

# Sleep SMART: Sleep for Stroke Management And Recovery Trial

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# Design

- Phase 3, multicenter
- Prospective randomized open-, blinded-endpoint (PROBE)
- Controlled: aPAP vs usual care
- Secondary prevention with embedded recovery trial
- Ischemic strokes, high risk TIAs ( $ABCD^2 \geq 4$ )
- Randomize ~3,000 participants



# Aims

- Determine whether treatment of OSA with positive airway pressure starting shortly after acute ischemic stroke or high risk TIA:
  - (1) reduces recurrent stroke, acute coronary syndrome, and all-cause mortality 6 months after the event
  - (2) improves stroke outcomes at 3 months (among those with ischemic stroke)



# Inclusion

- Age  $\geq 18$
- TIA with ABCD<sup>2</sup>  $\geq 4$  or ischemic stroke



# Exclusion

- pre-event inability to perform all of own basic ADLs
- unable to obtain informed consent of subject or representative
- incarcerated
- known pregnancy
- current mechanical ventilation or tracheostomy
- current or recent use of positive airway pressure
- anatomical or dermatologic barrier to CPAP use
- severe bullous lung disease

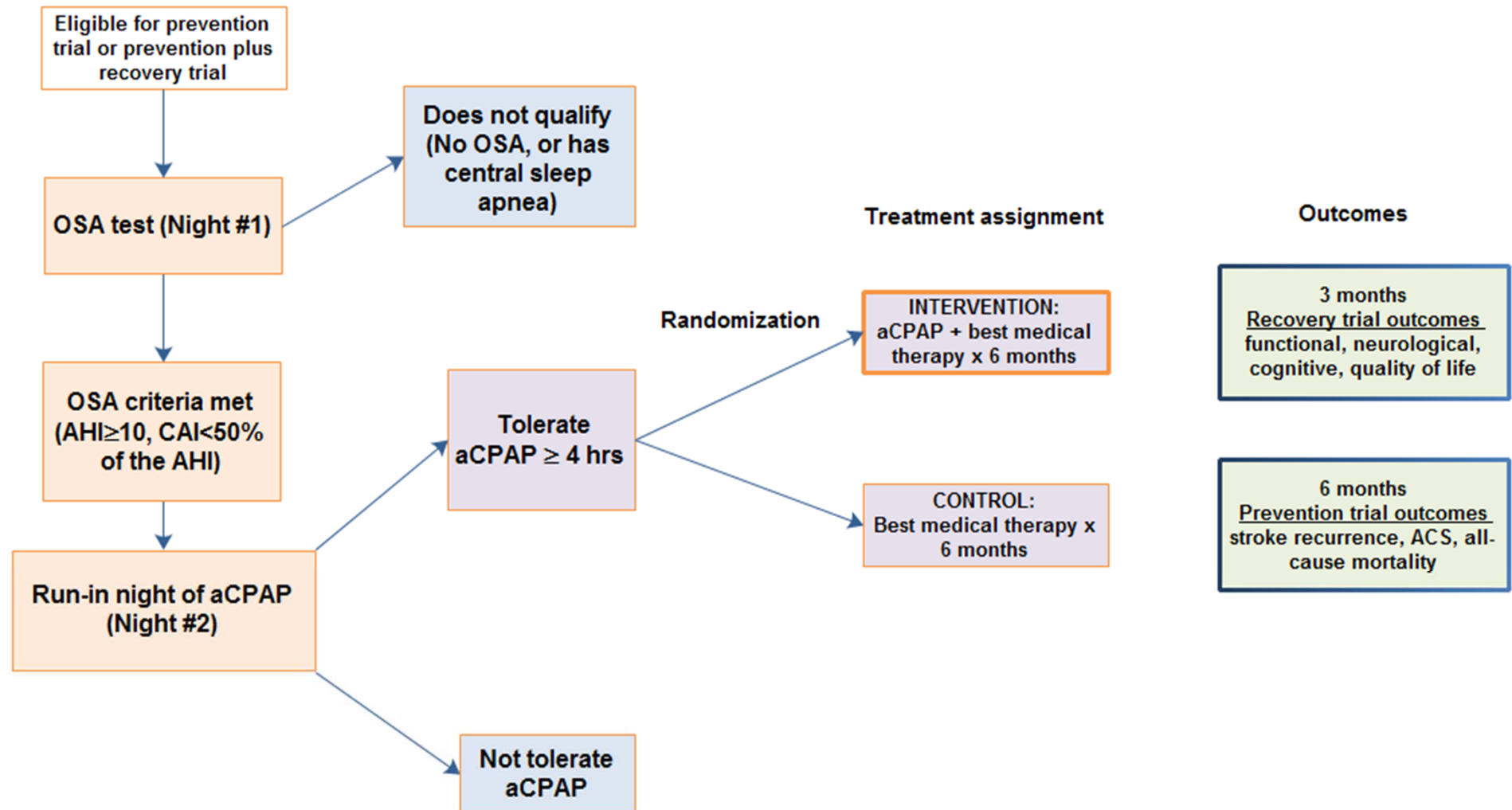


# Exclusion, cont

- history of spontaneous pneumothorax
- hypotension requiring pressors
- patient-specific medical risk of harm from CPAP
- history of massive epistaxis
- cranial surgery or head trauma in past 6 months, with possible CSF leak or pneumocephalus
- recent hemicraniectomy or suboccipital craniectomy



# Schema



# Assessments

	Baseline with reference to pre- stroke period	Baseline	3 months	6 months
Demographics		X		
Stroke risk factors		X		
Medical history (height, weight, etc)		X		
Informant-based prestroke cognitive status (IQCODE)	X			
Pre-stroke modified Rankin Scale (mRS)	X			
Pre-stroke depression (Patient Health Questionnaire-2 (PHQ-2))	X			
Post-stroke depression (Patient Health Questionnaire-2 (PHQ-2))			X	X
Blood pressure		X	X	X
Epworth Sleepiness Scale	X		X	X
SF-12 and sleep specific QOL measure (FOSQ-10)			X	X
General Morisky Medication Adherence			X	X
Functional outcome (mRS)			X	X
Neurological outcome (NIHSS)		X	X	X
Cognitive outcome (mini MoCA)			X	X
Quality of life outcome (short SSQOL)			X	X
Assessment for recurrent stroke, ACS, death			X	X





# Nox T3



# aCPAP



# Telemedicine

- Partnering with a sleep health company
- Leverage technology to provide state-of-the-art telemedicine care to our subjects
- aCPAP remotely monitored
- Care manager
  - technology team
  - respiratory therapy team
  - sleep medicine physicians

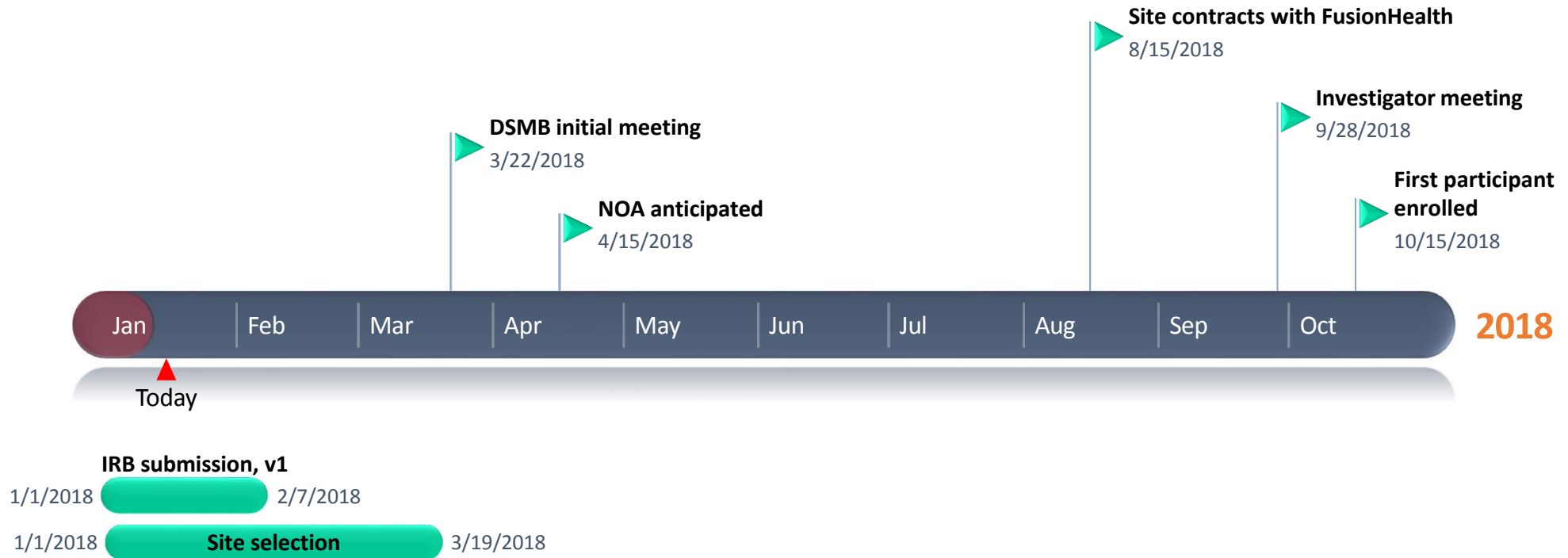


# Site selection

- N=110
- Exclusions for obvious problems:
  - No 24 hr RT coverage
  - Poor coordinator coverage
  - Lack of enthusiasm for the trial



# Preliminary timeline



# **THANK YOU:**

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