

STAR 36Month Media Kit

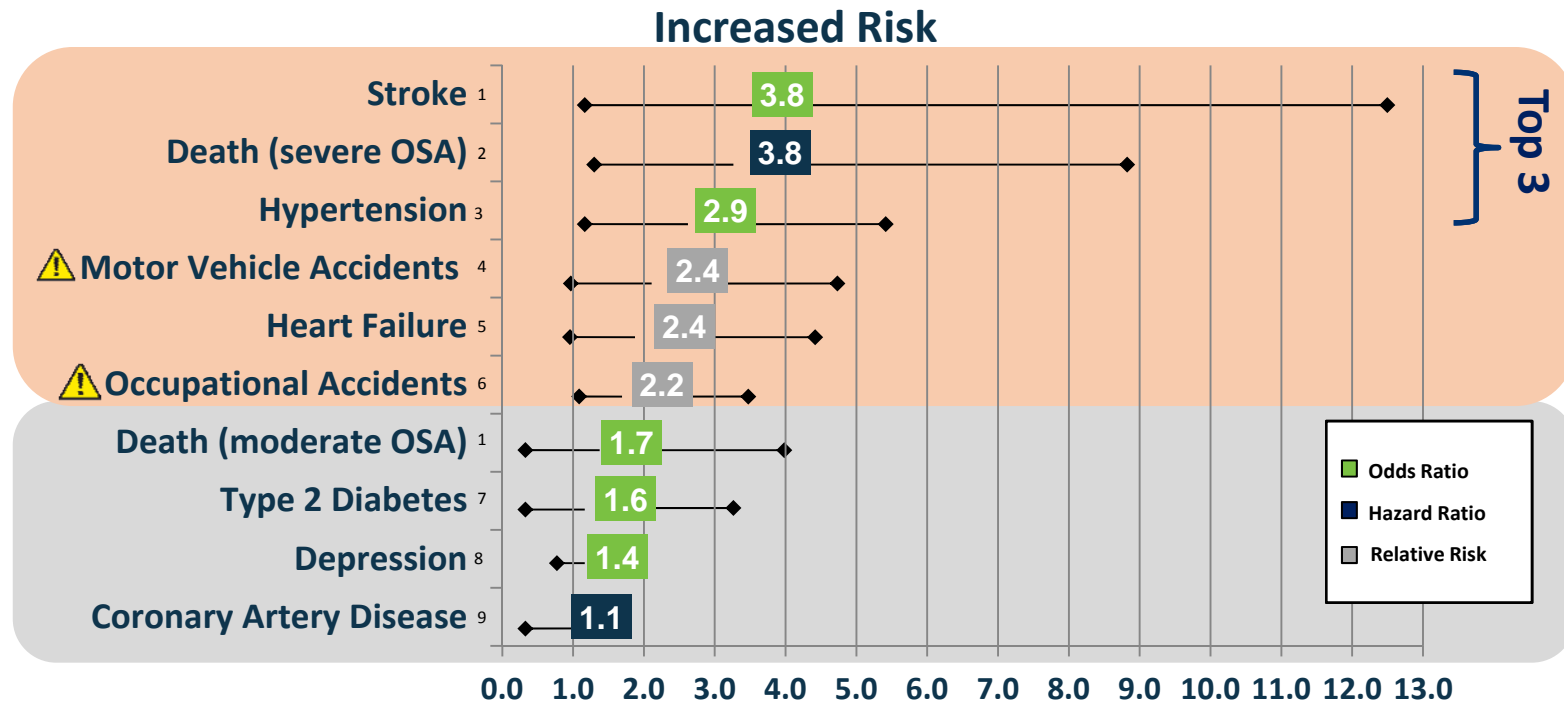
November 2015



Talking Points

- Obstructive sleep apnea (OSA) affects more than 18 million Americans
- It is important for people to find an effective treatment for their OSA
 - Untreated (OSA) can have devastating effects on heart and brain health, impair quality of life and increase accident risk
- CPAP is an effective first line therapy for OSA. However, studies show that less than 50% of patients that try CPAP use it. This leaves a substantial number OSA patients untreated and vulnerable
- Unlike CPAP which requires wearing a mask, Inspire therapy works inside the body and with a patient's natural breathing process. It is a small implant that delivers mild stimulation to key airway muscles to keep airway open during sleep
- Results from the landmark STAR Clinical Trial, which evaluated the safety and efficacy of Inspire therapy, were published in the January 2014 issue of the *New England Journal of Medicine*.

Untreated OSA Increases Risk for Comorbidities and Accidents



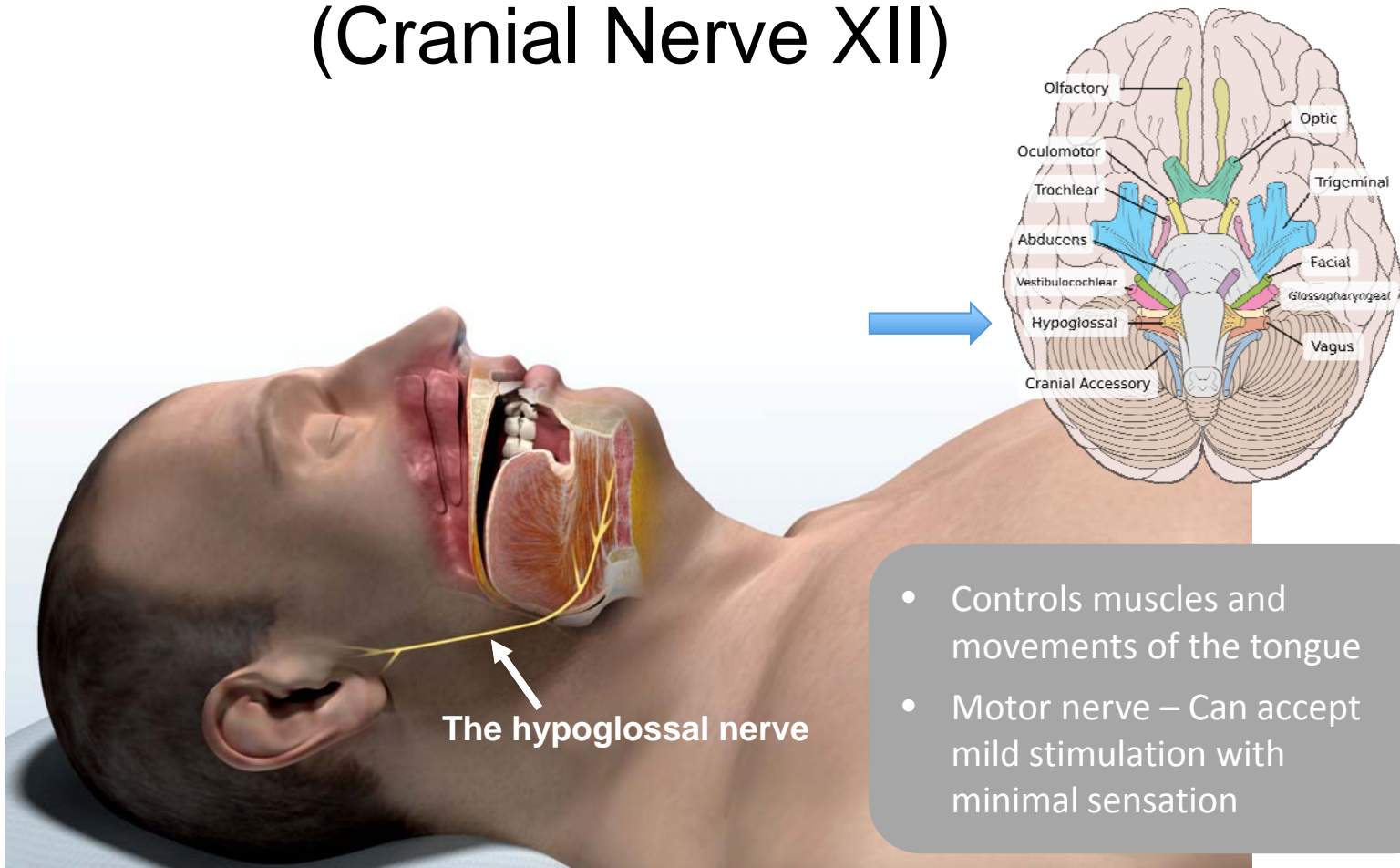
1. Artz et al, Am J Respir Crit Care Med 2005
2. Young et al, Sleep 2008
3. Peppard et al, N Engl J Med 2000
4. Tregear et al, J Clin Sleep 2009
5. Shahar et al, Am J Respir Crit Care Med 2001
6. Lindberg et al, Am J Respir Crit Care Med 2001
7. Reichmuth et al. Am J Respir Crit Care Med 2005;
8. Smith et al, CHEST 2002
9. Gottlieb et al, S Circulation. 2010

- Untreated OSA can have devastating effects on heart and brain health, impair quality of life, and increase motor vehicle and occupational accident risk

Talking Points

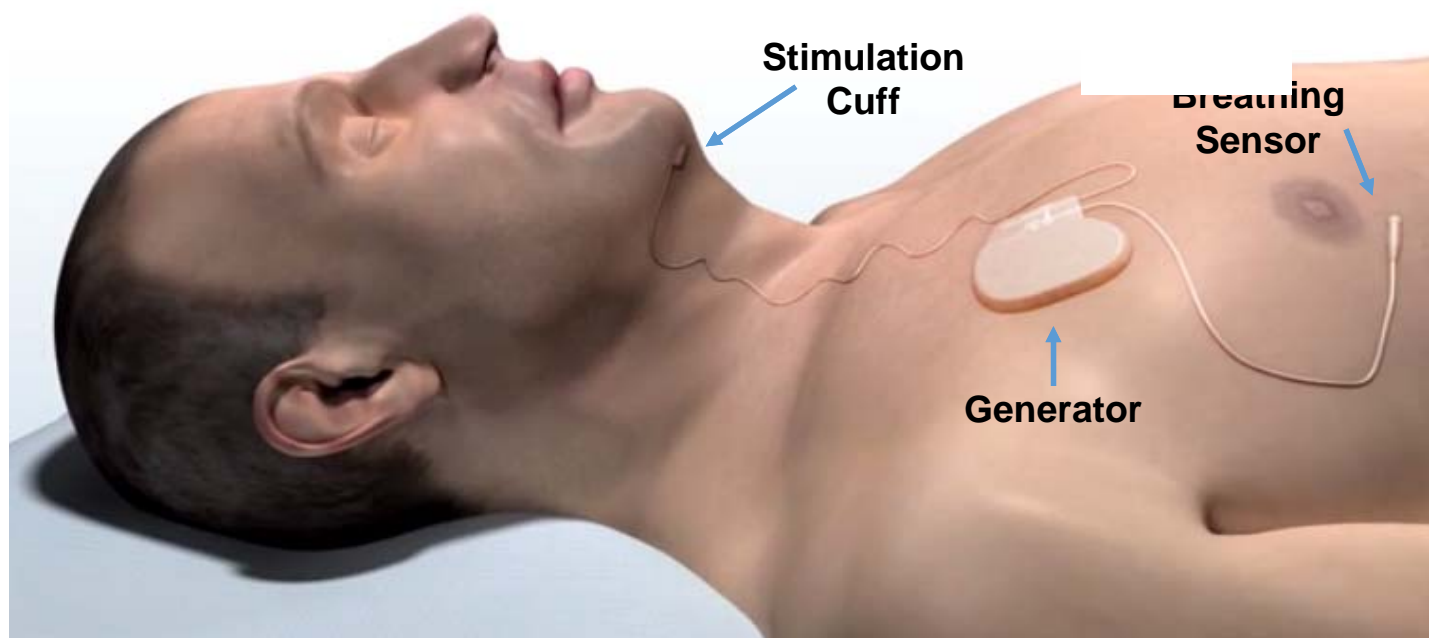
- New three year outcomes data from the Landmark STAR Clinical Trial was published in *Otolaryngology – Head and Neck Surgery*, the official peer-reviewed publication of the American Academy of Otolaryngology – Head and Neck Surgery Foundation.
- The peer-reviewed publication website is <http://oto.sagepub.com/>
- The new long-term study outcomes showed that the significant improvements observed at one-year were sustained at the three-year follow up mark. The outcomes include:
 - A 78 percent reduction in apnea-hypopnea index (AHI) from baseline
 - An 80 percent reduction in oxygen desaturation events from baseline
 - 80 percent of bed partners reported soft or no snoring as compared to 17 percent of bed partners at baseline
 - Quality of life measures, including daytime sleepiness and functioning, showed clinically meaningful improvements and a return to normal levels over baseline
- Inspire therapy was FDA approved in May 2014 and is available in over 50 leading medical centers in the United States and in 8 European countries

The Hypoglossal Nerve (Cranial Nerve XII)



- Controls muscles and movements of the tongue
- Motor nerve – Can accept mild stimulation with minimal sensation

The Inspire Upper Airway Stimulation System



- Fully implanted system
 - Uses well established technologies and surgical techniques
 - Typically performed on an outpatient basis
- Breathing sensor monitors a patient's breathing cycle
- Rhythmic, mild stimulation delivered to the hypoglossal nerve on each breath
- Mild stimulation delivered during the inspiration portion of the breathing cycle which is when the airway is most vulnerable to collapse

Hypoglossal Nerve Stimulation Effect

No Stimulation



Obstructed Airway

Base of Tongue



Palate



Tongue and palate collapse, obstructing airway during sleep

Mild Stimulation



Open Airway

Base of Tongue



Palate



Mild stimulation nudges the base of tongue forward, preventing the airway from collapsing during sleep

The Inspire Therapy Patient Experience

- Patients describe feeling a tingling sensation or mild muscle contraction
- Inspire therapy is adjustable for patient comfort. Patients can:
 - Start therapy
 - Pause therapy
 - Stop therapy
 - Increase or decrease energy
- In the STAR Trial:
 - 86% of patients reported using Inspire therapy every night
 - 93% of patients reported using Inspire therapy five or more night per week



Click here to hear from Inspire therapy Patients
<https://www.inspiresleep.com/inspired-lives/>

Physicians to Interview

Contact Information Available Upon Request

- B. Tucker Woodson, MD
 - Medical College of Wisconsin
- Ryan J. Soose, MD
 - Univ. of Pittsburgh Medical Center
- M. Boyd Gillespie, MD
 - Medical University of South Carolina
- Kingman P. Strohl, MD
 - UH Case Medical Center
- Meir Kryger, MD
 - Yale University School of Medicine
- Maurits Boon, MD
 - Thomas Jefferson University Hospital
- Brian Weeks, MD
 - Senta Clinic



Inspire Therapy Patients to Interview

Contact Information Available Upon Request

- Christine W.
 - Cleveland, Ohio
- Dan M.
 - Milwaukee, Wisconsin
- Al P.
 - Columbia, South Carolina

For more information on Inspire therapy
<https://www.inspiresleep.com>



Appendix: 36 Month Clinical Data



Inspire Therapy Clinical Evidence Development

12 Peer-Reviewed Publications as of November 2015

INSPIRE 1, 2, 3 FEASIBILITY STUDIES	STAR PHASE III TRIAL WITH RANDOMIZED CONTROLLED WITHDRAWAL STUDY	ONGOING STUDIES
First in Man Patient Selection Implant Technique Safety/Efficacy 4 Peer-Reviewed Publications	Safety/Efficacy FDA Approval Long-Term Follow-Up Cost Effectiveness 8 Peer-Reviewed Publications	European Post-Approval Study US Post-Approval Study Single Center Experience Projects European Randomized Controlled Study

Peer Reviewed Publications — STAR Trial Outcomes

STAR 1 YEAR: Strollo et. al. *The New England Journal of Medicine*. January 2014

STAR RANDOMIZED STUDY: Woodson et. al. *Otolaryngology Head and Neck Surgery*. September 2014

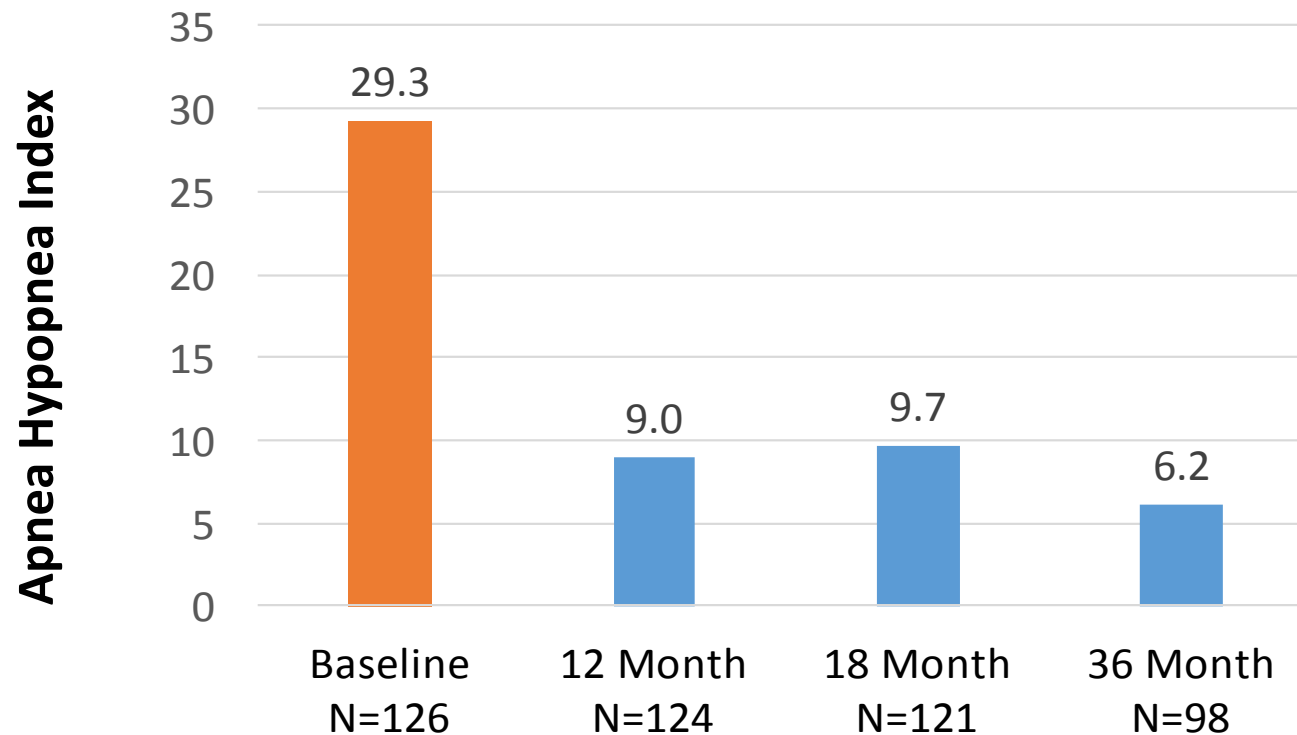
STAR 18 MONTHS: Strollo et. al. *SLEEP*. June 2015

STAR 2 YEAR: Soose et. al. *Journal of Clinical Medicine*. July 2015

STAR 3 YEAR: Woodson et. al. *Otolaryngology Head and Neck Surgery*. November 2015

Inspire Therapy

Long-Term Objective Outcomes: AHI

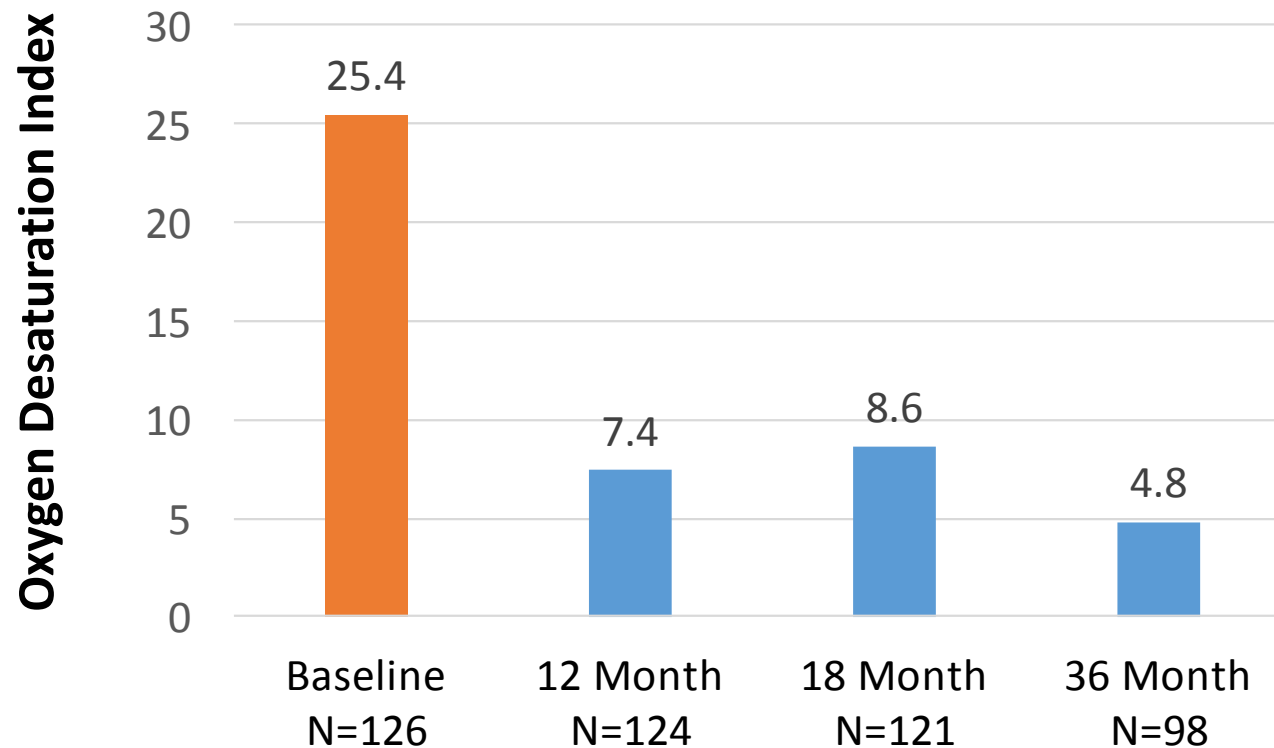


12 Month Data: Strollo et al *NEJM* 2014
18 Month Data: Strollo et al *SLEEP* 2015
36 Month Data: Woodson et al *OTO-HNS* 2015

Results in median, $p < 0.01$

Inspire Therapy

Long-Term Objectives Outcomes: ODI

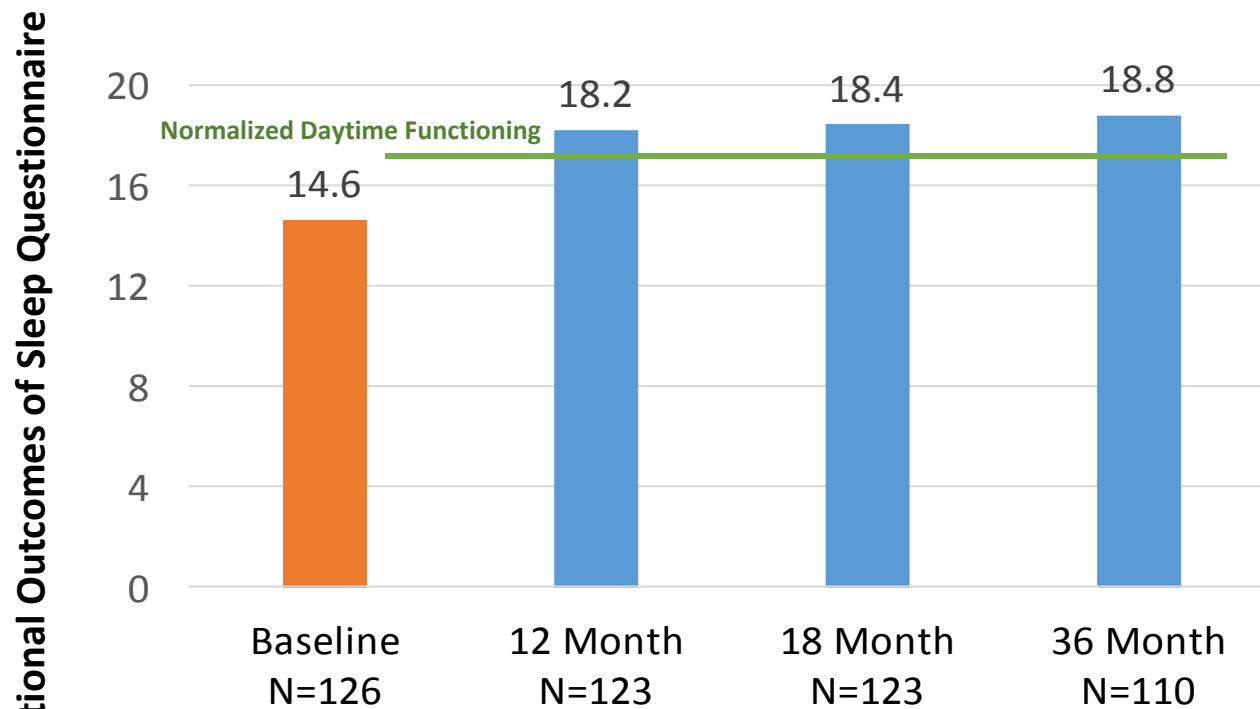


12 Month Data: Strollo et al *NEJM* 2014
18 Month Data: Strollo et al *SLEEP* 2015
36 Month Data: Woodson et al *OTO-HNS* 2015

Results in median, $p < 0.01$

Inspire Therapy

Long-Term Subjective Outcomes: FOSQ*



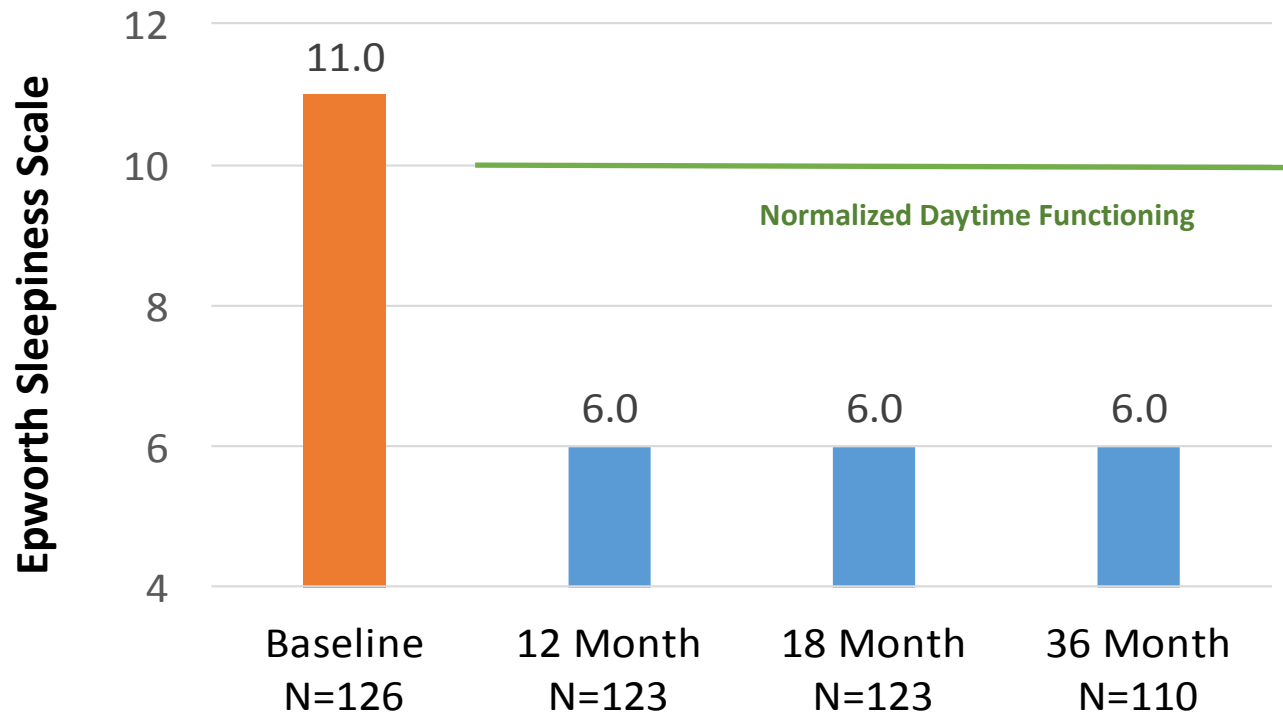
*All 5 FOSQ subscale variables showed clinically significant improvements. FOSQ subscale variables include (1) activity, (2) productivity, (3) social, (4) intimacy, and (5) vigilance.

12 Month Data: Strollo et al *NEJM* 2014
18 Month Data: Strollo et al *SLEEP* 2015
36 Month Data: Woodson et al *OTO-HNS* 2015
FOSQ: Soose et al *JCSM* 2015

Results in median, $p < 0.01$

Inspire Therapy

Long-term Subjective Outcomes: ESS

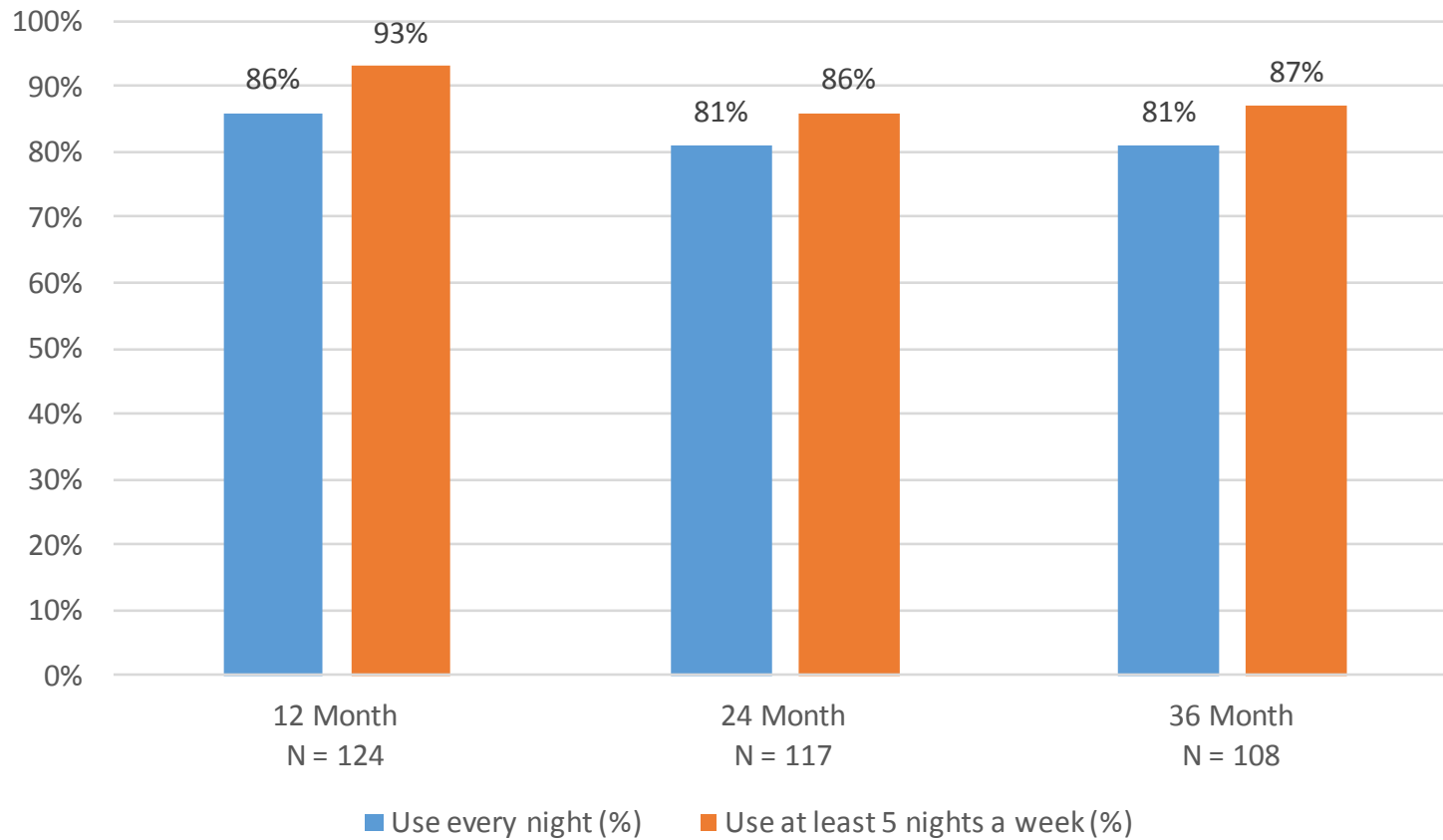


12 Month Data: Strollo et al *NEJM* 2014
18 Month Data: Strollo et al *SLEEP* 2015
36 Month Data: Woodson et al *OTO-HNS* 2015

Results in median, $p < 0.01$

Inspire Therapy Adherence

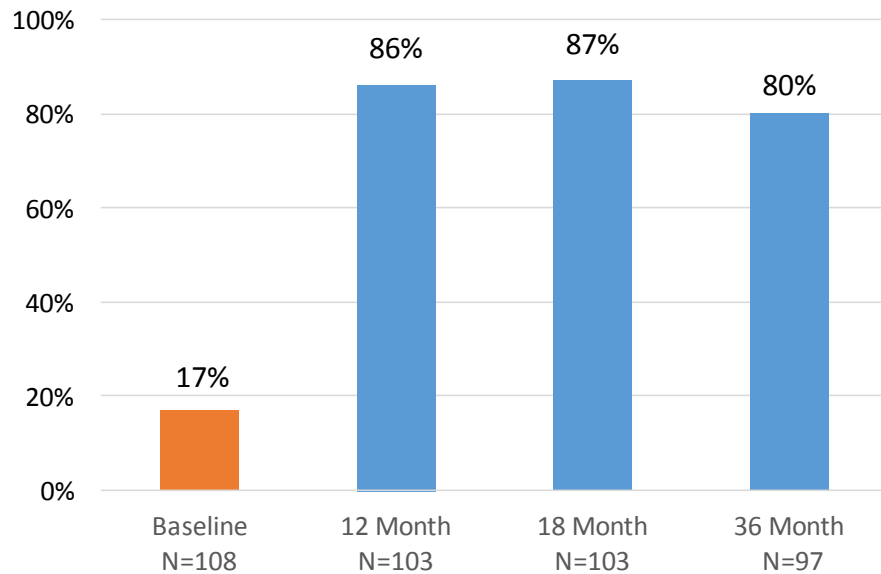
Patient Self-Reported



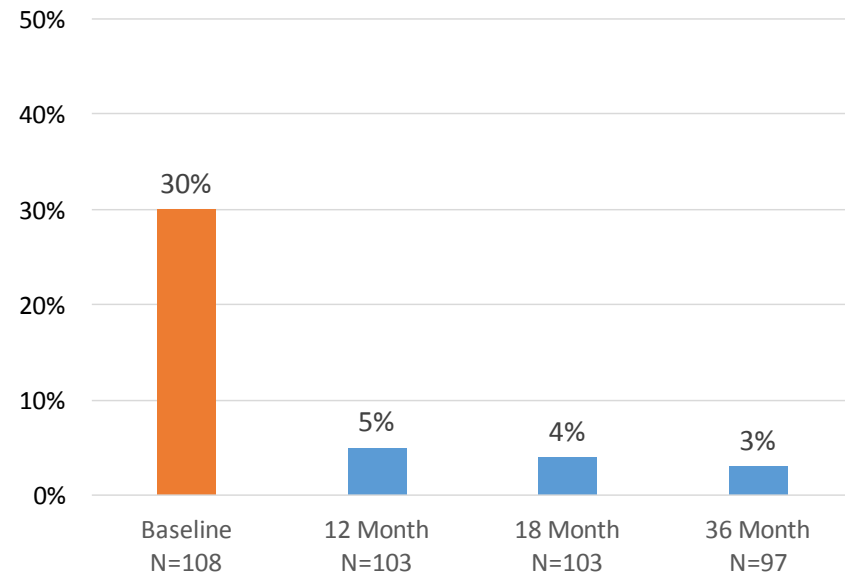
From STAR database

Partner Reported Snoring

No or Soft Snoring



Bed Partner Leaves Room



12 Month Data: Strollo et al NEJM 2014
18 Month Data: Strollo et al SLEEP 2015
36 Month Data: Woodson et al *OTO-HNS* 2015

