

SLEEP SMART NEWSLETTER

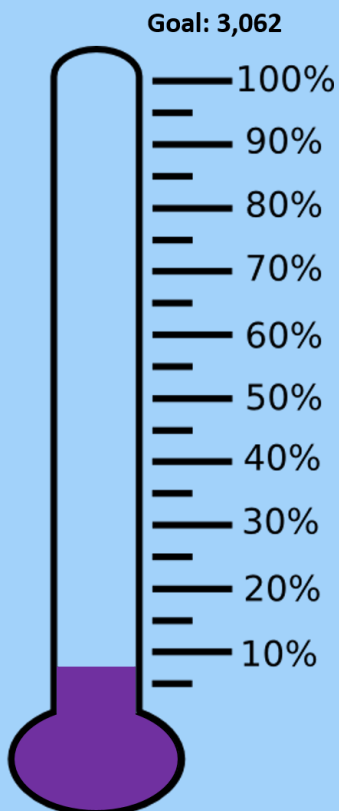
Sleep for Stroke Management and Recovery Trial

CORONAVIRUS (COVID-19)

Enrollment Hold Lifted

Sites may request to be reactivated (see page 2)

260 Participants randomized!



Congratulations to:

Wake Forest

Brooks Rehabilitation Hospital

Memorial Hermann Texas Medical Center

For randomizing our first subjects after the COVID
hold

Site Reactivation Guide

- Ensure local procedures allow for in-person interaction and enrollment
- Verify that study procedures/visits will not contribute to a shortage of resources (staff, PPE, etc) that are needed to take care of COVID-19 patients
- Verify that study procedures will not interfere with clinical procedures put in place to treat COVID-19 patients
- Update the COVID Impact Assessment in WebDCU; comment "confirmed" when reopening criteria have been met
- If needed: Alert local IRB that study-wide hold has been lifted by CIRB
- If needed: Submit protocol v5 ICF to local IRB
- Check "Alerts" tab in WebDCU; respond to DCRs and missing CRFs
- Ensure people documents in WebDCU have not expired
- Ensure at least one person has completed the informed consent process training; upload attestation in WebDCU

20 sites have been re-released to enroll:

- University of Cincinnati
- UT Houston
- Wake Forest
- Tampa General
- Sarasota Hospital
- West Chester Hospital
- Eastern Maine Medical Center
- Oregon Health & Science University
- Prisma Health Richland Hospital
- NYU Medical Center
- Maimonides
- University of Utah
- OSU
- McLaren Flint
- Brooks Rehab
- Harborview Medical Center
- University of Florida (Shands)
- UCSF Medical Center
- Saint Luke's Kansas City
- Cox Medical Center South

Facilitate Contact with FH Sleep SMART Care Team

- With permission, store the Care Team's number in the subject's cell phone
- Prior to discharge, facilitate a call between intervention subject and Care Team to initiate contact
- Intervention subjects who complete a call with the Care Team within 7 days after discharge will receive a \$10 Amazon gift card as a thank you

Contacting Subjects:

If you can't get in touch with the subject by phone to schedule the outcome assessment:

- Check the back of the consent form to see if you have permission to contact them by text or email.
- Alternative contacts may also be found in the back of the consent.
- The Sleep SMART website has an "unable to reach" template letter for subjects as well as a "lost to follow-up" for those on the verge of being lost to follow-up.

(<https://www.nihstrokenet.org/sleep-smart-trial/research-team>).

Upcoming :

FusionHealth Workshop

7/29/20

This will be a virtual, hands-on workshop

Webinar

7/27/20

Topic TBA

FusionHealth T3 reading times

10am and 2pm EST, 7 days per week

What can I do remotely?

If your site is NOT released to enroll:

- Complete all contracts: CTA, Fusion Health DUA and Consignment
- CIRB submission
- Sleep SMART trainings for all team members
- Complete DOA in WebDCU
- Complete dummy T3 test

If your site IS released to enroll:

- Ensure all trainings are up to date in WebDCU for all team members
- Schedule and complete 3 and 6 month visits by phone with a blinded assessor
- Respond to WebDCU queries
- Review the website to refamiliarize yourself with the available Sleep SMART tools

Reminders

- To be eligible for randomization, subjects have to be willing to be randomized to either arm. Please ask the subject directly after a successful run-in night to assure that this is true
- Video visits are not allowed, per protocol. Visits can be done over the phone if necessary
- Subjects who want to discontinue CPAP intervention should still have the 3 and 6 month follow-up assessments completed
- Remember to upload all CIRB Modification Letters to WebDCU in the CIRB Approved Administrative Amendments space holder
- Be sure to update the COVID-19 Impact Assessment in WebDCU

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

Eligibility questions: 9am to 8pm ET: sleepsmart@umich.edu

FusionHealth (Nox T3, KOEO, aCPAP, Masks): 9am to 5pm ET: 1-888-505-0280 ext 4006

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: Faria Khattak khattak@musc.edu and Jocelyn Anderson anderjoc@musc.edu