Sleep SMART

SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

CORONAVIRUS (COVID-19)

ENROLLMENT ON HOLD

- All in-person interactions including enrollment and randomization are on hold.
- 3 and 6 month follow up visits should still be performed via phone by a blinded assessor.
- Fusion Health will continue to remotely support intervention arm subjects

COVID 19 CORONAVIRUS DISEASE
STOP THE SPREAD OF GERMS

Help prevent the spread of respiratory diseases like COVID-19.

Avoid close contact with people who are sick.

Cover your cough or sneeze with a tissue, then throw the tissue in the trash.

Avoid touching your eyes, nose, and mouth.

Clean and disinfect frequently touched objects and surfaces.

Stay home when you are sick, except to get medical care.

Wash your hands often with soap and water for at least 20 seconds.

For more information: www.cdc.gov/COVID19

COVID-19 Impact Assessment

- NINDS has asked that we track the impact of COVID-19 on enrolling sites
- Please fill out the COVID-19 Impact Assessment in WEBDCU

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 assesor
- Respond to WebDCU queries
- Review the website to refamiliarize yourself with the available SleepSMART tools:
  - https://www.nihstrokenet.org/sleep-smart-trial/home
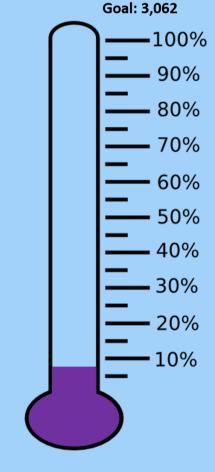
March Activity

Welcome New Sites!

- Temple University Hospital, Philadelphia, PA
- Marshfield Clinic, Marshfield WI
- Tampa General Hospital, Tampa FL
- George Washington University, Washington DC
- St. Louis University, St. Louis MO
- Bridgeport Hospital, Bridgeport CT

March Randomizations:

- SUNY Upstate Medical University
- Moses H. Cone Memorial Hospital
- Brooks Rehabilitation Hospital
- Prisma Health Richland Hospital
- Buffalo General Medical Center
- Cox Medical Center South
- Wake Forest Baptist Medical Center
- LSU University Health Shreveport
- McLaren Flint
- Oregon Health & Science University Hospital
- University of Nebraska Medical Center
- University of Chicago Medical Center
- University of Mississippi Medical Center
- St. Mary's Medical Center, Grand Junction
- Mission Hospital Memorial Campus
- University of Cincinnati Medical Center

253 patients have been randomized!

Goal: 3,062

- 100%
- 90%
- 80%
- 70%
- 60%
- 50%
- 40%
- 30%
- 20%
- 10%

FusionHealth T3 reading times
10am and 2pm EST, 7 days per week

Reminders

- Video visits are not allowed, per protocol. Visits can be done over the phone for the duration of the suspension of in-person activities
- We will be shipping out single use wristbands for the Nox T3 to sites that have been released to enroll. Look out for an email from Helgi.
- Subjects who want to discontinue CPAP intervention should still have the 3 and 6 month follow-up assessments completed
- All 3 and 6 month assessments must be conducted by a blinded assessor
- Remember to upload all CIRB Modification Letters to WebDCU in the CIRB Approved Administrative Amendments space holder

Unreachable intervention subjects

FusionHealth is sometimes unable to reach some intervention subjects. When this occurs, Rebecca from Fusion may contact you to ask you to reach out to the subject. People are more likely to respond to the local research team they know!

WebDCU: Alerts tab

The 'Alerts' tab in WebDCU gives an easy and quick overview of all the issues that need to be addressed including:

- Open DCRs
- Responded DCRs
- Open rule violations
- Pending, missing, expired, and rejected reg docs

When the Alerts tab is highlighted in red, that means that there is an issue that needs to be addressed

Next Webinar

April 29, 2020
1-2pm ET

Dr. Jeff Durmer will be discussing adherence

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

Legend: G = green cell, B = blue cell, blank = no cell

Panel 1

Sites	FH DUA	FH Consignment	CTA	CIRB Approval
R01 Case Western Reserve University				
Mercy Health - St. Vincent Medical Center	B	B	B	B
Cleveland Clinic, Cleveland	B	B	B	B
UH Cleveland Medical Center	G	G	G	G
Spectrum Health Hospitals Butterworth Hospital	B	B	B	B
MetroHealth Medical Center	B	B	B	B
Ruby Memorial Hospital	G	G	G	G
R02 Columbia University				
NYP Columbia University Medical Center	G	G	G	G
Buffalo General Medical Center	G	G	G	G
SUNY Upstate Medical University	G	G	G	G
Strong Memorial Hospital	G	G	G	G
R03 Emory University				
Grady Memorial Hospital	B	B	B	B
R04 Massachusetts General Hospital				
Beth Israel Deaconess Medical Center	G	G	G	G
Massachusetts General Hospital	G	G	G	G
Tufts Medical Center	G	G	G	G
Eastern Maine Medical Center	G	G	G	G
Baystate Health				
Brigham and Women's Hospital	G	G	G	G
Boston Medical Center	G	G	G	G
R05 Medical University of South Carolina				
Greenville Hospital System	G	G	G	G
Palmetto Health Richland	G	G	G	G
Guilford Neurologic Associates (Moses Cone)	G	G	G	G
MUSC University Hospital	G	G	G	G
R06 MedStar Health Research Institute				
University of Maryland	G	G	G	G
George Washington University	G	G	G	G
UVA Medical Center	G	G	G	G
R07 Icahn School of Medicine at Mount Sinai				
NYU Langone- Tish Hospital Medical Center	G	G	G	G
Maimonides Medical Center	G	G	G	G
Montefiore Medical Center	G	G	G	G
R08 Northwestern University				
Loyola University Medical Center	G	G	G	G
University of Illinois Hospital and Health sciences	G	G	G	G
Northwestern Memorial Hospital	G	G	G	G
Medical College of Wisconsin	G	G	G	G
Rush University Medical Center	B	B		
University of Chicago Medical Center	G	G	G	G
R09 The Ohio State University				
OSU Wexner Medical Center	G	G	G	G
R10 Stanford University				
Mercy San Juan Medical Center	G	G	G	G
Oregon Health and Science University Hospital	G	G	G	G

Panel 2

Sites	FH DUA	FH Consignment	CTA	CIRB Approval
R11 University of California Los Angeles				
Cedars Sinai Medical Center	G	G	G	G
Kaiser Permanente Los Angeles Medical Center	G	G	G	G
Ronald Reagan UCLA Medical Center	G	G	G	G
UC Irvine				B
UCLA Kaiser Fontana	G	G	G	G
University of New Mexico			B	
Doctors Medical Center of Modesto	G	G	G	G
Hoag Memorial Hospital Presbyterian	G	G	G	G
R12 University of California San Diego				
UCSD Health La Jolla	G	G	G	G
UCSD Medical Center - Hillcrest	G	G	G	G
Dignity Health- St. Joseph Hospital	G	G	G	G
Chandler Regional Medical Center	G	G	G	G
Ochsner Medical Center	G	G	G	G
R13 University of California San Francisco				
John Muir Concord Campus	G	G	G	G
John Muir Walnut Creek Campus	G	G	G	G
UCSF Helen Diller Medical Center	G	G	G	G
Community Regional Medical Center of Fresno	B	B	B	B
R14 University of Cincinnati				
University of Louisville Hospital	G	G	G	G
University of Cincinnati Medical Center	G	G	G	G
St. Elizabeth Edgewood			B	
Mercy Hospital Fairfield			B	
Christ Hospital	G	G	G	G
The Jewish Hospital			B	
West Chester Hospital	G	G	G	G
R15 University of Iowa				
University of Iowa Hospitals & Clinics	B	B	B	B
University of Nebraska Medical Center	G	G	G	G
Sanford Medical Center	G	G	G	G
St. Luke's Methodist Hospital	G	G	G	G
R16 University of Miami				
Jackson Memorial Hospital	G	G	G	G
UF Health Shands Hospital	G	G	G	G
Sarasota Memorial Hospital	G	G	G	G
Brooks Rehabilitation Hospital	G	G	G	G
Tampa General Hospital	G	G	G	G
Mayo Clinic Jacksonville				B
Baptist Hospital of Miami	B	B	B	B
University of Miami Hospital	G	G	G	G
R17 University of Michigan				
Detroit Receiving Hospital				B
Henry Ford Hospital	G	G	G	G
Mercy Health Saint Mary's	G	G	G	G
University of Kentucky Hospital	G	G	G	G
McLaren Flint	G	G	G	G
R18 University of Minnesota				
United Hospital	G	G	G	G
Valley Baptist Medical Center - Harlingen				
University of Minnesota Medical Center	G	G	G	G
St. Cloud Hospital/Centracare	G	G	G	G
Southern Illinois University Memorial	G	G	G	G
Mayo Clinic Hospital Rochester – St Mary's Campus	G	G	G	G

Panel 3

Sites	FH DUA	FH Consignment	CTA	CIRB Approval
R19 University of Pennsylvania				
Temple University Hospital	G	G	G	G
Hospital of the University of Pennsylvania	G	G	G	G
Robert Wood Johnson University	B	B	B	
R20 University of Pittsburgh				
UPMC Presbyterian Hospital	G	G	G	G
St. Luke's University Hospital - Bethlehem Campus	G	G	G	G
UVMC Main Campus (Vermont)	B	B	B	B
R21 The University of Texas Health Science Center at Houston				
Memorial Hermann-Texas Med Center	G	G	G	G
University of Texas Southwestern	G	G	G	G
University Health Shreveport	G	G	G	G
R22 University of Utah				
Intermountain Medical	G	G	G	G
St. Mary's Grand Junction CO	G	G	G	G
Banner University Medical-Phoenix			B	
Banner University Medical-Tucson			B	
University of Utah Health	G	G	G	G
R23 University of Washington				
Evergreen Health Medical Center	G	G	G	G
Virginia Mason Medical Center	G	G	G	G
Harborview Medical Center	G	G	G	G
R24 University of Wisconsin				
University of Wisconsin University hospital	G	G	G	G
Gundersen Lutheran Medical				
Marshfield Clinic Health System	G	G	G	G
R26 University of Alabama at Birmingham				
UAB Hospital	G	G	G	G
University of Mississippi Medical Center	G	G	G	G
R27 Wake Forest University				
Wake Forest Baptist Medical Center	G	G	G	G
Novant Health Forsyth Medical Center	B	B	B	B
Novant Health Presbyterian Medical Center				
Mission Hospital	G	G	G	G
R28 The Washington University				
Barnes-Jewish Hospital	G	G	G	G
OSF Saint Francis Medical Center	G	G	G	G
St. Louis University Hospital	G	G	G	G
Cox Medical	G	G	G	G
St. Luke's Hospital of Kansas City	G	G	G	G
University of Tennessee			B	B
R29 Yale University				
Yale-New Haven Hospital	G	G	G	G
Hartford Hospital	G	G	G	G
Staten Island University Hospital	B	B	B	B
North Shore University Hospital	G	G	G	G
No RCC				
UC Davis	B	B		B
Bridgeport CT	G	G	G	G
Geisinger Clinic PA				
Advanced Neurology Specialists MT	B	B		
Baylor Scott & White Institute of Rehab TX			B	
Norton Healthcare	G	G	G	G
Capital Health-NJ	G	G	G	G
TMC HealthCare				