

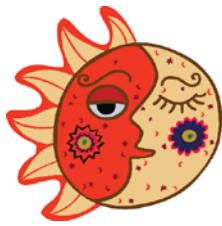
Title: Sleep duration and risk for obesity in Mexican American children

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STUDY OVERVIEW

The Summertime: Kids in Motion study is a 3-week study of Mexican American children in the San Francisco area. This study includes six home visits, with the intention of making this study convenient for participants and increase study completion. The RA will make 2 home visits (Monday, Friday) and 1 phone call (Saturday) in Week 1; 1 visit (Friday) and 1 phone call (Saturday) in Week 2; and 1 phone call (Friday) and a final visit (Saturday) in Week 3. In Week 1, children will continue their normal activities. In Week 2, children will be randomized to follow a short (restricted) sleep or long (healthy) sleep schedule. In Week 3, children will be asked to follow the sleep schedule opposite from Week 2. Behavioral assessments over the three weeks will include sleep duration for (Tuesday night-Friday night), physical activity and sedentary behavior (Wednesday-Friday), and dietary intake (Thursday and Friday). A full description is provided below.

STUDY PROCEDURES AND DATA COLLECTION

Recruitment

Recruitment is critical to the study. Participants will be recruited from the community, such as community organizations, youth summer programs, churches, swat meets, parks, and UCSF clinics. Community organizations may be best to recruit from during the week, whereas parks and churches may be the best during the weekend.

When recruiting from any community organization, it will be important to contact them ahead of time over the phone. When going out into to make the initial contact, always have your SFSU student ID or UCSF badge with you and introduce yourself as a research assistant working Dr. Suzanna Martinez, a researcher at the Univ. of California, San Francisco. You will then describe the study—a study examining how circadian behaviors such as sleep is related to physical activity and eating patterns—and that you are recruiting families with 8-10-year-old Mexican American/Mexican children. Describe the study protocol in short, and that this is a 3-week study. If the organization contact is willing to allow you to recruit participants from that location, then ask when would be the best time to catch parents so that you can speak with them and provide them with study information to participate.

Once you have established the best time to recruit parents, at either community organizations or parks, etc., return at those times to approach parents and give them background on the study. Let them know that you are a student conducting research with Dr. Suzanna Martinez at the University of California, Nutrition Policy Institute. We are conducting a study to understand more about sleep and how it is related to children's health. If parent(s) are interested, provide them with more information about the study – that you are recruiting 8-10 year olds and their mother to participate in a 3-week study. There are a total of 4 home visits and 3 phone calls. On the first visit, mothers will be asked to complete a survey and you will measure the child and mom's height and weight. The rest of the home visits and phone calls will be made to ask children about the foods that they eat. Though out the 3-week period, children will be asked to wear a small monitor. One week they will sleep normal, one week they will sleep less, and one week they will sleep more.

If mother/parent is interested, then proceed with the screener [see Study Screener]. If it is confirmed that the family is eligible, then ask them if they would like to schedule their first visit for the upcoming Monday. If Monday is a bad day, then ask if Sunday or Tuesday would be better. If the parent seems disinterested, if it's ok with them, let them know that they can always think about it and that you can contact them at another time. Try not to let the parent refuse. Once they refuse, they are no longer eligible to participate. Ask them if it would be better to call them at a later date. If they agree, then document their name and number.

In the case that the parent is in a rush and needs to call you, or if they saw the information on the flyer and called the number, you will return their calls. [See Recruitment Phone Script for more information.]

If parent agrees to a home visit, schedule the date and get their contact information. The day before the scheduled meeting, you will want to call the parent to remind them of the visit and to make sure that both mom and child are present for the visit. Also, let them know that you will be doing measuring height and weight so that they may want to dress in light clothing/to avoid heavy clothing.

Week 1

Monday (First home visit)

Consent. Upon arriving to their house, introduce yourself as a research assistant(s) working with Dr. Suzanna Martinez at the University of California, Nutrition Policy Institute. Wait until the parent invites you in and once you are situated, you can proceed with the participant consent. During this process, you will hand the mother a consent form and let her know what information the document contains. Ask her whether she would like to have it read to her or whether she prefers to read it on her own. If she rather read it on her own, then you can use this time set up the research equipment (scale, stadiometer and computer). Once she has read the form, review the form and the study details with both mother and child. Note that they will be given an incentive for their time and participation. Ask if there are any questions. Once their questions are answered, both mother and child will sign the document. You will also provide them with a copy of the consent form. Make sure to keep the signed form.

After consent. The RA will administer the online Qualtrics survey to the mother using the laptop computer. Individual interviews will last approximately 90 minutes, and will be conducted in the participant's preferred language (Spanish/English). Ask whether the mother prefers to complete the survey on her own on the computer or if she would like you to administer the survey. You can also allow the mother to review the questions on her own if she prefers. Remind her that you will be there to assist her with any questions during this process. If they ask questions about which is the best answer, let them know there is no right or wrong answer. Choose the best answer that is true for her and the child being studied.

After completing the survey, you will then explain that you'll be measuring height, weight and waist for mother and child. If the mother wishes to answer the survey on their own, you can use this time to measure the child. Either way, you will start by measuring the child first and then go on to the mother. [See Anthropometry Protocol.] Then, the RA will provide the accelerometer to the child, and will verbally explain and demonstrate how to wear the monitor to both mother and child [see Activity Monitor Protocol]; written directions will be left with the mother and child [Activity Monitor Instructions]. The child will be asked to wear the monitor for 4 consecutive days

each week (starting on Tuesday and ending on Saturday at noon), except when bathing or swimming. On Wednesday - Friday, children and mothers will be asked to complete a sleep and food diary for the child and to document times that the accelerometer is removed. Mother and child will be given a food reference guide (with illustrations of serving sizes of different foods) to assist them when completing the diary. A pen and accelerometer will be provided in a small box, and the diary, food guide, and accelerometer directions in a folder. Let them know that you will be contacting them through the week to remind them to wear the accelerometer and fill out diaries. Ask whether they prefer texts or phone calls and confirm the best number to be reached at. Lastly, ask them the best time to stop by on Friday for the next visit.

Texts and phone calls. Wednesday through Friday, mothers (and children if applicable) will receive two daily text messages (morning and evening) to remind children to wear the accelerometers and to complete the diaries.

Friday (Second home visit)

Upon arriving, greet the family and wait to be invited in. Make sure that the child has all the items such as the diary and food guide. First, you will have him/her remove the accelerometer and you will download the accelerometer data. Check to see that the child was compliant and that the accelerometer has 50% charge left. If child is missing one day, then ask him/her to keep the accelerometer until Sunday at noon. If they did not comply the whole week then ask them to repeat the week. If they do not want to repeat the week, then ask if they can re-wear it the following week. If they decide to withdraw, then thank them for their time as their participation is voluntary. Let them know that if they change their mind, they should call the number on the consent form.

After downloading data, each participant will be visited to complete a 24-hour dietary recall about Thursday, which will be conducted for Thursday using the Nutrition Data System for Research (NDS-R; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). The child will be asked to use their diary and food guide to help facilitate the recall; the RA will go through the diary and recall with the child. [See 24-hr Diet Recall Protocol]. During this visit, you will have the opportunity to show the child how to use the food guide. Also, you will help mothers select a bedtime and wakeup time for the following weeks. Write this down on the front page of the *Sleep and Food Diary*, and on the *Telephone/Texting Contact Form*. At the end of the visit, families will be given a \$25 gift card in appreciation of their time and participation. Before leaving, ask when would be a good time to call on Saturday.

Saturday (Phone call)

The RA will call the child on Saturday to complete a 24-hour dietary recall about Friday. Follow the same protocol as on Friday. After this you can remind the child that he/she is free to remove the accelerometer until Tuesday (unless they are being asked to re-wear), and that you will be making a reminder phone call on Tuesday.

Week 2

Children will be randomized into one of two sleep conditions: long (healthy) sleep or short (restricted) sleep. Participants have already been pre-assigned an ID number and random assignment has been predetermined in order to have an equal number of boys and girls in each condition. [See Participant Randomized Sleep Schedule.] On Tuesday mid-morning, mothers

will be called to notify them regarding which sleep schedule their child will follow in Week 2. You will remind parents of the set bedtime and waking time for both conditions to make sure that their child complies with the sleep schedule. This information should be written on the front page of the *Sleep and Food Diary*, and on the *Telephone/Texting Contact Form*. Children will follow the sleep schedule from Tuesday to Friday night (ending on Saturday).

For the long sleep condition, children will be asked to sleep ≥ 10.5 hrs.

For the short sleep condition, children will be asked to sleep < 8 hrs. If parents are concerned regarding this sleep schedule, you should acknowledge their concern. Remind them that this was discussed in the study consent form, and that you will be monitoring their child for daytime drowsiness, which is a possible side effect. It is ok for their child to nap. Also, reassure them that you will be monitoring their child and calling them to make sure that they are not experiencing too much daytime drowsiness.

Child-mother pairs will continue to receive 2 daily texts or phone calls (Wednesday-Friday) as a reminder to wear the accelerometer, to complete sleep and food diaries, and to remind them of their bedtime and wake up time (as discussed).

Children in the Short Sleep Condition will be called and asked to complete the Pediatric Daytime Drowsiness Scale (Thursday). You will calculate their drowsiness score and discuss with Dr. Martinez if the score is 13 or higher. The parent will also be advised. Encourage their child to take naps and that this part of the study is almost complete. If they wish to withdraw from the study, then that is ok, as their participation is voluntary.

Friday (Third home visit)

Children will be visited on Friday. Make sure that the child has the diary and food guide. Have him/her remove the accelerometer and download the accelerometer data. Check for compliance and accelerometer charge. If child is missing one day, then ask him/her to keep the accelerometer on until Sunday at noon. If they did not comply the whole week then ask them to repeat the week. If they do not want to re-wear and decide to withdraw, then thank them for their time.

After checking accelerometer compliance, you will perform a 24-hour dietary recall about Thursday. Once again, you will use the diary and the food guide. Upon completion of the visit, the family will be given a \$25 gift card for their time and participation in Week 2. Before leaving, ask when would be a good time to call on Saturday.

Saturday (Phone call)

Child participant will receive a phone call on Saturday and asked to complete a 24-hour dietary recall about Friday. Follow the same protocol as on Friday, using the diary and food guide. After this you can remind the child that he/she is free to remove the accelerometer until Tuesday (unless they are being asked to re-wear), and that you will be making a phone call on Tuesday as a reminder.

A 3-night period between sleep conditions will follow.

Week 3

During Week 3, participants will cross over to the opposite sleep condition. Each child will follow the opposite sleep schedule from Week 2. This means that if they were in the short sleep condition in Week 2, then they will follow the long sleep condition in Week 3. You will remind mothers about bedtime and wakeup time to make sure that their child complies with the sleep schedule. This information should be written on the front page of the *Sleep and Food Diary*, and on the *Telephone/Texting Contact Form*. On Tuesday mid-morning, mothers will be called to notify them about which sleep schedule their child will follow in Week 3.

Child-mother pairs will continue to receive 2 daily texts or phone calls (Wednesday-Friday) as a reminder to wear the accelerometer, to complete sleep and food diaries, and to remind them of their bedtime and wake up time (as discussed).

Short Sleep Condition: You will call children in the short sleep condition to administer the Daytime Drowsiness Scale. Calculate their score, and follow the same procedure as Week 2. Follow same protocol as in Week 2. Remind the mother that this is the last week of the study and that their participation is almost complete. If the parent asks to withdraw from the study, then that is ok, as their participation is voluntary.

Friday (Phone call)

On Friday, children will receive a phone call and will be asked to complete a 24-hr dietary recall for Thursday. Follow procedures as in prior the weeks using diary and food guide.

Saturday (Last home visit)

The last visit will occur on Saturday, at which time the accelerometer data will be uploaded and the child will complete a final 24-hr dietary recall for Friday. All families will complete an exit interview to discuss challenges and positive aspects to participating in the study, ideas to facilitate participation, and barriers to and facilitators of longer sleep duration. [See Exit Survey.] Upon completion, families will receive a \$40 gift card.