**Sleep Innovations for Preschoolers With Arthritis (SIPA): Developing and Pilot Testing of a Self-Management Intervention**

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SIPA Intervention Description

An existing sleep intervention for typically developing young children (Sleep Health in Preschoolers - SHIP; shipstudy.org; National Institute of Child Health & Human Development 1R01HD071937-01A1) provided overall structure and content for SIPA. The SHIP intervention draws on a Social Cognitive Theory framework in an initial home visit and follow-up phone calls to coach parents through an iterative process of assessment, learning, goal-setting, and problem-solving to target multi-faceted early childhood sleep issues such as problems with sleep onset, night waking, and sleep duration. Building on the foundation of SHIP, we developed the web-based SIPA intervention via user-centered design processes. First, parents would receive from the research team *Weekly Emails* notifying them to access weekly materials; these emails would be automatically sent to registered users every week. Each email described steps to be done in the week and included a link that connected to the *Instructional Website* which provided a general guide through that week's content and activities. The *SIPA Website with Learning Modules* would then provide the detailed content that participants would need to review for that week. After the user reviewed the content, they would then go back to the Instructional Website to engage in activities such as taking a short knowledge quiz, applying what they learned on the SIPA website to set 1-2 sleep goals and details plans to fulfill the goals for the coming week (see Figure 1below for the user flow).
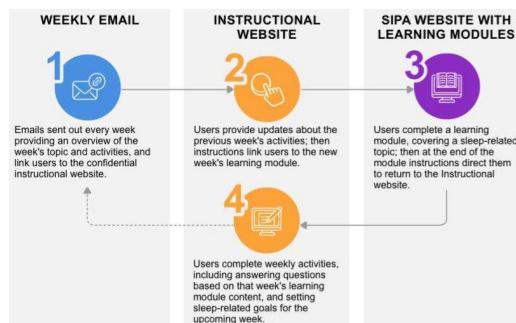


Figure 1

For example, on Week 2, parents will be learning about how to set up a healthy sleep environment for their young children with JIA. They will receive an email leading them to the Instructional website first, then guide them to the learning module. After learning about this topic on the learning modules website, parents would then go back to the Instructional website, go 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, parent will answer questions about the goals and activities they did in the previous week. Below is a list of the weekly topics and activities.

Week 1 Intro to SIPA and Path to Sleep; Healthy Sleep (no goals or activities; information only).

Week 2
3.      Sleep environment
a.      Make bedroom a better sleeping space

          -Darker
          -Quieter
          -More comfortable (temp or bedding)
          -Designate a consistent sleeping space
          -Create a "sleeping cubby"

Arthritis, Pain, and Sleep (No new goals; information only)

### Week 3 Bedtime routine
a. Create a clear wind-down window
b. Start using a bedtime routine
c. Modify the bedtime routine
d. Use the same bedtime routine every night
e. All caregivers follow the same bedtime routine

### Week 4 Bedtime scheduling
a. Start bedtime routine at the same time every night
- Go to bed within 30 minutes of the same time
- Go to bed at the same time every night
- Get weekends on the same schedule as weeknights
- Gradually inch bedtime back

b. Adjust family schedule to allow for 10-12 hours of sleep a night

### Week 5 Falling Asleep
a. Stay in room after saying goodnight
b. Fall asleep without caregiver in the same bed
c. Fall asleep without caregiver in the room
d. Limit request & bedtime stalling after saying goodnight
e. Go to sleep in own bed

### Week 6 Staying Asleep
a. All caregivers follow the same rules after saying goodnight
b. Fall asleep independently within 20 minutes of saying goodnight
c. Self-soothe and fall back asleep after wakings
d. Fall asleep independently when cared for by others

### Week 7 Waking up
a. Staying in bed until set wake time
b. Positive wake up plan
c. Helping with pain and stiffness

### Healthy Media Use
a. Use less media during the day
b. No media use 1-2 hours before bedtime
c. Caregivers replace violence or scary media with developmentally healthy content
d. No media in the sleeping space

### Week 8 Other/Misc
a. Nightmares and sleep stealers
b. Make changes to nap schedule or drop nap
c. Develop a positive attitude about sleep

d.      Reduce nightmare triggers
e.      Address bedtime fears
f.      Transitioning out of the crib
g.      Nursing and bedtime
h.      Siblings respect each others' sleep

Assessment Plan

### T0 BASELINE ASSESSMENT

The PI will have a phone conversation with eligible and interested participant parent, talk about the purpose of the study, show parents and their child the sleep watch, and obtain consent from parent participants using REDCap (see SIPA2 Consent). The PI will then email the baseline assessment REDCap link to the consented parent (see assessment table below). The estimated time burden for parent is 1.5 hours. The PI will also mail a kit with an actigraphy watch with instructions. Parent will have their child wear the watch for 10 days, and parent will fill out a sleep diary every evening for their child, with 5-min time burden daily. After 10 days, the parent will mail back the watch with the prepaid envelop. The PI will contact the parent via their preferred contact method (phone/email) mid-week to check in and will be available to answer questions. This method of collecting Actigraphy data have been successful in our previous studies. After the parent has confirmed the mailing of the actiwatch, they will begin the 8-week intervention program. At week 3 of the intervention, the research team will have received the actiwatch back and will provide a brief report of the actigraphy results to the parent as part of the intervention, including a screenshot of the actigraphy graph, summary report (average bedtime, risetime, sleep duration, etc.).

The SIPA intervention will be interactive and personalized. Each parent will have a specific REDCap account with their email. Every week, parent will receive an email sent automatically through REDCap with instructions for this week's activity, designed to take about 30 minutes to complete.  The SIPA weekly modules will begin with a learning module, then direct participants through goal setting, anticipated barriers, and problem solving.  The REDCap pages will include fillable responses to queries, instructions, and assignments.  Tasks for parents and their young children will use multimedia elements to enhance delivery of information, such as links to videos and pictures targeting self-efficacy, motivation, and patient activation.  The materials used are modified from an existing intervention, Sleep Habits in Preschoolers (SHIP), which has been pilot tested and has enrolled 450 typical developing preschool children and their parents (PIs: Garrison, consultant on SIPA, and Ward, part of the CISSM team).

Submissions and progress will be monitored by the PI and CoI (Bromberg, Clinical Pscyhologist), who will send email, call or text with reminders (whichever the family prefers) and answer questions as needed, review progress, and help problem solve any technology issues or barriers to implementing skills. This online structure and feedback process is modeled after the work by Dr. Palermo, who has successfully implemented web-based interventions with parents and children, and is on the CISSM advisory committee. Dr. Bromberg (CoI) was an interventionist on Dr. Palermo's web-based interventions.

<u>T2 – IMMEDIATE POST INTERVENTION ASSESSMENT</u>

At the end of the 8-week SIPA intervention, actiwatches will be mailed to the parents for their children to wear for 10 days. They will also complete the daily sleep diary as described before.  Actigraphs will be returned via prepaid envelopes. Parent will also complete a post-intervention assessment via REDCap (see assessment table below) and have a brief phone interview with a research team member about the intervention (15 min). The estimated time burden for parent is 1.5 hours.


<u>T3 – 1 MONTH POST INTERVENTION ASSESSMENT</u>

At 1-month post intervention, parent will complete a follow-up assessment via REDCap (see assessment table below). The estimated time burden for parent is 1.5 hours.

Summary of Assessments completed by parents

| Assessment Items | Prescreening | T0 | T2 | T3 |
|---|---|---|---|---|
| Pediatric Sleep Questionnaire | x | | | |
| Child Sleep Habits Questionnaire | x | | | |
| Demographics | | x | | |
| Children's Sleep Wake Scale (CSWS) | | x | x | x |
| Children's Sleep Hygiene Scale (CSHS) | | x | x | x |
| PedsQL Generic Core, Rheumatology, Multidimnesional fatigue, Pain, and Family Impact | | x | x | x |
| PROMIS Sleep Disturbances for parent | | x | x | x |
| Parent Stress Inventory (PSI) | | x | x | x |
| Perception of child vulnerability | | x | x | x |
| Pittsburgh Sleep Quality Index (PSQI) for parent | | x | x | x |
| Self-management measures<br>• Self-efficacy to manage chronic disease scale<br>• Sleep Problem Acceptance Questionnaire | | x | x | x |
| SIPA Post-Intervention Questionnaire and Interview | | | x | |

Statistical Analysis Plan

This is a pilot study not powered to conduct any inferential statistical tests. Descriptive statistics of the survey results will be used to inform future trials.