

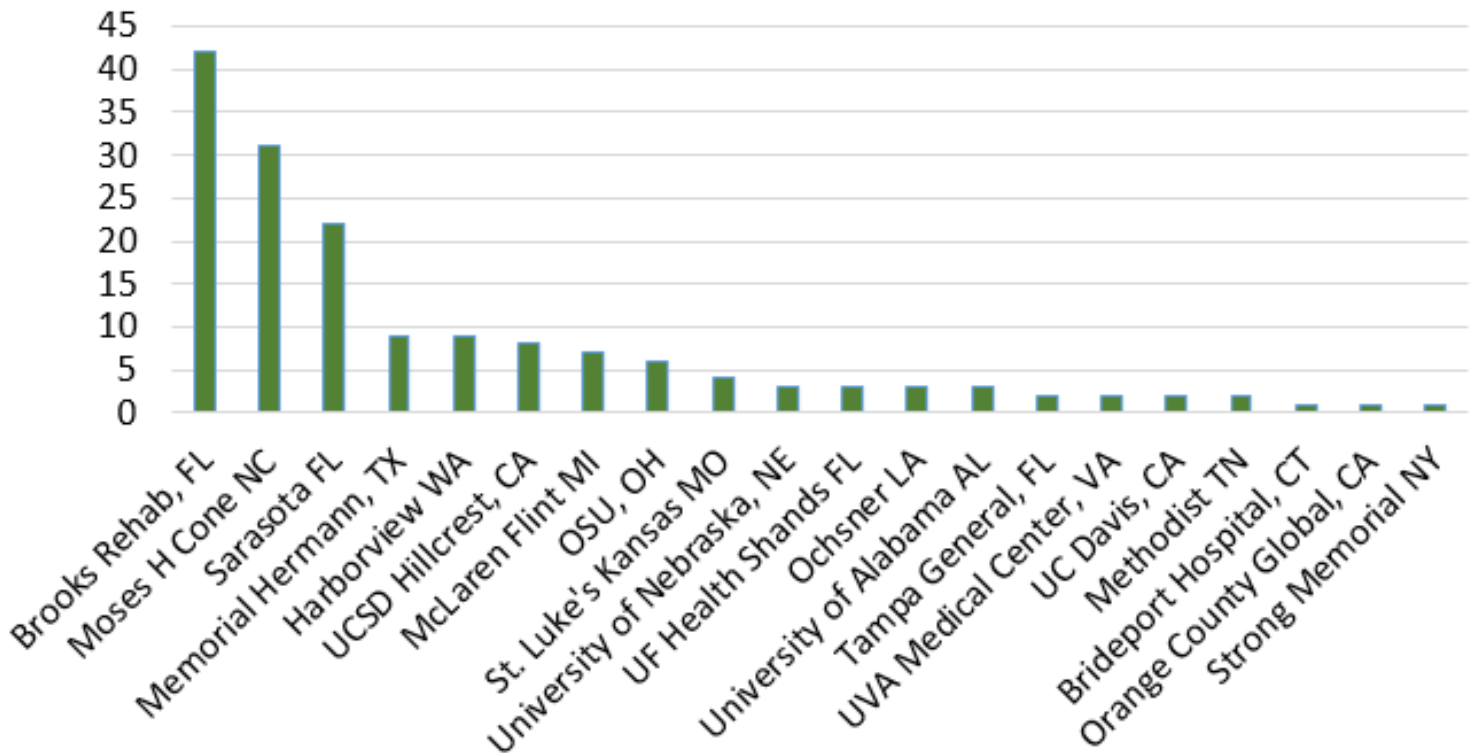


SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

All the sites who randomized in Nov & Dec with their total randomization numbers since study initiation! Thanks to all sites for your hard work!

Total Randomization Numbers



Current trial numbers

Total consented: 1123

Total randomized: 384

Sites currently released to enroll: 85

Reminders

- There will be no December webinar, if you miss us you can watch all of our previously recorded webinars here:
<https://www.nihstrokenet.org/sleep-smart-trial/webinars>
- The November webinar was a study refresher, please review it if you think you need one.
- If you chose (H) Use KOEO system on your DOA as a responsibility, you will need to reach out to Helgi to create an account. KOEO accounts are not created automatically.
- If you are trying to submit an Adverse Event for COVID-19, we recommend you use 'Corona Virus Infection'. Otherwise, please use a MedDRA term that best represents the event that occurred.
- Please print the 6 FusionHealth MOPs we have. They are located on our website and in the WebDCU Toolbox. These are great step by step guides on using KOEO, the T3, and CPAP.
- Financial Conflict of Interest Form: All site PI FCOI forms completed and submitted for continuing review should be uploaded in WebDCU to the CIRB Financial Interest Disclosure form placeholder. The expiration date will be 24Nov2021.

Next Webinar

January 11,
2021 from 2-3pm
ET

The webinar will
focus on
Inpatient CPAP
use

New video available

- We have a new video to introduce the care team to intervention (CPAP) subjects. The video can be found on the patient tab on our website:
<https://www.nihstrokenet.org/sleep-smart-trial/patients>
- This video is critical in helping with adherence before subjects leave the hospital

Holiday T3 Scoring hours

Normal hours will
remain.
10am/2pm EST

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

Where are the CRF's located?

In WebDCU, click on the Project Setup tab -> CRF Collection Schedule. There are 2 ways you can print CRFs. You can print the entire visit, which is located on the top of the screen as circled in red. You can also print each individual CRF listed on the left.

CRF Name	Baseline	Randomization	Hospital Discharge	3 Month	6 Month
E101 Eligibility	X M				
E102 Randomization		X M			
E104 Adverse Event	OR M	OR M	OR M	OR M	OR M
E106 Medical History	X M				
E117 Vital Signs	X M				
E123 Hospital Discharge			X M		
E126 End of Study					
E139 HADS - D	X			X	X
E143 NIH Stroke Scale	X M			X M	X M
E144 Modified Rankin Scale	X				
E151 Short SSQOL				X M	X M
E167 Short MoCA				X M	X M
E202 IQCODE	X				
E209 Clinical Management and Medication Adherence				X M	X M
E241 Epworth Sleepiness Scale	X			X	X
E244 Informed Consent Version 4	X M				
E245 Informed Consent Version 5		X M			
E255 PROMIS - Global Health				X	X
E290 10 Meter Walk Test				X M	
E291 ABCD² Score	X M				
E292 Modified Rankin Scale 9Q				X M	X M
E309 COVID-19 Assessment		X			
E501 STOP - BANG	X				
E502 Sleep Duration Questionnaire				X	X
E503 Blood Pressure Follow-Up				X M	X M
E504 Primary Outcomes Report					
E505 CPAP Follow-Up Questionnaire					
E506 aCPAP Run-In Night	X M				

3 month mRS-9Q

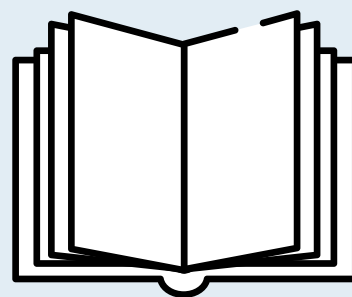
- Please get this assessment completed in window
- Each individual question must be asked (subject or proxy)- cannot be abstracted from the medical record
- Ideally done by a blinded assessor, but prioritize in window
- Can be done by phone
- **All site coordinators and PIs will be receiving an email from Kayla if a 3 month window is pending and the visit has not been completed.**

Corrective Action Plan

- After one additional out of window or missed 3-month or 6-month visit, a CAPA will need to be completed by your site. Once on a corrective action plan, if an additional visit is missed this will trigger site probation.

Adjudication requests

- The investigator's narrative summary is a vital component of the outcome events packet. Sometimes packets can be over 100 pages, and getting a clear summary of where to focus efforts is really important. Everything is always reviewed, but a good narrative can save a ton of time.
- In particular, it would be helpful if the narrative summarizes the initial index stroke (e.g. symptoms/exam/imaging), and then describes what new symptoms or exam findings lead to the diagnosis of an outcome stroke. The information about the index stroke, and any change from prior baseline, is sometimes hard to find otherwise.
- Include any data on prior stroke/MI in this packet. It is useful to compare symptoms and imaging on new event with prior events.



Unanticipated Event PD Report

The PI is responsible for identifying and assessing the given event and documenting it in WebDCU via the Unanticipated Event-PD Report. Certain events that are reported will require prompt reporting within 10 days of site awareness. Joelle will submit all events that require prompt reporting to the CIRB as Reportable New Information (RNI). The CIRB will then provide a letter of acknowledgement that will be uploaded into WebDCU by Joelle. If further actions are needed, the site will act on the letter requirements and provide them to Joelle. If your site has an event that requires prompt reporting, please be sure to reach out to Joelle to confirm the event has been reported to the CIRB. Events that do not require prompt reporting will be reported at continuing review.

Implementing a warm transition

Before hospital discharge, help initiate contact between *intervention (CPAP) subjects only* and the Care Team: 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.



Happy Holidays from the Sleep SMART team! Thank you for all of your work in what was a very challenging year. Top randomizer awards for 2020 will be announced after the holidays!

Contacts

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

Fusionhealth (Nox T3, KOEO, aCPAP, Masks): 9am to 5pm ET: 1-404-480-5149 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

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