

Summary of Sleep SMART Enrollment, Randomization, and Study Procedures (Version 8/8/24)

During acute or rehab hospitalization

- Screen records for consent eligibility (email sleepsmart@umich.edu for urgent eligibility questions)
- Confirm that NIHSS ≥ 1 prior to consent. Use medical record to identify most recent NIHSS and/or confirm with clinical team.
- If an eligible patient declines consent, please enter him/her into the screen failure report
- Use script to introduce study, show recruitment video, have consent conversation
- Obtain consent (use IC Process Checklist), document all contact info for subject and alternative; obtain local medical record release for next 6 months
- Register subject in WebDCU (<https://webdcu.musc.edu/>) by [Add Subject] button on the home screen.
- Obtain all baseline information from chart, interview, and interview of a close proxy (IQCODE)
- Confirm that baseline post-consent NIHSS ≥ 1 and document on baseline CRF.
- Enter Medicare Beneficiary ID in non-WebDCU form (Qualtrics) (format: 1EG4TE5MK73)

Night 1 (ideally the night or next major sleep period just following consent) (\$25 to subject for baseline info + Nox T3 testing):

- Replace batteries in Nox T3 unit and oximeter
- Set up Nox T3 in KOEO system (app.noxhealth.com in chrome): First Name: "Sleep SMART"; Last Name: [Subject ID]; DOB: "1/1/1900"; Identification: [Subject ID]
- Check Troubleshooting Guide and FH MOPs for technical issues. If cannot find, then email sleepsmarttechsupport@noxhealth.com with technical questions (KOEO, Nox T3). On weekends and after 7PM on weekdays, please use email only. Alternative: Fusion at 1-404-480-5149 extension 4006 during business hours.
- May hang Nox T3 / CPAP information sheet in subject room
- Use script. Apply overnight sleep apnea test (Nox T3). Start recording if possible just prior to anticipated sleep.
- Next morning: download Nox T3 study data into KOEO (app.noxhealth.com in chrome)
- That day: Will receive email after T3 has been processed (processing times: 10am/2pm eastern)
- Check in KOEO for eligibility to continue based on Nox T3 results
- ONLY IF NOT eligible for Run-In Night, provide Nox T3 test report to subject and clinical team, let them know participation in Sleep SMART is complete, and enter information in WebDCU.
- Use script to discuss results

If eligible for aCPAP Run-In Night (\$25 to subject for run-in night):

- On an S10 run-in night device, in Sleep Report, reset the time "period" from 1 month to 1 day. Not necessary for S11.
- Assure that new tubing, and humidifier basin are used, and that the air outlet is cleaned
- Preferably during the day, ask participant to select preferred mask type (showing masks in their packages). If participant has no preference, select the nasal mask. Identify the correct size (use templates for nasal and full face masks). **Use guidance re gentle mask intro including stepwise mask procedures and diaphragmatic breathing.**
- **Have subject use aCPAP for 15-20 minutes during this daytime session**
- Check mask fit: With subject lying down, adjust the headgear and check mask fit using the CPAP mask fit function. Make further adjustments as necessary. Indicate mask preferences in KOEO
- **During the day, have subject practice applying/removing mask many times**
- Place all masks tried at bedside (ideally just one mask).
- Apply aCPAP treatment overnight
- RT to assess subject overnight to assist with any challenges that might arise
- In AM, inquire about experience with aCPAP and whether subject would be willing to continue

- if eligible; use script
- Check device readout for randomization eligibility. If usage hours ≥ 4.0 hours and CAI from aCPAP < 10 / hour, and subject is willing to accept 6 mos of CPAP or 6 mos without CPAP, then he/she is eligible for randomization. Confirm that CPAP is set for “1 day” rather than “1 month” in Sleep Report period, if using S10 run-in night device.
- Enter aCPAP data in WebDCU
- Log into KOEO to indicate randomization eligibility
- Use script to discuss randomization assignment
- aCPAP filters do not need to be replaced every Run-In Night, but should be replaced monthly

If eligible for randomization:

- Randomize subject in WebDCU
- Update status in KOEO: provide treatment assignment
- Let subject know result of randomization and what to expect – use script
- Ask if ok to set the subject up with the chatbot service. If yes, provide necessary information in Qualtrics. Alternatively, provide appropriate chatbot info sheet (for intervention or control); write subject ID on sheet; help subject text Tess the chatbot for the first time (will need subject ID).
- Provide stroke symptom recognition handout to subject
- Schedule 3-month assessment and place info into discharge paperwork (and into WebDCU, F123)
- At or after discharge, site PI or clinical team provides secondary prevention recommendations to PCP

If NOT eligible for randomization:

- Let FusionHealth know (<https://tinyurl.com/sleepsmartordering>) what equipment needs to be replaced. We suggest sites have ≥ 4 of everything. If any of your supplies are depleted to 3, then send FusionHealth a supplies request. Note, you will not need to order replacements after every unsuccessful Run-In Night.
- In WebDCU, complete F506 and then move the subject to End of Study and complete F126. Answers entered for Q04-Q08 should represent actual numbers and not placeholders for values not obtained. If you are unable to answer a question, then leave it blank and respond to the rule explaining why that value is not available.

Intervention arm (aCPAP):

- If assigned to intervention arm, log into KOEO and enter data to enroll in sleep coaching (FusionHealth care management program): update patient info (enter PHI), **include all patient and alternative contact info as found toward back of consent**, document equipment provided to subject
- Provide new aCPAP box and include the items from the run-in night: tubing, humidifier basin, masks
- Provide education to subject and caregiver about aCPAP
- Play care management video for subject/caregiver/family
- Instruct subject to apply aCPAP nightly during hospitalization, and any time that the subject intends to sleep or nap, with assistance if needed from nurse or RT
- Let nursing know that subject needs to use CPAP; hang CPAP reminder sign in room
- Have RT assist with nightly use (utilize personal motivational coaching techniques and small step positive reinforcement – e.g. incremental increases in use time, AHI control, leak management using aCPAP display functions)
- Assist subjects if willing to put Sleep SMART sleep coach number (470-655-6688) in their cell phone
- Help subject make initial call to sleep coach (470-655-6688) prior to discharge
- Offer to help subject register for myAir for self-monitoring (myair.resmed.com)
- Discharge subject with all of his/her aCPAP equipment; show subject the contents of the CPAP bag

including the handouts and magnet that are included

- Provide aCPAP and mask instructions (included in their boxes, carrying case, etc.) to subject
- Remind subject to use aCPAP every time subject sleeps; to take aCPAP on trips and any future hospitalizations; to plan for follow-up visits at 3 months and 6 months
- **Remind subjects that their sleep coach will be in contact with them**
- **Remind subjects that they will receive a \$10 Amazon gift card if they complete a call with their sleep coach within 7 days of discharge and provide the team with an email address**
- **Provide CPAP order if intervention subject discharged to site other than home**
- **Before discharge, offer to put appointments on calendars for 3-month and 6-month outcome visits**
- **At time of hospital discharge, document hospital discharge with date in KOEO**
- **When subject is discharged from hospital, please call (FusionHealth) Sleep SMART Care Team at 470-655-6688 to let them know**

Outcome assessments (timed from randomization) (\$75 to subject for each outcome assessment) – all assessments to be blinded (not just mRS-9Q)

- 3-month (-30 days/+30 days from randomization) entire assessment by blinded study team member (includes walk test)
- 6-month (-14 days/+60 days from randomization) entire assessment by blinded study team member (includes CPAP questionnaire – save for end of visit)
 - Options: return for in-person assessment; study team go to home; telephone if in-person not possible (video assessments not included in protocol)
 - If difficulty reaching: check consent for alternative means to reach subject or alternative contact. **Use outcome attempt checklist.** Unable to reach letter template, final lost-to-follow letter on website (www.nihstrokenet.org/sleep-smart-trial/research-team)
 - Provide sleep apnea test (Nox T3) results to subject and clinical team (AFTER subject completes all 6-month assessments, or immediately after any necessary early termination of participation in Sleep SMART)
 - If desired by subject, help arrange local Sleep Medicine follow-up to start after termination of participation in Sleep SMART
 - If assigned to aCPAP arm, subject keeps device and supplies
 - Please refer to the Sleep SMART Data Collection Guidelines (DCG) located in [Project Documents] for more information on how to complete the case report forms.

Outcome window summary:

	Last Day to complete		Visit window where outcome can still be completed but considered as late	No more attempts should be made after
	Primary outcome window	outcome within visit window		
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

Outcome windows are calculated from date of randomization.