

SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

Thank you to the following sites for the month of September randomizations. We currently have randomized 1293 subjects. That is 42.23% of our recruitment target.

Providence St. Vincent, Portland OR- Alexis Young & Biggya Sapkota MD UC Irvine Medical Center, Orange CA- Josue Prado & Masaki Nagamine MD Buffalo General, Buffalo NY- Tommaso Sciortino, Annemarie Crumlish, & Amit Kandel MD

Carolinas Rehabilitation, Concord NC- Christine Patino & Nicole Rup MD Maimonides Medical Center, Brooklyn NY- Maryna Mootoo & Qingliang Wang MD Casa Colina, Pomona CA- Jeanette Gumarang & Caroline Schnakers PhD UC Davis, Sacramento CA- Duyen Dao-Tran & Kwan Ng MD Harborview Medical Center, Seattle WA- Brooke Haines & Sandeep Khot MD Brooks Rehabilitation Hospital, Jacksonville FL- Taisiya Matev & Parag Shah MD SUNY Upstate, Syracuse NY- Sigiriya Smolen, Lena Deb, & Gene Latorre MD Hospital at the University of Pennsylvania, Philadelphia PA- Caroline Velten, Nichole Gallatti, & Steven Messe MD

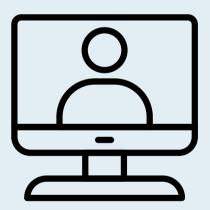
Chandler Regional, Chandler AZ- Allegra Sahelian & Dan Capampangan MD North Shore, Manhasset NY- Kirendra Pasram, Sabah Iqbal, & Rohan Arora MD Doctors Medical Center of Modesto, Modesto CA- Dorothy Trivedi & James Jaffe MD UCSF Medical Center, San Francisco CA- Eliot Lee & Wade Smith MD St. Luke's Hospital of Kansas City, Kansas City MO- Christine Kennish & Karin Olds MD

St. Cloud Hospital, St. Cloud MN- Rachael Albrecht & Muhammad Suri MD Kaiser Permanente Fontana, Fontana CA- Breanne Silesky & Conrad Liang MD Hartford Hospital, Hartford CT- Radu Radulescu & Francoise Roux MD Henry Ford Hospital, Detroit MI- Teresa Wiegand & Angelos Katramados MD

Sleep SMART PM Amanda Rasnake

Please welcome Amanda! She will be covering for Kayla starting October 17th until the end of January while she is out on maternity leave. She is part of the prime team at the University of Michigan. Her email is arasnake@med.umich.edu





Next Webinar

Our October webinar will be 10/23 at 1pm ET

Outcome visits

If a CPAP subject no longer wants to use CPAP, they can still participate in the 3 & 6 month visits if willing. If a control subject starts using CPAP, they can also participate in their follow up visits. This is not considered an automatic withdrawal of consent.

Coordinator of the Month Tommaso Sciortino, MD Buffalo General Medical Center

The prime team would like to recognize Tommaso for his enrollment efforts. Buffalo had the highest number of enrollments for the months of August and September! He has been an absolute pleasure to work with.



Annemarie from Buffalo said "Tommaso joined their team in May 2023 and hit the ground running. We were impressed with his effort right out of the gate. He has consistently demonstrated exceptional responsiveness and dedication by going above and beyond in his commitment to enrollment and randomization in the SleepSMART Trial. Tommaso shows up every day with a smile and a "can do "attitude. We are lucky to have him on our team."

Highlighted Tool

WebDCU User Manual #52 in WebDCU



WebDCU[™] User Manual

National Data Management Center Medical University of South Carolina Version 15.0 03 Jan 2023 This document reviews how to use WebDCU. It is a useful tool if you need to do the following:

- Obtain a user account
- Add/edit study team members on the DOA
- Submit Regulatory Documents
- Find project documents
- Enter data for a subject
- Respond to queries

Adding/Editing Study Team Members on Electronic DOA Log

- From the study's main menu page, click on [User Management], and then
- Click on the blue number link to the left of your site name.
- Click [Edit Record] in the upper right-hand corner.
 - To add a site team member to the DOA log, select their name from t drop down box under section 6: Team Member Request and enter the study. Select the study team member's role(s) by selecting the appropri Please refer to the Study Role key at the bottom of the page. Next, sele pertaining to the DOA responsibilities assigned to this study team me key at the bottom of the page.
 - To remove a site team member from the DOA log, enter an end date under section 5: Active Team Members.
 - To change the roles and/or responsibilities of a current site team first need to enter an end date for their current roles and responsibilitie

Excerpt on how to add/edit team members

Tess who?



Site Name
Subject ID
What was the subject randomized to?
O Intervention (CPAP)
○ Control (No CPAP)
What is the subject's cell phone number?

Just a reminder that we are still using Tess for all randomized subjects. In order to make Tess more user friendly, we created a Qualtrics link, https://umich.qualtrics.com/jfe/for m/SV_b73MvftChJgdfAa. Now instead of having a participant text Tess for the first time, the subject's information can be entered using this link. All that is needed is subject ID, randomization assignment, and cell number!

Recruitment, reconsidered

A patient who meets inclusion criteria and does not have obvious exclusion criteria still seems ... "too old", "too frail", "too unhappy", "too busy", "too incapacitated", "too xxx" ... to be a good candidate for Sleep SMART. Should we still spend time explaining the study to assess interest?

YES – please remain open to doing so. Entry criteria for Sleep SMART were deliberately fashioned to cast a broad net. Please consider recruitment of patients who meet criteria; you generally don't need to apply further filters except where implied in the protocol or MOP.

My subject meets randomization criteria, but should they be randomized?

You must ask them! The patient has to be willing to accept a 50% chance of CPAP for 6 months and a 50% chance of no CPAP for 6 months.





Eligibility criteria questions: 9am to 8pm ET: sleepsmart@umich.edu Fusionhealth (Nox T3, KOEO, aCPAP, Masks): 8am to 7pm ET M-F: 1-404-480-5149 ext 4006 or sleepsmarttechsupport@noxhealth.com. Please use email after hours.

WebDCU emergency randomization hotline: 1-866-450-2016 Project Managers: Kayla Novitski kcgossel@med.umich.edu | Amanda Rasnake arasnake@med.umich.edu | Joelle Sickler sicklejb@ucmail.uc.edu

WebDCU help: Faria Khattak khattak@musc.edu | Emily Kaestner kaestner@musc.edu

Regulatory help: Jordyn Schultz schuljd@ucmail.uc.edu

All previous webinars and newsletters can be found on https://www.nihstrokenet.org/trials/sleep-smart-trial/webinars. Password is Sleepy