



SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

Thank you to the following sites for a great March!

University of Cincinnati, Cincinnati OH- Sadie Caldwell & Natalie Kreitzer MD Toledo Hospital, Toledo OH- Melanie Pakulski & Mouhammad Jumaa MD Yale New Haven Hospital, New Haven CT- Radu Radulescu & Klar Yaggi MD Boone Hospital, Columbia MO- Mihaela Popescu & Justin Malone MD Methodist University Hospital, Memphis TN- Quentin Thacker & Balaji Krishnaiah MD Carolinas Rehabilitation Northeast, NC- Christine Patino & Nicole Rup MD Brooks Rehab Hospital, Jacksonville FL- Taisiya Matev & Prag Shah MD Moses H. Cone, Greensboro NC- Glynda Reaves & Pramod Sethi MD NYP Columbia University, New York NY- Angela Velazguez & Joshua Wiley MD University of Alabama, Birmingham AL- Tammy Davis & Soo Young Kwon MD UC Davis, Sacramento CA- Amy Hyatt & Kwan Ng MD Oregon Health & Science University, Portland OR- Taylor Toto & Wayne Clark MD UT Southwestern Medical- Dallas TX, Victoria Lindsey & Mehari Gebreyohanns MD BSW Institute for Rehabilitation, TX- Lacy Mcdonald & Chad Swank PhD, PT University of Maryland, Baltimore MD- Rachel Brenowitz & Seemant Chaturvedi MD Barnes Jewish, St. Louis MO- Porche Braun & Eric Landsness MD Hartford Hospital, CT- Radu Radulescu & Francoise Roux MD Sarasota Memorial Hospital, Sarasota FL- Matt Moehr & Mauricio Concha MD Banner University, Tucson AZ- Scott Richards & Chelsea Kidwell MD St. Mary's Medical Center, Grand Junction CO- Lisa Bertrand & Logan Mcdaneld MD UCSD Health La Jolla, La Jolla CA- Thomas Staniszewski & Dawn Meyer PhD, NP

Coordinator of the Month Congratulations to Jennifer Bandy from OSF Saint Francis Medical Center in Peoria IL!



From left to right: Ashwath Ravisankar, Dr. Sasikanth Gorantla, Jenny Bandy, Emily Ellis, & Isidra Baker. Missing from the photo are Praneeth Chebrolu and Kimberly Hartwig!

When we nominated Jenny to be the Coordinator of the month, she said her success was because of their great team at OSF. Jenny is always asking the Sleep SMART team great questions- sometimes bringing up issues we haven't thought about! She is incredibly detail oriented and it's obvious that subjects love her when she describes her patient interactions! Jenny and the OSF team have really hit the ground running in the last few months. We want to congratulate their whole team for their success during these difficult times!

New mask fitting guidance

OLD	NEW
Try all three mask types	With packages closed, show all three mask types to participant
Costly	If participant preference, have subject try that mask type.
Not very green	If no preference, select nasal mask
More complex for study teams	Use mask fit function on device to receive information on mask fit prior to 15-20 min trial
	Perform the 15-20 min daytime trial
	Intervention participant takes home any mask tried

How do I enter the mask fit results into KOEO if I haven't tried all 3?

You will enter what mask you think would be the second best and worst fitting mask based on your best judgement, and still enter the mask the patient moves forward with as the best fitting mask!

-Thanks Jenny from OSF for asking this!

Reminders

- An assessor blinded to treatment assignment should complete all components of the 3- and 6-month outcomes.
- To ascertain race and ethnicity, please ask the participants themselves how they identify!
- Please remember to introduce Chatbot enrollment to all Randomized participants!



Scratch-off Tickets

Scratch offs are being mailed to each site from Kayla. If you have not provided an address by email, please do so soon. Remember to add a scratch-off ticket when you mail outcome assessment reminders to subjects.



Nox T3 Scoring Hours Scoring hours are 10am and 2pm ET, 7 days per week.

Next webinar date Tuesday, April 19th at 2pm.

Coordinator Training

Coordinators – new and experienced – please complete new Sleep SMART training resource on optimal strategies to approach patients about Sleep SMART. This will help ensure similar, effective, and hopefully rewarding approaches across sites. To access for the first time, use the link found in the email sent to you from 4help@umich.edu. For return users, go to umich.instructure.com.

Ending trial participation early

If you are part of Arcadia, you may have seen an email last week regarding a similar issue. Intervention subjects who stop using CPAP and control subjects who seek CPAP treatment should not automatically be moved to End of Study. Please continue to pursue 3- and 6-month outcomes for these subjects if they are willing.

Common consent scenarios and what to do in each. We will be reviewing this in detail on the next webinar!

Consent Situation	Subject has trouble physically signing and dating the ICF	Subject is illiterate	Subject is blind	Subject does not speak English	Subject prefers to have friend/family member sign documents	Subject lacks cognitive ability to make decisions about study participation
Process	The subject should make their mark if able If an impartial witness cannot be found for this scenario, the site should create a Note to File (NTF) to detail the process followed and the reason an impartial witness was unable to be used.	Use Witnessed Consent Process	Use Witnessed Consent Process	Use short form and Use Witnessed Consent Process	Subject needs to consent for themself	Use LAR and obtain verbal assent from subject if appropriate

Serial number reminder

 Please be really careful entering the serial number and device number into KOEO

•If it's incorrect, Fusion will not be able to access your participant's CPAP data





Contact Information

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

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Regulatory help: Jordyn Schultz schuljd@ucmail.uc.edu and Emily Stinson stinsoey@ucmail.uc.edu

Please visit our Sleep SMART website to find helpful study-related materials: https://www.nihstrokenet.org/sleep-smart-trial/home