

Sleep for Stroke Management and Recovery Trial

Current trial numbers

Total consented: 1958 Total randomized: 644 Sites currently released to enroll: 98

August & September randomizations

- Moses H. Cone, NC
 Buffalo General, NY
 UCSF Medical Center, CA
 UC Davis, CA
 - Wake Forest, NC
 - St. Mary's Medical, CO
- University of Cincinnati, OH
 - SUNY upstate, NY
- University of Chicago, IL
- St. Luke's Bethlehem, PA
- Brooks Rehab, FL
- UCSD La Jolla, CA
- NYP Columbia, NY
- Maimonides Medical, NY

- University of Alabama, AL
- Mayo Clinic Jacksonville, FL
- Christ Hospital, OH
- University of Utah, UT
- University of Maryland, MD
- Penn State Hershey, PA
 - North Shore, NY
- Memorial Hermann, TX
- University of Nebraska, NE
- Greenville Hospital, SC
- Cox Medical Center, MO
- McLaren Flint, MI
- BSW Institute, TX

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

Special kudos to these 5 sites related to outpatient CPAP adherence! Site interactions with intervention participants during the hospitalization can get participants off on the right foot.

- <u>McLaren, Flint</u>- Marci Roberts, Stephanie Bruma, & Mahmoud Rayes MD
- Wake Forest- Leilani Johnson & Cheryl Bushnell MD
- <u>UCSD, La Jolla</u>- Teri McQuaid, Karen Rapp, & Dawn Meyer PhD, NP
- <u>St. Mary's, Grand Junction</u>- Lisa Bertrand & Logan McDaneld MD
- <u>Sarasota Memorial</u>- Matthew Moehr, Jeanette Wilson, & Mauricio Concha MD

FAQ: What do intervention subjects do with their CPAP once their participation has ended?

It is theirs to keep! Even if an intervention subject withdraws prior to the 6 month visit, they still get to keep their CPAP.

FAQ: Who can complete the 3 and 6 month follow up visits?

A blinded assessor AKA someone on your DOA who doesn't know what the subject was randomized to! There are no educational degree requirements for this individual, the person just needs be listed on the DOA with the proper responsibilities.

Financial Conflict of Interest (FCOI) upload

Please upload your FCOI that accompanied your 2021 continuing review. Only the site PI's FCOI should be uploaded in WebDCU, along with an FCOI for anyone else on your team who has a positive disclosure

Local IRB Acknowledgement	
Protocol Signature Page (Protocol v5 - 26Mar2020)	
Protocol Signature Page (Protocol v6 - 06Jul2020)	
Protocol Signature Page (Protocol v7 - 06Oct2020)	
Protocol Signature Page (Protocol v8 - 15Jun2021)	
Site Specific Stand-alone Bill of Rights	
Site Specific Stand-alone HIPAA Authorization Form	E E
StrokeNet CIRB Financial Interest Disclosure Form	
People Documents	
ABCD2 Curriculum Fusion Health Fusion Health Fu	ision Health Fusion Health

Contest!

TikTok-style video contest: All sites interested should submit a Sleep SMART-related, brief video (<1 minute) to Kayla for a chance to win \$\$\$. The video could include humor, dance, music, etc.



Next Webinar

October 11th at 1PM ET

This webinar will present everything from enrollment to completing the 3 & 6 months visits. If you are new to Sleep SMART or need a refresher- do not miss.

Reminders

- Use the document "Data Collection Guidelines" to reference when filling out any CRFs. This will show you how each assessment should be completed.
- If you consent a subject, they <u>must</u> be added as a new subject in WebDCU. Anyone consented must have a study ID.

Implementing a warm transition



Before hospital discharge, help initiate contact between intervention (CPAP) subjects only and the sleep coach: Program Care Team number in subject's cell phone if they agree, help them make a first call while they are still hospitalized (leaving message with Fusion if call is not answered), and remind them they can receive \$10 for another call completed within the 7 days after discharge from their enrollment hospitalization.

Contact Information

Eligibility criteria questions: 9am to 8pm ET: sleepsmart@umich.edu Fusionhealth (Nox T3, KOEO, aCPAP, Masks): 9am to 5pm ET: 1-404-480-5149 ext 4006 or sleepsmarttechsupport@noxhealth.com WebDCU emergency randomization hotline: 1-866-450-2016 Project Managers: Kayla Novitski kcgossel@med.umich.edu and Joelle Sickler sicklejb@ucmail.uc.edu WebDCU help: Jocelyn Anderson anderjoc@musc.edu and Faria Khattak khattak@musc.edu Regulatory help: Emily Stinson stinsoey@ucmail.uc.edu