeting and you'll spend some time meeting with a researcher who will introduce you to the daily pain diaries.

2. For one week before you start the investigational treatment, we will have you and your child report on their daily tummy pain and emotions using the daily pain diaries. Each day, you will fill out a short survey about your child's pain in the morning, evening, and bedtime using a paper booklet to record your answers.

3. Come to an interview session to answer questions about your child. One of our trained interviewers will meet with you/the caregiver. There is no need for your child to attend this part of the study, but it is OK for your child or other children to attend if this is more convenient for you. The interview will be held either at: 1) our lab space or 2) in your home via video telephone or computer chat. Our interviewer will ask you about how your child has been feeling and acting. This interview typically takes between two to three hours to complete.

We will use digital voice recording equipment to record the interview and the investigational therapy sessions. The digital recordings will be identified by an ID number only. The digital recordings are used for evaluating interviewer and therapist competence and serve as a backup source of data in addition to the electronic version of the survey for the interviews. These recordings will be destroyed at the end of the study.

4. Come to a meeting at our research laboratory in Brightleaf Square. You child will be asked to watch a few sets of G rated movie clips and then answer questions about how they are feeling. Prior to watching the video clips, we will ask you to help us place a few electrodes (small stickers which

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will connect to a thin wire) on your child's tummy, chest, and hands. This will tell us about how fast your child's heart is beating (ECG), how much your child's hands are sweating (GSR), and how rapidly your child's stomach muscles are contracting (EGG). We will also ask you to help put a small belt around your child's waist to record their breathing while watching the videos. While your child is watching the videos with the researcher, you will fill out a set of questionnaires about how you and your child have been feeling and acting. We will then have you help your child fill out a few short questionnaires and our research assistant will ask your child a few questions about how they have been feeling and their tummy pain. This should take between 1-2 hours.

5. Participate in 10 investigational treatment sessions or meetings. Two meetings will occur in your home via your computer or telephone and the other eight will take place in-person with your therapist. Each treatment appointment will last about 45 minutes to 1 hour.

6. During the treatment sessions, we will ask you to answer a few questions about how helpful and clear you think the treatment sessions are.

7. Following treatment, you will complete another week of daily pain diaries, three times per day (morning, before dinner, and evening).

8 You will also return for another 2-3 hour parent-only interview. We'll ask you questions about how your child has been feeling and acting recently.

9. You will return for a final meeting at our research laboratory in Brightleaf Square where your child will complete a second set of computer tasks and answer a few questions about how they are feeling. While they are completing the computer task you will complete a second set of questionnaires about how you and your child have been feeling and acting. This typically takes between 1-2 hours.

10. Lastly, we will send you an e-mail 6 months after completing the study, with a link to a set of questionnaires about how your child has been feeling and acting. This set of questionnaires typically takes between an hour to an hour and a half to complete.

For the 10 investigational treatment sessions, two (2) sessions will be completed in your home via a web-camera. **To be eligible for this research study, you must have a computer or cell phone with an internet connection and video capabilities.** A web camera will be provided to you for this purpose if needed. You are responsible for the cost of maintaining your internet or cell phone. Eight (8) sessions will be completed in-person with your study therapist at the Duke Center for Developmental Epidemiology at Brightleaf Square, near Downtown Durham, or at Duke's Lakeview Pediatric office space, within Lakeview Pavilion. These 8 sessions will be digitally recorded in order to a) improve the treatments; and b) to make sure the therapists are doing a good job.

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You will be able to choose a day and time convenient for you for each study appointment. The 2 parent interviews will take 2-3 hours each, the 2 movie clip tasks will take 1-2 hours each, and the treatment sessions will each take around 45 minutes.

HOW LONG WILL I BE IN THIS STUDY?
You and your child will participate in this research study for approximately 4 months.

WHAT ARE THE RISKS OF THIS STUDY?
Possible side effects of the ECG, GSR, and EGG are skin irritation and redness from the ECG, GSR, and EGG electrode pads.

There is also the potential risk of loss of confidentiality. Every effort will be made to keep you and your child's information confidential, however, this cannot be guaranteed. To minimize this risk, you and your child will be assigned a unique code number. The key to this code will be kept in a locked file cabinet in Dr. Zucker's locked office.

There is a potential risk that participants will feel uncomfortable answering questions in some of the questionnaires or interviews. To minimize this discomfort, you are not required to answer any question that makes you feel uncomfortable. We will ask your child questions about their feelings, sensations in their body, and how their tummy feels, among other related topics. Some of these questions may be upsetting to your child. Your child is not required to answer any question that makes him/her feel uncomfortable. If your child does become upset by these questions, the study psychologist (Dr. Zucker) will be there to provide on-site support or to give information regarding referrals for further support as needed.

The following steps will be taken with children whose abdominal symptoms worsen during the course of the study.
1. They will be referred for additional medical care.
2. Any medical care they receive will be documented.
3. They will be allowed to continue in the study so that they continue to receive psychological services.

There may be risks, discomforts, or side effects that are not yet known.

WHAT ARE THE BENEFITS TO TAKING PART IN THIS STUDY?
If you agree to allow your child to take part in this research study, there may be direct medical benefit to him/her. A possible benefit is that you and your child may learn more about how you and your child's bodies work and how to listen to the body's clues that help you and your child identify emotions, hunger, and other messages from the body related to the tummy. We hope that in the

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future the information learned will contribute to a potential better understanding of frequent tummy aches (functional abdominal pain) in children. However, we cannot guarantee that any of this will happen.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
You do not need to participate in this study to obtain medical care for your child's abdominal pain. You can seek treatment for your child's abdominal pain, which may include medications, talk therapy, or other research studies, with your child's regular doctor or another doctor, or the study team can provide you with a referral to a different doctor.

WILL OUR INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify you or your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you and your child will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you and your child will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Zucker's office. Your information will be stored in a secure electronic database.

Your child's records may be reviewed in the future, in order to meet federal or state regulations. Reviewers may include representatives of the National Institutes of Health and the Duke University Health System Institutional Review Board. If any of these groups review your child's research record, they may also need to review your child's entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

The study results will be retained in your research record for at least six years after the study is completed, and your child's study results will be retained for at least six years after the study is completed or until your child reaches age 21, whichever is longer. At that time either the research information not already in your or your child's medical record will be destroyed.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, you and your child's identity will never be revealed.

WHAT ARE THE COSTS OF BEING IN THIS STUDY?
There are no costs to you or your child associated with participation in this research

WHAT ABOUT COMPENSATION?
Participants will be compensated up to $310. You will be compensated $5 for each day that all three (morning, before dinner, and prior to bedtime) of the Daily Pain Diary Surveys are fully completed.

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You will receive up to $35 for the first week (7 days) of filling out the Daily Pain Diary Surveys. You will again be asked to fill out these Daily Pain Diary Surveys, three times a day, for another week (7 days), after completing the investigational treatment sessions, for up to an additional $35. The maximum compensation for filling out all 2 weeks (14 days) of Daily Pain Diary Surveys is $70. Also, you will be compensated $35 for participating in an interview prior to the investigational treatment sessions and $35 for participation in an interview after the investigational treatment sessions, for a total of $70, if both interviews are completed. You will receive $40 for participation in the first laboratory assessment session and $100 for the second laboratory assessment session. Both of these sessions will be held at the Duke Center for Developmental Epidemiology. Finally, you will receive a $30 Amazon gift card after completing the 6 month follow-up survey of questionnaires. Your child will receive a small toy after each of the two lab sessions and toys throughout the treatment sessions. You will not receive compensation for the 10 investigational treatment sessions.

In order to receive payment for your participation in this study, you will be asked to provide your social security number and home address on a Payment Verification Form. This form will be collected separately from your consent form and will not be linked to any information you provide. If you don't want to provide your social security number, you can still be in the study, but you will not receive payment.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you or your child is injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you or your child in the event of a study-related injury.

WHAT ABOUT OUR RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You and your child may choose not to be in the study, or, if you and your child agree to be in the study, you may withdraw from the study at any time. If you and your child withdraw from the study, no new data about you and your child will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

You or your child's decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you and your child are entitled, and will not affect you or your child's access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Zucker in writing and let her know that you and your child are withdrawing from the study.

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Her mailing address is PO Box 3454, DUMC Durham, NC 27710.

We will tell you about new information that may affect you and your child's health, welfare, or willingness to stay in this study.

Your doctor may decide to take you and your child off this study if your child's condition gets worse, if either of you do not comply with the study's requirements, or if your study doctor determines that it is no longer in either of your best interest to continue. The sponsor or regulatory agencies may stop this study at anytime without your consent. Reasons why this might occur include loss of funding or the development of better approaches to this problem. If this occurs, you will be notified and your study doctor will discuss other options with you.

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.

WHOM DO I CALL IF I HAVE ANY QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury please contact Dr. Zucker at 919-308-9140 during regular business hours and after hours and on weekends and holidays.

For question about your rights as a research participant, to discuss problems, concerns or suggestions related to the research, to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) at 919-668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits, have been explained to me and my child. I have been allowed to ask the questions I have, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions about my and my child's rights as a research subject, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree that my child and I will participate in this research study with the understanding that I may withdraw myself and child at any time. I have discussed the study with the child and he/she has agreed to participate. I have been told that I will be given a signed copy of this consent form."

_____	_____	_____
Signature of Parent or Legal Guardian	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time