REducing Anxiety in CHildren Undergoing Procedures

PI: Debra Shockey

Document Date: 8/11/2017

NCT #: 03054077

Virginia Commonwealth University Internal Review Board (IRB): HM 200008056

Initial approval Date: 10/14/2016

Most recent approval date: 4/14/2017

Consent approval stamped: 3/3/2017

Script

Child and parent arrive on Children's Perioperative Unit (CPU) and settle into room.
T1 occurs as standard of care and routine assessment parameters. (See corresponding mYPAS-SF form).
Study is introduced to the family and questions answered. If family is interested in participating, consents and assents are signed. Once signed, child/family is considered enrolled into the study.

Study investigator asks parent to complete demographic information form, and asks both child and parent about the child's age and experience with an iPad.

Hi! My name is _____. I am a (Nurse, NP, Nursing student) and I work with children. I am interested in seeing if an iPad is something that is helpful to use if children have to wait for appointments or procedures, kind of like what you are doing today waiting for your procedure. Would you like to help out by answering some questions while your Mom(my)/Dad(dy) fill out papers for me?

How old are you? (child). How old is your child? (parent)
Have you ever played with an iPad? What kind of things have you played on the iPad? (child) Has your child ever played with an iPad? What kind of things has your child played on the iPad? (parent).
Study investigator records these answers on study forms.

I have an iPad that you can play with while you are waiting here at the hospital. It has 3 games you can choose from. You can play it the whole time you are waiting and then play it again when you wake up. Which game would you like to play?

Investigator indicates which game is chosen on demographic sheet.

T2 occurs just prior to introduction of anesthesia. (See corresponding mYPAS-SF form). This may mean that the iPad travels to the OR. If the iPad does travel, it will be retrieved and returned to the Peds CPU to await the child's return post-surgical procedure.

T3 occurs when child awakens from the sedated procedure in the CPU. (See corresponding mYPAS-SF form).

Hi! _____ (insert name of child) your procedure is all done and I have the iPad here if you would like to continue your game. Would you like to play with it?

Child continues to play with the iPad until cleared to be discharged at which time the iPad is collected and the Chick Fil A gift card is given.

Thanks for helping me out today and playing with the iPad. I hope that you had a good time. While you are getting ready to go home, I will take the iPad so that I can recharge it, and since you were so helpful, I want you to have this Chick Fil A gift card.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: REducing Anxiety in CHildren Undergoing Procedures: Project REACH UP!

VCU IRB NO.: **HM20008056**

INVESTIGATOR: **Debra P. Shockey, DNP, RN, CPNP**
Children's Hospital of Richmond/VCU Health System
Division of Pediatric Hematology/Oncology
Assistant Professor
VCU School of Nursing
Richmond, Virginia 23298
Phone: (804) 828-1930
(757) 871-1495

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand.

PURPOSE OF THE STUDY

The purpose of this research study is to find ways to decrease anxiety in children aged 4-12 who are receiving medicine to help them sleep while they are having a procedure done. Specifically, we want to see if playing games on an iPad before and after surgery will help decrease anxiety.

Your child is being asked to participate in this study because your child is scheduled to receive medication to help them sleep during a procedure.

DESCRIPTION OF THE STUDY AND YOUR CHILD'S INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this permission form after you have had all your questions answered and understand what will happen to your child.

In this study your child will be observed three times for a period of 30 seconds each time. These observations are part of the standard of care provided to children during their treatment at the hospital. Your child will be observed to determine his/her anxiety level or how nervous or worried he/she is about what is going on. Each time your child is observed, a study staff member will record information about your child's behavior on a paper anxiety screening tool. This paper anxiety screening tool has been used by the team for several months in an effort to measure a child's anxiety level prior to his/her sedated procedure.

You will also be asked to answer several questions about your child, including your child's age, gender, ethnicity, experience with the iPad/tablet device, anxiety level and reason for being at the hospital. Answers to the questions will be recorded on a paper form specifically for the study.

After you have signed the permission form, your child will be randomly assigned to one of two groups via a number generator. Both groups will have three observation points of 30 seconds each as previously described.

You and your child will be settled into your pre-procedure holding room by a staff member. Once you are settled in the room, a staff member will observe your child for 30 seconds to measure his/her level of anxiety. This is the first observation time.

Following the first observation, children assigned to Group 1 will receive the usual standard of care for a child prior to a sedated procedure. Children assigned to Group 2 will receive the usual standard of care for a child prior to a sedated procedure and will be given a study iPad with an age appropriate game selection to play until the point of going to sleep.

Both Group 1 and Group 2 participants will have a second 30 second observation, completed by a member of the study staff, just prior to your child's sedation for the procedure. This is observation number two.

When your child returns from the procedure and awakens, children assigned to Group 1 will receive the usual standard of care for a child post sedation. Children assigned to Group 2 will receive the usual standard of care for a child post sedation and will resume playing the iPad game until discharge.

Both Group 1 and Group 2 participants will again have a third and final 30 second observation by a study staff member. This is observation number three.

Just prior to discharge from the Children's Perioperative Unit, children assigned to Group 2 will return the iPad.

At discharge your child will receive a Target gift card for participating in the study.

This study is complete at the time your child is discharged from the surgery center. No further follow up is required. It is anticipated that 24 children will participate in this study.

RISKS AND DISCOMFORTS

There is a potential risk for loss of confidentiality through participation in this study but every effort will be made to be respectful to your child's privacy and no data will be identified by your child's name.

BENEFITS TO YOU AND OTHERS
Your child may not get any direct benefit from this study, but, the information we learn from children in this study may help us design better programs for children who are nervous before medical procedures.

COSTS
There are no costs for participating in this study.

PAYMENT FOR PARTICIPATION
Your child will receive a $10.00 gift card to Target for participating in this study. The gift card will be given to your child at the time of discharge from the surgery center.

You may be asked to provide your social security number in order to receive payment for your participation. Your social security number is required by federal law. It will not be included in any information collected about you for this research. Your social security number will be kept confidential and will only be used in order to process payment.

ALTERNATIVES
Your child's alternative is not to participate in this study.

CONFIDENTIALITY
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 Website will include a summary of the results. You can search this Web site at any time.

Data is being collected only for research purposes and will be de-identified through the creation of ID numbers related to the study. These records will be stored indefinitely with any identifiers removed after the study ends. Access to all data will be limited to study personnel.

We will not tell anyone the answers you or your child give us; however, information from the study and the permission form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services or other federal regulatory bodies.

What we find from this study may be presented at meetings or published in papers, but your child's name will not ever be used in these presentations or papers.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your child's participation in this study is voluntary. Your child may decide to not participate in this study. Your child's decision not to take part will involve no penalty or

loss of benefits to which your child is otherwise entitled. If your child does participate, your child may freely withdraw from the study at any time. Your child's decision to with draw will involve no penalty or loss of benefits to which your child is otherwise entitled.

Your child's participation in this study may be stopped at any time by the study staff without your consent. The reasons might include:

- the study staff thinks it necessary for your child's health or safety;
- your child has not followed study instructions;
- administrative reasons require your child's withdrawal.

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Debra P. Shockey, CPNP
VCU Health System
debra.shockey@vcuhealth.org
(757) 871-1495

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
P.O. Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/human_research/volunteers.htm.

CONSENT

I have been given the chance to read this permission form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing for my child to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

_____

Name of Child

_____

Name of Parent or Legal Guardian
(Printed)

_____

Parent or Legal Guardian Signature Date

_____

Name of Second Parent or Legal Guardian (Printed) -optional

_____

Second Parent or Legal Guardian Signature-optional Date

_____

Name of Person Conducting Informed Consent Discussion
(Printed)

_____

Signature of Person Conducting Informed Consent Discussion Date

_____

Principal Investigator Signature (if different from above) Date

Project: REACH UP!

Statistical Analysis Plan

This study was designed as a small pilot study with its purpose to discern the means and SD between the groups to determine the appropriate effect size for future work. The pilot study size was set at 12 children for the control group and 12 children for the intervention group. Recruitment occurred at the day of the child's scheduled procedure and participants were randomized via a computer algorithm varying by block sizes of 2 and 4 to blind the investigator at the time of consent.

Analysis included comparison of time points as related to scores on the mYPAS-SF, with group 1 time points (anxiety scores) compared to group 2 time points (anxiety scores). The comparison was desired to see if there was an effect on the scores with the introduction of the iPad (intervention). Means and SD of each time point were calculated and a t test was used to analyze the two groups and then correlate within and between the groups. To discern effect size, the Cohen's d calculation was used.