UNIVERSITY OF WASHINGTON
CONSENT FORM
Sleep Innovations in Preschoolers with Arthritis (SIPA): Pilot Testing of a Self-Management Intervention

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We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

We developed a web-based intervention to help young children with arthritis sleep better. We are asking parents who have a 2-5-year-old child with arthritis to be in our study. Taking part in research is voluntary. In our prior study, we found that some young children with arthritis had more sleep problems. We want to understand if this online sleep program would improve sleep in these children. If you are interested in participating, you and your child will participate in a 3-month program where you will be learning about improving your child's sleep. We would ask you to answer some questions online, complete online daily sleep diaries for your child and your child to wear a wristwatch for 10 days before and after the program, and participate in weekly online activities to learn about sleep topics for 8 weeks, and set goals and make changes in your daily life to improve your child's sleep.

PURPOSE OF THE STUDY

The purpose of this study is to improve children's sleep. We want to understand if an online sleep program - Sleep Innovations in Preschoolers with Arthritis (SIPA) would improve sleep in children with JIA.

STUDY PROCEDURES

If I agree to join this study, what would I need to do?
If you and your child join the study, we ask that you participate for about 3 months. We would ask you to answer some questions online, complete online daily sleep diaries for your child, and your child to wear a wristwatch. All the information about the study procedures are listed below.

Explanation of the Research Procedures:

If you join the study, you will complete online questionnaires at 3 different times, and your child will wear a wristwatch at 2 different times (see study timeline on page 2 of this form):

Surveys: We would ask you to complete surveys about sleep, pain, fatigue, emotional health, day-to-day activity, quality of life, and family impact. Some examples of items include, "we are reluctant to show our affection to one another, or "I worry about what will happen to my child"). These surveys would be completed at home online with tablet, phone, laptop, or computer and would take 90 minutes each time to complete.

Wristwatch (Actiwatch): The Wristwatch looks like a small watch that can be placed on your child's wrist or ankle. It records body movement. Dr. Yuwen will mail you the watch, and provide instructions on how to put the watch on and take the watch off. Children will also wear a wristwatch on their non-dominant wrist for ten days each time for two times (except during swimming and bathing).

Sleep Diary: We would also ask you fill out a sleep diary for your child for 10 days when using the wristwatch. You will complete a sleep diary once a day on an electronic device (e.g., computer, phone, tablet) each evening at bedtime. In the daily sleep diary we would ask information about what time your child went to bed, how long it took to fall asleep, number of night awakenings, what time you woke up, symptoms experienced during the day or night (e.g., pain, fatigue), daily activities (e.g., sports, illness, exercise), medications. The sleep diaries would be completed each day and take an estimated 5 minutes to complete.

You as the primary caregiving parent of your child with JIA will complete the study intervention.

Study Timeline

At the time of enrolling in the study (Time 0): you will complete surveys online and receive a wristwatch for your child to wear for 10 days.

Beginning of the SIPA Intervention (Time 1): after completion of 10 days of wristwatch and diary, you will receive another packet with SIPA intervention materials, and begin the program.

Completion of SIPA intervention for 8 weeks following T1 (Time 2): you will complete surveys online and receive a wristwatch for your child to wear for 10 days.

One month following completion of the SIPA intervention (Time 3): you will complete surveys online.

SIPA Intervention program:

The SIPA intervention will be interactive and personalized. You parent will have a specific account associated with your email. Every week, you will receive an email sent automatically with instructions for this week's activity, designed to take about 30 minutes of reading and doing other activities on the program. SIPA is accessible through the Internet. A member of the research team will call you on the phone and would give you instructions about how to access the study website. You will be using this website regularly for 8 weeks. It would focus on training in skills to improve your child's sleep. For example, in one week you will be learning about how to set up a healthy sleep environment for your child. You will be guided through a set of activities to set goals (e.g., creating a sleeping cubby), and generate a concrete plan to carry out the goals. In the subsequent week, you will answer questions about the goals and activities you did in the previous week. During your participation, a member of the study team would contact you to check in with you and your child, and to see if there are any problems using the program.

SIPA Exit interview: We would ask you and your child to complete an exit interview about what you liked and did not like about the online sleep program, how we can improve the sleep diary, and what things we may want to change about the study. This survey would take 10 minutes to complete.

RISKS, STRESS, OR DISCOMFORT

What are the potential harms or risks if I join this study?

There are potential harms or risks if you and your child take part in this study. These are described below.

Time Commitment: Participant burden, specifically time commitment, is the most likely risk related to this study. In order to reduce subject burden from the length of the data collection, you will complete questionnaires at your convenience on REDCap. REDCap is designed so that participants can save their information, log off and return to it at any time.

Anxiety: Emotional distress or anxiety is a potential risk. It is likely that some may experience mild anxiety or discomfort related to completing the questionnaires. In the likelihood of substantial stress or discomfort upon completing questionnaires the researcher would refer you to your legal medical provider, provide crisis line information, and provide a list of community counseling resources.

Skin irritation: Your child may experience mild skin irritation from wearing a watch device on your wrist. They will have the option of wearing the wristwatch over a long sleeve shirt to prevent skin irritation. If your child cannot tolerate the watch, you may remove the watch.

Confidentiality: We have several safeguards planned to protect against the loss of confidentiality. Your contact information will be stored separate from study data and identifying numbers in a file on a password-protected server. All electronic data will be stored on password- protected servers. Information will be compiled from all the participants in the study and, when published, data will be reported in aggregate form.

We have addressed concerns about your privacy in the Confidentiality of Research section of this consent form.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you and your child choose not to be in this study, you could find information about improving your child's sleep through books or on the internet.

BENEFITS OF THE STUDY

Potential Benefits for You:
There may be no direct benefits to participants in the study; however, being in this study might benefit you and your child. A possible benefit is that you and your child may learn more about your child's sleep, and helpful strategies to improve your child's sleep.
Potential Benefits for Others:
We hope to use information we get from this study to benefit others who have JIA and sleep problems. This information will help us better understand sleep problems in children with JIA, whether our online sleep program is helpful in improving sleep, and how we might improve the sleep program.

SOURCE OF FUNDING

The study team is receiving funding support from the National Institute of Health/National Institute of Nursing Research.

CONFIDENTIALITY OF RESEARCH INFORMATION

How would you keep my information confidential?

If you participate in this study, the information that you and your child provide is important. A unique study code number will identify your child. This code number will be attached to you and your child's confidential data. We will not put your/your child's name on any research data. The master list that links a person to their study number is stored in a locked cabinet separate from the research data files. The link between your identifiers and the research data will be destroyed after the records retention period required by state and or federal law.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is May 30th, 2020. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

However, de-identified data from this study will be shared with other researchers through the Biomedical Research Informatics Computing System (BRICS). BRICS is data sharing repository managed by the National Institutes of Health with the goal to accelerate research through the development of a data repository for researchers. Only de-identified data, which does not include anything that might directly identify you or your child, will be shared with BRICS users and the general scientific community for research purposes.

The information we collect will be used for research purposes and will be kept in a locked cabinet and secure computer files. No names or other identifying information will be used in any publications or presentations that may result from this study.

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.

USE OF INFORMATION AND SPECIMENS

Returning Results to You

It is possible that the sleep surveys used during screening and/or the study may identify a possible sleep disorder in your child. We would give this information to you so that you may contact your primary care provider to discuss a referral to sleep specialist clinician. We will also provide you the results of the wrist watch about your child's sleep as part of the SIPA intervention.

Using Your Data in Future Research

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You or your child's decision will not affect the care that your child receives. If the information we obtain about you and your child is important to her/his health or indicates there may be a problem that can be treated, we will inform your child's doctor. The investigator may also withdraw you and your child from the study. If this happens, the reasons will be explained to you and your child. Taking part in research is always a choice. If you and your child decide to be in the study, you and your child can change your mind at any time. We ask that you tell the principal investigator of this study, **Dr. Yuwen.** You can contact Dr. Yuwen by phone at 253-692-4478.

Address: School of Nursing and Healthcare Leadership, Box 358421, University of Washington Tacoma, WA 98402

You will receive one $40 gift card after completing of each study period (T0 – 3, see details of study timeline on page 2 of this form). This would be a total of $160 per family if you complete all assessment time points. Participant payment is made as soon as possible after you and your child completes participation.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact Dr. Yuwen at wyuwen@uw.edu or 253-692-4478.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

FUTURE RESEARH STUDIES

Would you like to know about future research studies? Dr. Yuwen would like to contact you in the future to tell you about other research studies you might want to take part in. Research is always a choice. We are only asking you, if you would like to hear about other studies.

What happens if I check "YES"? If you check the "YES" box, you're allowing us to contact you if a study that you could take part in comes up. You can decide to stop allowing us to contact you at any time. You would need to let Dr. Yuwen know if you did not want to be contacted in the future.

What happens if I check "NO"? Deciding not to take part will NOT affect your care. There will be no penalty or loss of benefits to you for deciding that you do not want to be contacted in the future.

Your contact information will not be shared with anyone outside this research team.

- ❑ Yes, it is ok for you to contact me about future research studies.
- ❑ No, please do not contact me about future research studies.

Please tell us what would be the best way to contact you:

- ❑ Phone: _____
- ❑ E-mail: _____
- ❑ Mailing Address: _____

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject **Signature of subject** **Date**

Copies to: **Researcher**
Subject