

Human Subject Research Plan

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Site Coordinator	Nicole Windmon
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School District	n/a

Title	Smart Sleep Doctor
Problem	How can a wrist-mounted sleep tracker provide a platform for long-term sleep quality and sleep disorder tracking?
Objective(s)	I want to create an affordable and portable sleep tracker that will give users a platform for long-term sleep quality and disorder tracking because overnight sleep labs are inconvenient and often prohibitively expensive.
Hypothesis	Using a wrist-mounted sleep tracker, objective sleep quality and sleep disorders can be tracked.
Number of Students	1
Age range, gender, and number of human subjects	13 - 40 years old, 5 male volunteers, 5 female volunteers

Risk Assessment	<p>Written parental consent will be obtained for all participants under 18, and the risks associated with this experiment will be properly explained to each participant and their legal guardian. Each participant will be reassured that they can opt out at any point in the experiment. The experiment is observational and does not include any behaviors that are abnormal for the participants. The participants go to sleep at a self-selected sleeping time, and the recording period is ended when the participant wakes up naturally. Because the sleep tracker is non-intrusive and the experiment is part of a normal routine for the participants, there is very little physical and emotional risk involved in this experiment. If the participant feels uncomfortable with the experiment, they can opt-out at any time and their data will be deleted and any trials already recorded are only used with the consent of the participant. The sleep tracker electronics are surrounded by a 3-D printed case made of PLA, which is non-toxic. Because PLA is not recommended for close contact with skin for extended periods of time due to the abrasiveness of the material, the bottom which is in contact with the skin is covered in a felt adhesive padding. The strap is made of nylon, which is also safe for the skin. Each potential participant will be asked if they are allergic to these materials. The battery of the sleep tracker is a lipo battery, which could result in overheating or an explosion, but the current draw of the Arduino is at most 50 mAh so that overheating is not an issue, and the battery is an industry standard that has been extensively tested without problems.</p> <p>https://devel.lulzbot.com/filament/Monofilament%20Direct/SDS/Polylactide%20PLA%20R17009A%20SDS.pdf</p> <p>https://www.amazon.com/Felt-Adhesive-Orthopedic-Aetna-Corporation/dp/B0053D30TC</p>
Location	<p>The experiment will be conducted in the regular bedroom of the participants, as will the survey.</p>

Procedure/ Research Techniques	There will be 3 trials for each participant in the experiment, with each being 1 week apart. Before the recording period begins, switch out the felt adhesive and reset the sleep tracker. Record sleep in the bedroom of the participants, with self-determined lights-out and lights-on time. Each participant is given a sleep tracker to place on their non-dominant wrist for the duration of the overnight recording. After the recording period is over, give a survey to the participants on their experienced quality of sleep based on several AASM standard measures of sleep, including TST(total sleep time), sleep efficiency, WASO(wake after sleep onset), and sleep onset latency. Sleep Tracker: The sleep tracker consists of an Arduino Nano 33 BLE Sense microcontroller, which collects data using the built-in 9 axis IMU and sends the data to a micro-SD card through the Adafruit SD module for permanent storage. The Arduino is powered by a 1000mAh Lipo battery from Adafruit through a 3.3v to 5v Adafruit PowerBoost 500. The electrical components are surrounded by a 3-D printed case made of PLA. The bottom is covered in felt adhesive to prevent the PLA from being in contact with the skin for extended periods of time. The tracker is held on the wrist by an adjustable watch strap made of nylon. Survey: How would you rate the quality of your sleep last night? (1-10) How many times did you wake up after falling asleep last night? How long do you think it took for you to fall asleep? For how many hours were you asleep last night? Do you think the presence of a sleep tracker affect the quality of your sleep?
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Human Consent Form

Purpose	I want to create an affordable and portable sleep tracker that will give users a platform for sleep quality and sleep disorder tracking outside of sleep labs.
Participant Procedures	If you decide to participate, you will be asked to sleep overnight in your room with a wristwatch-shaped sleep tracker with a PLA plastic case on your left wrist starting at a time of your choosing. Whenever you wake up, the recording period will end and the sleep tracker will be removed from your wrist and a survey asking about the quality of your sleep during the recording will be given to you by a researcher.
Time Required for Participation	Three nights of normal sleep, ~25.5 hours, with 3 overnight trials per person, and one week in between trials.

Risks to You	The data from the overnight recording will never be shared with anyone outside of the project, and will never be published on the internet. The device may be uncomfortable to wear, and may cause irritation to the skin. If you feel pain or discomfort at any time during the recording period, you can opt-out and remove the sleep tracker and the data will be deleted. If the experiment is causing stress, you can opt-out, and no data will be saved or used from that trial.
Benefits to You	You will be able to see the objective quality of your sleep and help with the development of a sleep disorder tracker.
Confidentiality	At the beginning of the experiment, you will be assigned a tracking number. All data and surveys will be tracked by that number, not your name. The data will be saved on the computer of the researcher as a text file with the tracking number as the name. The researcher will never share the information with anyone outside the experiment without written permission from the participant.
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Bibliographic References

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- Reference 2 Luciane de Souza, Ana Amélia Benedito-Silva, Maria Laura Nogueira Pires, Dalva Poyares, Sergio Tufik, Helena Maria Calil, Further Validation of Actigraphy for Sleep Studies, *Sleep*, Volume 26, Issue 1, January 2003, Pages 81–85,
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- Reference 3 Meinhold, Roman. "SOMNOLOGY." *Applied Science*, Salem Press, 2012, pp. 1681–1686.
- Reference 4 Z Beattie, A Pantelopoulos, A Ghoreyshi, Y Oyang, A Statan, C Heneghan, 0068 ESTIMATION OF SLEEP STAGES USING CARDIAC AND ACCELEROMETER DATA FROM A WRIST-WORN DEVICE, *Sleep*, Volume 40, Issue suppl_1, 28 April 2017, Page A26,
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Reference 5 Atkinson, J. (2017, October 27). Polysomnography Reports –Interpreting the Data. Retrieved from <https://www.aastweb.org/hubfs/International Congress Presentations/4 Atkinson Polysomnography Reports.pdf>.

Certification References

Role	Name	Email Address	Qualifications	Status
Teacher/ Advisor	Nicole Windmon	nwindmon@webb.org	Dr. Windmon has a background in organic chemistry and teaches an integrated physics and chemistry course at Webb. She is also the site coordinator for Webb and runs an activity where she advises students for the Science Fair.	Verified
Designated Adult Supervisor	Nicole Windmon	nwindmon@webb.org	Dr. Windmon has a background in organic chemistry and teaches an integrated physics and chemistry course at Webb. She is also the site coordinator for Webb and runs an activity where she advises students for the Science Fair.	Verified

Reviews

Date	Status	Action
Mon, 18 Nov 2019 23:28:46 -0800	Not Approved - Will written parental consent be obtained for these subjects under 18? To decrease emotional stress, will they be reassured they can opt out at any time? Please give more details describing the device subjects will be wearing and if there are any risks to the skin, etc. Will the device be cleaned between subjects, etc.? Describe possible physical risks from wearing the device or emotional stress from participating.	View
Mon, 09 Dec 2019 18:32:01 -0800	Approved	View

Thu, 21 Nov 2019 23:53:57 -0800 Not Approved - risks, consent and opting out not fully addressed (see notes); bibliography needs one non internet source [View](#)

Mon, 09 Dec 2019 21:02:21 -0800 Approved [View](#)