NOVEMBER 2023

SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

Thank you to the following sites for the month of November randomizations. We currently have randomized 1343 subjects. That is 44% of our recruitment target.

OSU Wexner Medical Center, Columbus, OH- Luke Herren & Sushil Lakhani MD

Casa Colina, Pomona CA- Jeanette Gumarang & Caroline Schnakers PhD

Carolinas Rehabilitation, Concord NC- Christine Patino & Nicole Rup MD

University of Alabama Hospital, Birmingham, AL- Mitzi Roberts & Kristen Sandefer MD

UCSD Health, La Jolla, CA- Maryo Jajo & Dawn Meyer PhD, FNP-C

Chandler Regional Medical Center, Chandler AZ- Allegra Sahelian & Dan Capampangan MD

WVU Healthcare Ruby Memorial Hospital, Morgantown, WV- Jay Sherman & Mouhannad Azzouz MD

Barnes Jewish Hospital, St. Louis, MO- Angela Wolford & Eric Landsness MD, PhD

Buffalo General, Buffalo, NY- Tommaso Sciortino, Annemarie Crumlish, & Amit Kandel MD

St. Mary's Medical Center, Grand Junction, CO- Lisa Bertrand & Logan McDaneld MD

Penn State Hershey Medical Center, Hershey, PA- Reba Chivari & Raymond Reichwein MD

UC Davis Medical Center, Sacramento, CA- Duyen Dao-Tran & Kwan Ng MD

Orange County Global Medical Center, Santa Ana, CA- Marylinn Torres & John Chen MD

Rush University Medical Center, Chicago, IL- Henna McCoy & Laurel Cherian MD

Memorial Hermann Texas Medical Center, Houston, TX- Ariana Aquino Hernandez & Anjail Sharrief MD, MPH

Coordinator of the Month

Maria Swiatek, MSN, RN, CCRN-E, SCRN, ASC-BC, NVRN-BC

Carolinas Medical Center Atrium Health, Charlotte, NC

The prime team would like to recognize Maria for being very active with enrollments and very responsive and dedicated. On a recent check in call, she described often staying until 7pm so she could teach the evening bedside nurse how to start the Nox T3. She also attends daily research rounds to identify potentially eligible patients. Your efforts and dedication are appreciated!

PI Dr. Rahul Karamchandani said: “Maria is outstanding! She is incredibly dedicated to her patients and consistently goes above and beyond for them and her studies. We appreciate how thorough she is and how she consistently follows up and follows through to keep all of us on track. We are incredibly proud to call her a member of our team!”

Congratulations Maria!

Highlighted Tool

KOEO/KOEO Interactive Tool (KIT)/Nox T3 Troubleshooting Guide #90 in WebDCU

This document reviews how to troubleshoot common issues in KOEO, KIT, and with Nox T3's. It is a useful tool if you are having trouble with the following:

- Login in or password difficulties
- T3 setup task
- Paring T3's and pulse oximeters
- Uploading T3 data files

1. If you receive the message "Device not configured" on the T3 - this usually means the appropriate Setup tasks were not completed in KOEO.

2. Please remember to complete the Repeat T3 setup task before conducting the repeat test -- this MUST be completed in order to conduct a second test.

3. If there is a T3 issue, please reach out to FusionHealth!

Message from FusionHealth

Because our current masks (the N30i, P10, and Evora full face) come with the various cushions, individual cushions for these items will no longer be available through our ordering form. If you find yourself in rare circumstances requiring cushions for the Evora, N30i, or P10, please reach out to us via email (sleepsmarttechsupport@noxhealth.com), providing your specific reasons for the request.

Data Entry and Data Clarification Request (DCR) Responses

- All CRF data must be submitted within 5 days of collection
- All responses to DCR's must be submitted within 5 days of query generation

Expired Essential Documents

It is your site's responsibility to keep essential documents current throughout the entire trial. If your site currently has documents in WebDCU that have expired, please log in and upload current documents. If a study team member has a lapse in training, you will need to upload a note to file (NTF) along with the new training certificate. The NTF should explain the lapse in training and note if it affected the conduct of the trial. Study team members should not be performing clinical trial activities if they have a lapse in training or have not yet completed training.

Nox T3, KOEO, aCPAP, & Mask Questions

A friendly reminder to direct all questions related to Nox T3, KOEO, aCPAP, and Face Masks to FusionHealth at sleepsmarttechsupport@noxhealth.com (preferred) or 1-404-480-5149 ext. 4006 8am to 7pm ET M-F.

Response times are fastest when the group email address is used - please avoid emailing individuals directly.

Next Webinar

Wellness Communication-Newest Presentation
by Dr. Jennifer Molano and her Team
Thursday, November 30, 2023 3-4pm EST

Outcome visits

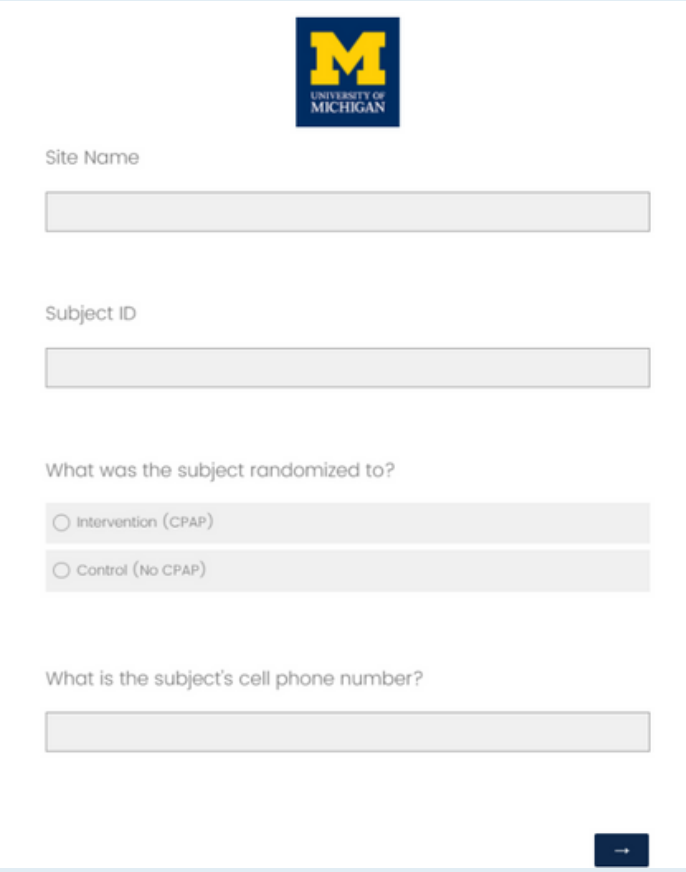
If a CPAP subject no longer wants to use CPAP, they can still participate in the 3 & 6 month visits if willing. If a control subject starts using CPAP, they can also participate in their follow up visits. This is not considered an automatic withdrawal of consent.

Outcome assessment completion time windows

	Primary outcome window	Last Day to complete outcome within visit window	Visit window where outcome can still be completed but considered as late	No more attempts should be made after
3 mos outcome	days 60-120	day 120	days 121-165	day 165
6 mos outcome	days 166-240	day 240	days 241-270	day 270

3-month outcomes should be pursued until the 6-mos window opens. However, only those obtained within window (day 60-120) will contribute to the primary outcome analysis. Similarly, 6-mos outcomes should be pursued until day 270, although only those collected between day 166-240 will contribute to the primary outcome. Please always do your best to obtain 3 and 6-month outcomes well within the "green" windows in the table just above.

Tess who?



Just a reminder that we are still using Tess for all randomized subjects. In order to make Tess more user friendly, we created a Qualtrics link, https://umich.qualtrics.com/jfe/form/SV_b73MvftChJgdfAa. Now instead of having a participant text Tess for the first time, the subject's information can be entered using this link. All that is needed is subject ID, randomization assignment, and cell number!

Reminder: Updated warnings and contraindications to N20 and F20 (magnet-containing masks)

Updated Contraindications

Masks with magnetic components are contraindicated for use by patients where they, or anyone in close physical contact while using the mask, have the following:

- Active medical implants that interact with magnets (i.e., pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, cerebrospinal fluid (CSF) shunts, insulin/infusion pumps)
- Metallic implants/objects containing ferromagnetic material (i.e., aneurysm clips/flow disruption devices, embolic coils, stents, valves, electrodes, implants to restore hearing or balance with implanted magnets, ocular implants, metallic splinters in the eye)

Updated Warning

Keep the mask magnets at a safe distance of at least 6 inches (150 mm) away from implants or medical devices that may be adversely affected by magnetic interference. This warning applies to you or anyone in close physical contact with your mask. The magnets are in the frame and lower headgear clips, with a magnetic field strength of up to 400mT. When worn, they connect to secure the mask but may inadvertently detach while asleep.

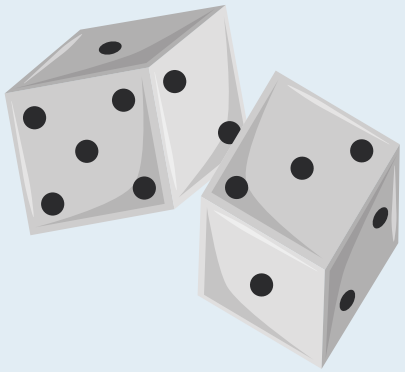
Implants/medical devices, including those listed within contraindications, may be adversely affected if they change function under external magnetic fields or contain ferromagnetic materials that attract/repel to magnetic fields (some metallic implants, e.g., contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, and bone substitute devices). Consult your physician and manufacturer of your implant / other medical device for information on the potential adverse effects of magnetic fields.

As initially communicated by Amanda via email on 11/28, ResMed has updated its contraindications and warnings related to its magnet-containing masks (see below). Relevant masks include the N20 and F20 – masks you may still have in your supply. The updates extend the previous guidance mostly by including contraindications for specific implants among patients and their bedpartners/caregivers irrespective of the distance from the magnets.

We will seek CIRB approval for an information sheet that can be provided to participants who qualify for and are given a magnet-containing mask. **In the meantime, please do not provide an N20 or F20 to any Sleep SMART participant.** Instead, please use one of the three magnet-free masks: the P10, N30i, or Fisher & Paykel Evora full face mask. Once the information sheet is CIRB-approved, we will let you know. At that time, you may resume use of the N20 and F20 for participants who qualify for their use.

My subject meets randomization criteria, but should they be randomized?

You must ask them! The patient has to be willing to accept a 50% chance of CPAP for 6 months and a 50% chance of no CPAP for 6 months. Participants/families with strong preferences should not be randomized.



Contact Information

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

Fusionhealth (Nox T3, KOEO, aCPAP, Masks):
sleepsmarttechsupport@noxhealth.com (preferred)
or 8am to 7pm ET M-F: 1- 404-480-5149 ext 4006

WebDCU emergency randomization hotline: 1-866-450-2016

Project Managers: Amanda Rasnake arasnake@med.umich.edu | Joelle Sickler sicklejb@ucmail.uc.edu

WebDCU help: Faria Khattak khattak@musc.edu | Emily Kaestner kaestner@musc.edu

Regulatory help: Jordyn Schultz schuljd@ucmail.uc.edu

All previous webinars and newsletters can be found on https://www.nihstrokenet.org/trials/sleep-smart-trial/webinars. Password is Sleepy