

SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

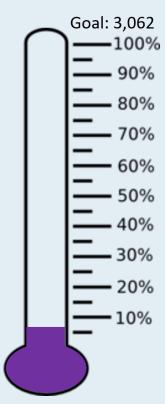
Welcome New Sites!

- Mission Hospital Memorial, Asheville NC
- Greenville Hospital System, Greenville SC
- Mercy San Juan, Carmichael CA
- Hartford Hospital, Hartford CT
- Sanford Medical Center, Fargo ND
- · University of Nebraska, Omaha NE

Congratulations to the top 5% of sites to randomize in Sleep SMART in 2019

- Brooks Rehab Hospital- Jacksonville Fl- Taisiya Matev & Parag Shah MD
- Sarasota Memorial Hospital, Sarasota FL- Jeanette Wilson & Mauricio Concha MD
- Barnes-Jewish Hospital, St. Louis MO- William Holt & Eric Landsness PhD, MD
- Palmetto, Columbia SC- Phil Fleming & Souvik Sen MD

192 patients have been randomized!



January Randomization's:

- St. Cloud Hospital
- St. Joseph's Hospital and Medical Center
- UCSD Health La Jolla
- UCSD Hillcrest Hospital
- University of Cincinnati Medical Center
- University of Maryland Medical Center
- University of Mississippi Medical Center
- University of Wisconsin University Hospital
- Wake Forest Baptist Medical Center

- Barnes Jewish Hospital
- Brooks Rehabilitation Hospital
- Henry Ford Hospital
- · Hospital of the University of Pennsylvania
- Kaiser Permanente Los Angeles Medical Center
- McLaren Flint
- Montefiore Medical Center
- Moses H. Cone Memorial Hospital
- Palmetto Hospital

Reminders

- ALL 3 and 6 month assessments must be done by a blinded assessor
- If the window for the 3 month visits ends and you have not been able to reach a subject, please continue to reach out to them until the 6 month window begins.
- Those who decline informed consent should be logged into WebDCU under Study Progress tab > Screen Failure Report.
- Don't forget to collect the IQCODE. This assessment should not be done by the subject. It should be completed by someone close to the subject.
- The baseline NIH Stroke Scale should be done after the subject is enrolled.
- Please report AEs. If you need guidance, please see pg 59 of the Sleep SMART MOP.
- Have webinar ideas or topics you want to see covered? Let us know!

Did You Know? Site Payments

The primary study coordinator at your site can request access to the WebDCU™ payment module information for your site personnel by requesting they be added to the "Site Financial Manager" user group. A request can be made via the [User Permission Request] table in WebDCU™ or you can send an email to the trial-specific DCU Data Manager to request this access. To have access to this user group, the person does NOT need to be on the site DOA.

Next Webinar

February 24, 2020 from 1-2pm ET

This webinar will focus on care management, so please tune in!

Patient Concerns about CPAP and SleepSMART: Asthma

Patients with lung diseases such as asthma may wonder whether CPAP might worsen their condition, make it harder for them to breathe, or interfere with other treatments such as administration of supplemental oxygen. In fact, breathing in patients with lung diseases can worsen during sleep. However, correction of sleep apnea by use of CPAP often diminishes or eliminates that deterioration during sleep. For example, nocturnal asthma or poorly controlled asthma may improve when OSA is treated by CPAP. Moreover, supplemental oxygen for patients who use it can be administered through a CPAP machine.

FusionHealth T3 reading times

Mon-Fri: 10am, 2pm EST Sat/Sun: 10am, 4-6pm EST

Informed Consent Re-training

On 1/16 sites that are released to enroll were sent an email regarding informed consent re-training. The email contained a PowerPoint presentation that addressed common consent issues that we have been seeing across sites. The email also included an informed consent checklist and a consent attestation that needed to be signed by the PI and Primary Site Coordinator by 1/31.

We ask that every site use the informed consent checklist when consenting a subject to avoid common consent issues. This document can be found in WebDCU in the Toolbox or under the Recruitment/Enrollment Tab on https://www.nihstrokenet.org/sleep-smart-trial/research-team.

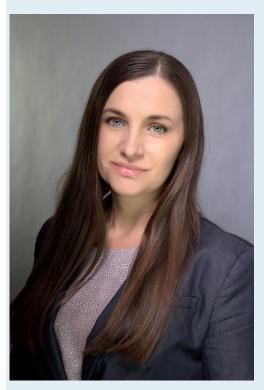
Common consent issues

- Consent conducted by study personnel not listed to consent on DOA
- •Subject consented with the non-IRB-stamped, but current version of the consent
- Witness consent process not used when indicated
- Patient signed a consent form but was found not to be eligible
- Person obtaining consent did not sign the informed consent
- Study coordinator initialed and dated correction for the subject
- LAR used when not appropriate

Please visit our Sleep SMART website to find helpful studyrelated materials: https://www.nihstrokenet.org/sleep-smarttrial/home

Sleep SMART Coordinator of the month

Congratulations to Taisiya Matev! Brooks Rehabilitation Hospital, Jacksonville, FL



Taisiya was chosen as the coordinator of the month for her dedication to the Sleep SMART. Her site continues to remain at the top of our leader board for most randomized subjects with 21 total! Taisiya has helped in improving numerous study documents to better serve subjects in Sleep SMART and has gone out of her way to help other site coordinators by addressing enrollment questions and providing tips.

If you are a site that has a coordinator that you think should be featured, let us know!

New study team member

You may have noticed Emily being copied on recent emails from Kayla, Helgi, or Joelle. Emily Herreshoff is at the University of Michigan and will be helping out on Sleep SMART once Kayla goes on maternity leave in April.

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

Sites 24	Copic Appropriate Sites FATURA FATURA FATURA SITES	ordiginated Cr. A. Sites FH. Cordiginated Cr. A. Cordiginated Cr.
RO1 Case Vestern Reserve University Mercy Health - St. Vincent Medical Center	R11 University of California Los Angeles Cedars Sinai Medical Center	R19 University of Pennsylvania Temple University Hospital
leveland Clinic, Cleveland		Hospital of the University of Pennsylvania
H Cleveland Medical Center	Kaiser Permanente Los Angeles Medical Center Ronald Reagan UCLA Medical Center	Lehigh Valley- Cedar Crest
	UC Irvine	Robert Wood Johnson University
pectrum Health Hospitals Butterworth Hospital letroHealth Medical Center	UCLA Kaiser Fontana	
		R20 University of Pittsburgh
uby Memorial Hospital	University of New Mexico	UPMC Presbyterian Hospital
02 Columbia University	Doctors Medical Center of Modesto	St. Luke's University Hospital - Bethlehem Campus
YP Columbia University Medical Center uffalo General Medical Center	Hoag Memorial Hospital Presbyterian	UVMC Main Campus (Vermont) R21 The University of Texas Health Science Center at Houston
	R12 University of California San Diego UCSD Health La Jolla	Memorial Hermann-Texas Med Center
JNY Upstate Medical University	UCSD Medical Center - Hillcrest	
rong Memorial Hospital		University of Texas Southwestern
03 Emory University	Dignity Health- St. Joseph Hospital	University Health Shreveport
ady Memorial Hospital	Chandler Regional Medical Center	R22 University of Utah
04 Massachusetts General Hospital eth Israel Deaconess Medical Center	Ochsner Medical Center	Intermountain Medical
	R13 University of California San Francisco	St. Mary's Grand Junction CO
Massachusetts General Hospital ufts Medical Center	John Muir Concord Campus	Banner University Medical Phoenix
urts Medical Center astern Maine Medical Center	John Muir Walnut Creek Campus UCSF Helen Diller Medical Center	Banner University Medical-Tucson
astern Maine Medical Center austate Health		University of Utah Health
	Community Regional Medical Center of Fresno	R23 University of Vashington
righam and Women's Hospital	R14 University of Cincinnati	Evergreen Health Medical Center Virginia Mason Medical Center
oston Medical Center 05 Medical University of South Carolina	University of Louisville Hospital University of Cincinnati Medical Center	virginia Mason Medical Center Harborview Medical Center
reenville Hospital System	St. Elizabeth Edgewood	R24 University of Visconsin
almetto Health Richland	Mercy Hospital Fairfield	University of Wisconsin University hospital
uilford Neurologic Associates (Moses Cone)	Christ Hospital	Marshfield Clinic Health System
1USC University Hospital	The Jewish Hospital	R26 University of Alabama at Birmingham
06 MedStar Health Research Institute	West Chester Hospital	UAB Hospital
niversity of Maryland	R15 University of Iowa	University of Mississippi Medical Center
eorge Washington University	University of Iowa Hospitals & Clinics	R27 Vake Forest Universite
VA Medical Center	University of Nebraska Medical Center	Wake Forest Baptist Medical Center
07 Icahn School of Medicine at Mount Sinai	Sanford Medical Center	Novant Health Forsyth Medical Center
YU Langone- Tish Hospital Medical Center	St. Luke's Methodist Hospital	Novant Health Presbyterian Medical Center
Naimonides Medical Center	R16 University of Miami	Mission Hospital
Iontefiore Medical Center	Jackson Memorial Hospital	R28 The Vashington University
08 Northwestern University	UF Health Shands Hospital	Barnes-Jewish Hospital
oyola University Medical Center	Sarasota Memorial Hospital	OSF Saint Francis Medical Center
niversity of Illinois Hospital and Health sciences	Brooks Rehabilation Hospital	St. Louis University Hospital
orthwestern Memorial Hospital	Tampa General Hospital	Cox Medical
Medical College of Wisconsin	Mayo Clinic Jacksonville	St. Luke's Hospital of Kansas City
ush University Medical Center	Baptist Hospital of Miami	University of Tennessee
niversity of Chicago Medical Center	University of Miami Hospital	R29 Yale University
09 The Ohio State University	R17 University of Michigan	Yale-New Haven Hospital
SU Wexner Medical Center	Detroit Receiving Hospital	Hartford Hospital
10 Stanford University	Henry Ford Hospital	Staten Island University Hospital
lercų San Juan Medical Center	Mercy Health Saint Mary's	North Shore University Hospital
regon Health and Science University Hospital	University of Kentucky Hospital	No RCC
	McLaren Flint	UC Davis
	R18 University of Minnesota	Bridgeport CT
	United Hospital	Geisinger Clinic PA
	Valley Baptist Medical Center - Harlingen	Advanced Neurology Specialists MT
	University of Minnesota Medical Center	Baylor Scott & White Institute of Rehab TX
	St. Cloud Hospital/Centracare	Norton Healthcare
	Southern Illinois University Memorial	Capital Health-NJ
	Mayo Clinic Hospital Rochester – St Mary's Campus	Capital Featurity