Web-based Management of Pediatric Functional Abdominal Pain

NCT02327377

2-5-2018

MONROE CARELL JR.
Children's Hospital
at Vanderbilt

Department of Pediatrics
Division of Adolescent and Young Adult Health

Dear Parent:

We would like to invite you and your child to participate in research study about abdominal pain in children. Below is more information about the study.

1. Why are you doing this research?

We are doing this research to learn if we can use the Internet to teach children with abdominal pain and their parent's ways to manage pain.

2. What will I do and how long will it take?

You and your child will be given access to a new Pain Management Website. You each will have a private password to log onto the website. We have two Pain Management Websites; we will assign you randomly (e.g., like flipping a coin) to one of the Websites. The websites have 8 sections. For example, the child's website has sections on different ways to cope with pain and what to do about pain at school. The parent's website has sections on what to do when your child has pain and how to help your child cope. Each week for 8 weeks, you and your child will spend 20-30 minutes doing the readings or assignments on one section. Your child will continue to receive his/her regular medical care while he/she is using the website.

We want to know if your child's pain gets better after using the Pain Management Website, so we will ask each of you to complete some questionnaires before and after you use the Website. You and your child will each be paid for completing the questionnaires. The first time you complete questionnaires will be while you are at the clinic today. You and your child will use our iPad to answer questions about your child's pain, mood, sleep, and activities. You also will be asked about your own health and what you do when your child has pain. This will take 20-30 minutes and you can do it before or after you see the doctor. Each survey has a unique link created by the secure Research Electronic Data Capture (REDCap) website. The secure survey link can also be e-mailed if you do not have time to complete the surveys today. We will also ask each of you to create unique passwords for you and your child to log on to the Pain Management Website. Your child will complete a total of 7 diary entries by logging in to the Website (with a unique password). We will complete the first diary entry today at the clinic. Then, your child will log in from home to do the pain diary for the following 6 days. Each day your child will be asked questions about his/her pain and activities. It will only take a minute or two. Your child will also complete 7 diary entries after the program is completed, 6 months from now, and 12 months from now. As soon as your child finishes the Diary (a week from now), both of you will be given access to the Pain Management Website.

Today at the clinic, you and your child will each get $20 in cash or gift card for answering study questions. After today, you and/or your child will be paid with a gift card each time you complete a survey on the online questionnaire website:

- Next week, for the pain diary (your child will get $30)
- 1 month from now (you and your child will each get $40)
- 2 months from now (you and your child will each get $50)
- 6 months from now (you and your child will each get $50)
- 12 months from now (you and your child will each get $60)

If you and your child complete all portions of this study, your family will receive a total of $470 over the next year. If you withdraw from the study early or are unable to complete a questionnaire, you will still be paid for the portions of the study that you did complete. Only one parent will complete questionnaires about their child's pain, but both parents and other family members may visit the website to learn about pain.

3. What are the potential harms or risks if we do this study?

Some of the questions are personal or may be embarrassing. You and your child may skip any questions that you do not want to answer. If you or your child is injured because you are in this study, you can get reasonable, immediate, and necessary medical care for the injury at Vanderbilt without charge to you. There are no plans for Vanderbilt to pay for the costs of care beyond the injury, or to give you money for such injury.

4. What are the potential benefits if I join this study?

Potential benefits to you:
The Internet program might help you and your child manage your child's pain better.

Potential benefits for others:
We hope that information from this study will help other children with pain in the future.

5. Do I have to be in this research study and can I stop if I want to?

It is completely your choice for you and your child to be in this study. Your child will be treated the same by your doctors whether or not you choose to be in the study. If either of you decide at that you no longer want to be in the study, you can withdraw simply by telling the research staff. If a review of your child's medical record indicates a diagnosis that makes him or her ineligible for the study, we will discontinue you and your child's participation in the study.

6. How will you keep my family's information confidential?

All reasonable efforts will be made to keep the information obtained from your family private and confidential. Your answers to questionnaires will not be shared with your child, and your child's answers will not be shared with you. Additionally, your family's responses will not be included in your child's medical record at Vanderbilt or anywhere else. No names or other identifying information will be put in the files with information from you and your child. Instead, files will be coded only with a number. Only members of our research staff have access to the code indicating which name goes with which number. This information is kept in a locked filing cabinet. Absolute confidentiality cannot be guaranteed, however. Your family's research record may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as Vanderbilt University Medical Center, National Institute of Health, and the Office of Human Research Protection. If we believe your child or someone else is in danger, we will take all necessary action, including possibly reporting to authorities, in order to prevent serious harm to your child or to others.

7. Who do I talk to if I have questions?

If you have questions or want more information, please contact Dr. Walker at [redacted] or the Vanderbilt Institutional Review Board Office at [redacted].

Sincerely,

Lynn S Walker

Lynn S. Walker, PhD Professor of Pediatrics
Vanderbilt University School of Medicine
[redacted] Nashville TN 37212

Consent for your child to participate.

I have read this consent form, and I understand the procedures to be used in this study. All of my questions have been answered, and I freely and voluntary choose to participate and to allow my child to participate. I understand we can stop at any time.

______________________	______________________	______________________
Child’s full name	Parent/guardian signature	Date

Consent for you to participate. I have read this consent form, and I understand the procedures to be used in this study. All of my questions have been answered, and I freely and voluntarily choose to participate. I understand that I can stop at any time.

______________________	______________________	______________________
Parent/guardian’s full name	Parent/guardian signature	Date

Consent obtained by: ____
Signature

____
Printed name and title

Date of IRB Approval: 02/05/2018
Date of Expiration: 02/04/2019

Authorization to Use/Disclose Protected Health Information

Protected health information (PHI) is individually identifiable health information that has been entered into a medical record. Once this has occurred, use or disclosure of such information from the medical record must follow federal privacy guidelines. A decision to participate in this study means that you agree to let the research team use and share some of your child's PHI as described below.

As part of the study, Dr. Walker and her study team will review notes in your child's medical record pertaining to your child's clinic appointment today, any tests or procedures done to determine the cause of your child's current health problems. This chart review will be done solely to determine the resulting medical diagnosis and recommended treatment. This information from your child's medical record (i.e., his/her diagnosis, diagnostic tests and procedures conducted and treatment recommendations) will be added to your child's research record in Dr. Walker's files. However, none of the questionnaires that you and your child complete for our study will be added to your child's medical record at Vanderbilt or any other medical center. Your child's research record will be kept for 6-10 years after the study is completed. After that time, your child's research record will be destroyed. Your child's medical record will be maintained at Vanderbilt indefinitely.

It is important you understand that circumstances may arise in which Dr. Walker and her study team are required to share your child's research record with the groups listed below. If your child's research record is reviewed by any of these groups, they also may review your child's medical record to confirm the medical information noted in his/her research record regarding the diagnosis, related tests and procedures, and recommended treatment. Reviewing groups may include representatives from the National Institute of Health, the Vanderbilt University Institutional Review Board. Once your child's medical and/or research records are released to the persons or groups named above, we cannot guarantee that those persons or groups, in turn, will not release your child's health information to others who may not be legally required to follow the procedures and limitations in this Informed Consent and Authorization Form.

If you are willing to allow Dr. Walker and her study team to review your child's medical records for information related to today's clinic visit and any follow-up testing done pertaining to his/her current health concerns, please sign below. Please note that if you choose today to authorize our review of your child's medical record, you are free to change your mind and withdraw your authorization at any time by contacting Dr. Walker in writing. Dr. Walker's mailing address is *Vanderbilt Children's Hospital; Adolescent and Young Adult Health;* [redacted] *Nashville, TN 37212-*[redacted]. At that time we will discontinue further collection of any information from your child's medical record.

If you do not want to give authorization for Dr. Walker and her team to review your child's medical records, return the consent letter and this form unsigned to the interviewer.

My child's medical record may be reviewed for information related to today's clinic visit and any follow-up testing done pertaining to his/her current health concerns.

☐ Yes ☐ No

Signature:____Date: ________________