

## **Cover Page**

Study Title: Nighttime postural care: Caregiver training program and outcome measure feasibility

Principal Investigator: Jennifer Hutson

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## **ST CATHERINE UNIVERSITY**

### **Informed Consent for a Research Study**

**Study Title:** Nighttime postural care: Caregiver training program and outcome measure feasibility

**Researcher(s):** Jennifer Hutson MS, OTR/L, ATP

You are invited to participate in a research study called “Nighttime postural care: Caregiver training and outcome measure feasibility”. The study is being done by Jennifer Hutson, an assistant professor of occupational therapy at St. Catherine University in St. Paul, MN along with select students in the Master of Arts in Occupational Therapy program (MAOT).

The purpose of this research study is to 1. Examine the feasibility of a sleep care positioning training program, 2. Understand if one type of training is better than another, and 3. Understand the usefulness of an assessment that measures sleep issues. This study will allow researchers to understand if care providers (professional and non-professional) feel competent or capable in applying the sleep care positioning intervention to their child or client after receiving a specific training program. This study is important because it will help researchers determine if the training program and sleep assessment can be used in a future intervention study, ultimately having the potential to benefit postural care providers and clients. Approximately 40 people are expected to participate in this research. Below, you will find answers to the most commonly asked questions about participating in a research study. Please read this entire document and ask any questions you may have before agreeing to participate in the study.

#### **Why have I been asked to be in this study?**

You have been chosen because you:

- Have a child or client with Cerebral Palsy or impaired movement (i.e. uses wheelchair)

AND/OR

- Care for child whom might benefit from the sleep care positioning intervention

AND/OR

- Care for a child whose position during lying might affect sleep, pain, body shape or quality of life

#### **If I decide to participate, what will I be asked to do?**

If you meet the criteria and agree to be in this study, you will be asked to do the following:

- Complete baseline questionnaire (15 minutes)
- Complete one of two different sleep care positioning training programs. Learn about how to care for a child using the nighttime postural care intervention. Communicate information about the sleep habits and routines of your child or

- client (2-3 hours). Because we don't know for sure which of the two trainings are better, you will be randomly assigned to one of the two trainings.
- • Answer questions about the information to find out what you learned (10 minutes)
- • Demonstrate positioning of a researcher in the sleep care positioning system (30 minutes)
- • Complete a post-training questionnaire where you will provide feedback about the training program (15 minutes)

In total, we estimate the study will take up to 8 hours.

**What if I decide I don't want to be in this study?**

Participation in this study is completely voluntary. If you decide you do not want to participate in this study, please say so, and do not sign this form. If you decide to participate in this study, but later change your mind and want to withdraw, simply notify Jennifer Hutson, and you will be removed immediately. Your decision of whether or not to participate will have no negative or positive impact on your relationship with St. Catherine University, nor with any of the students or faculty involved in the research.

**What are the risks (dangers or harms) to me if I am in this study?**

Risks due to participation in this research study are unlikely. Potential for harm is no greater than what may occur when providing care to a child during a typical day at home or work. The information and feedback you provide in the questionnaires will be confidential and results will be presented in a way in which no one will be identifiable.

You will only be asked to demonstrate tasks that are considered safe for a care provider to use in the home or workplace. Injury or discomfort during application of the intervention is unlikely. One aspect of the in-person session involves positioning one of the researchers in the sleep system. Please let us know if you think the positioning task could present a physical risk for you.

In the event that this research activity results in an injury, we will assist you by helping to contact the appropriate personnel (for example, if you pull a muscle we will assist you in calling your medical professional). Any medical care for research-related injuries should be paid by you or your insurance company. If you think you have suffered a research-related injury, please let us know right away.

**What are the benefits (good things) that may happen if I am in this study?**

You will gain knowledge about the nighttime postural care intervention. This training may provide you with new ideas / ways to support your child or client during sleep.

**Will I receive any compensation for participating in this study?**

You will receive a \$50 gift card upon completion. Professional care providers can also choose to receive a certificate of contact hours from St. Catherine University.

**What will you do with the information you get from me and how will you protect my privacy?**

Only original documents will include your name. The pseudonym key and all paper files will be stored in a locked filing cabinet in the office of the primary investigator. Electronic files will be stored on the primary investigator's password protected computer and in REDCap, a HIPAA compliant data management software program. Only the primary investigator will have key access to the paper files. Co-investigators will have access to the files at the point of data collection and data analysis via the primary investigator. All records with identifiers will be destroyed one year after data collection and analysis is completed, by December 2019

Any information that you provide will be kept confidential, which means that you will not be identified or identifiable in the any written reports or publications. If it becomes useful to disclose any of your information, we will seek your permission and tell you the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure; you will have the right to grant or deny permission for this to happen. If you do not grant permission, the information will remain confidential and will not be released.

**Are there possible changes to the study once it gets started?**

If during the course of this research study we learn about findings that might influence your willingness to continue participating, we will inform you of these findings.

**How can I get more information?**

If you have any questions, you can ask them before you sign this form. You can also contact Jennifer Hutson, MS, OTR/L, ATP, at jahutson@stkate.edu if you have any additional questions and would like to talk to the faculty advisor. If you have other questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you may also contact Dr. John Schmitt, PT, PhD, Chair of the St. Catherine University Institutional Review Board, at (651) 690-7739 or jsschmitt@stkate.edu.

You may keep a copy of this form for your records.

**Statement of Consent:**

I consent to participate in the study. My signature indicates that I have read this information and my questions have been answered. I also know that even after signing this form, I may withdraw from the study by informing the researcher(s).

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Signature of Participant Date

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Signature of Researcher Date