



Detect and Defeat: Improving Awareness of the Differences in Narcolepsy and Novel Strategies for Treatment

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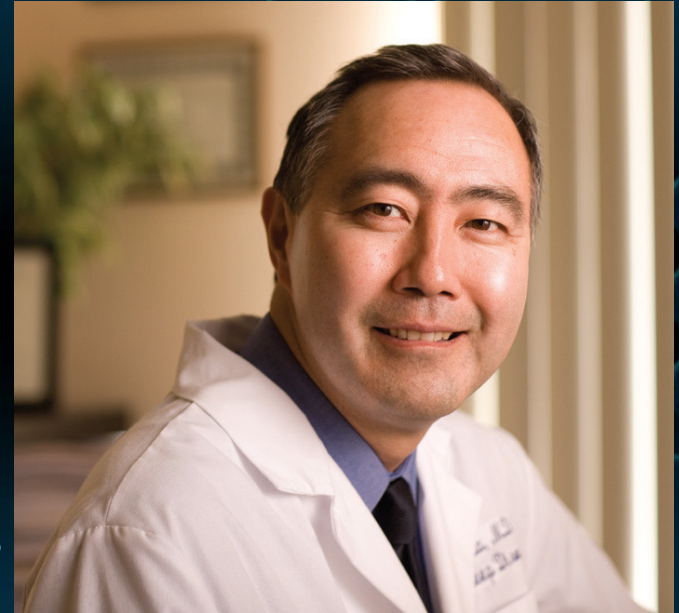




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Learning Objective **1**

Recognize the varied presentations of narcolepsy to facilitate a prompt and accurate narcolepsy diagnosis.



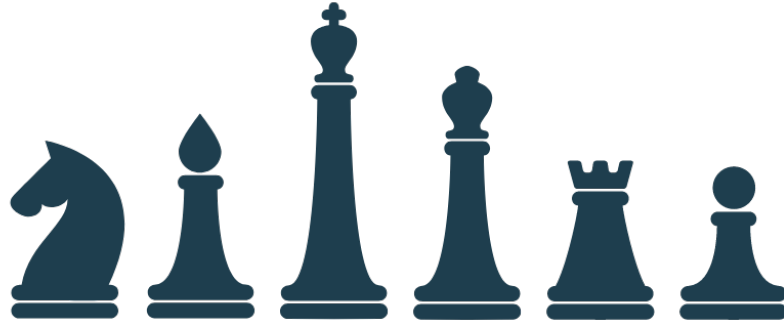
What is Narcolepsy?

- Narcolepsy is a rare, often debilitating disorder



- Prominent symptoms include:
 - Sleep–wake dysregulation
 - Disturbed nocturnal sleep
 - Cognitive, psychiatric, motor, metabolic and autonomic, and metabolic disturbances

Narcolepsy: The Five Main Symptoms



C

H

E

S

S

Cataplexy

Hallucinations

**Excessive
Daytime
Sleepiness**

Sleep Paralysis

Sleep Disruption

Audience Response

How confident are you in your ability to accurately diagnose narcolepsy?

- A. Extremely confident
- B. Confident
- C. Somewhat confident
- D. Not at all confident

The Diagnostic Challenge of Narcolepsy

- Comorbidity with other sleep disorders is common:
 - ~25% of patients with narcolepsy also have obstructive sleep apnea (OSA)
- Misdiagnosis and delayed diagnosis is all too common:

... 82% of patients with narcolepsy receive a diagnosis ≥ 1 year from symptom onset;
one-third > 10 years!

The Two Variants of Narcolepsy: ICSD-3 Criteria

Narcolepsy Type 1 (NT1) (Narcolepsy with Cataplexy)

A and B must be met.

- A. EDS for at least 3 months
 - Use validated questionnaires such as ESS
- B. At least one of the following:
 - Cataplexy and a positive MSLT*
 - Low mean sleep latency < 8 mins
 - ≥ 2 SOREMPs on MSLT-PSG
 - Low CSF hypocretin-1 concentrations ($\leq 110\text{pg/ml}$ or $< 1/3$ of normal)

Narcolepsy Type 2 (NT2) (Narcolepsy without Cataplexy)

A and B must be met.

- A. EDS for at least 3 months
- B. Positive MSLT*
 - Low mean sleep latency < 8 mins
 - ≥ 2 SOREMPs on MSLT-PSG
- C. Cataplexy is absent
- D. CSF hypocretin-1 concentrations $> 110\text{pg/ml}$ if measured
- A. Hypersomnolence and MSLT findings not better explained by other causes:
 - Insufficient sleep, OSAS, delayed sleep phase, drug intake/withdrawal

*Positive MSLT: mean sleep latency of < 8 minutes and ≥ 2 SOREMPs

CSF = cerebrospinal fluid; EDS = excessive daytime sleepiness; ESS = Epworth Sleepiness Scale; MSLT = Multiple Sleep Latency Test; OSAS = obstructive sleep apnea syndrome; PSG = polysomnogram; SOREMPs = sleep onset REM periods

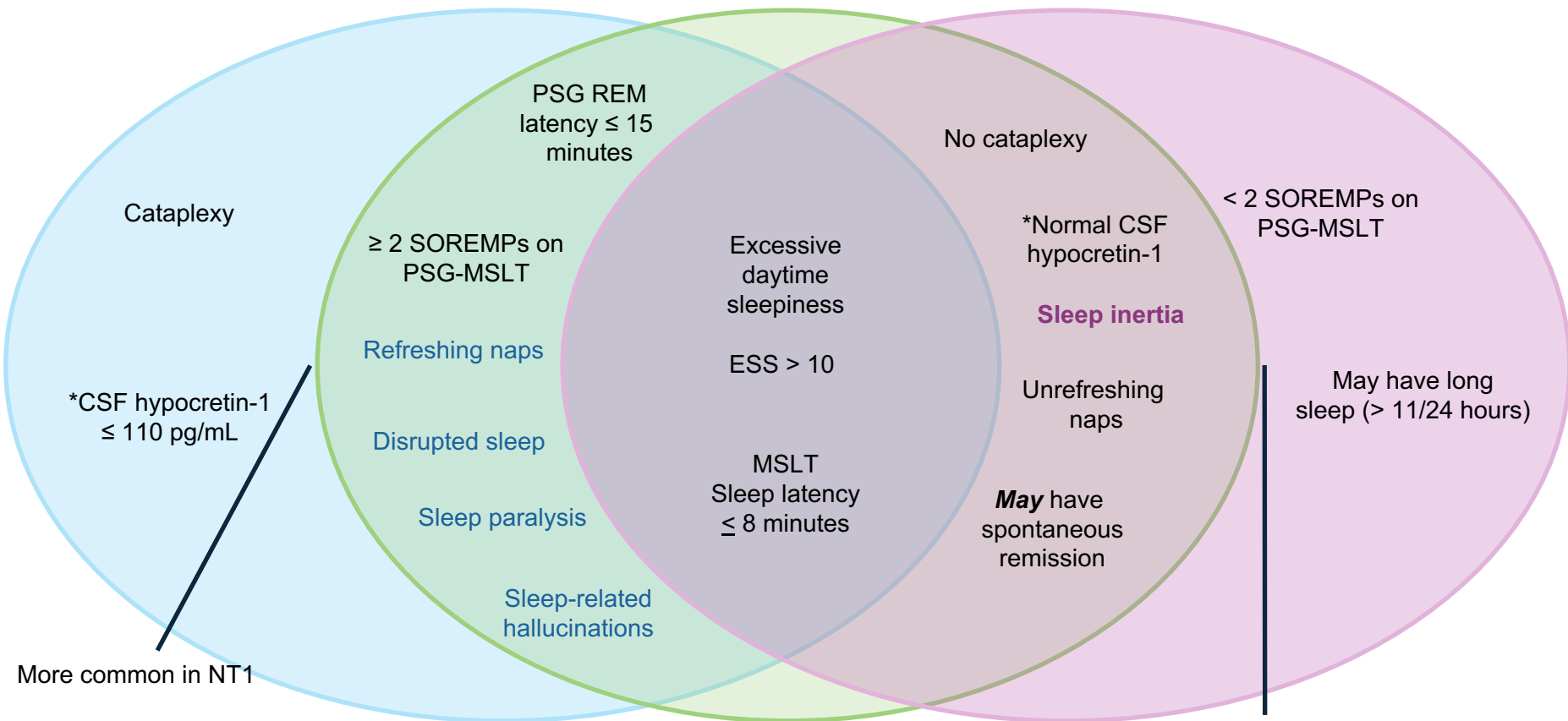
Sateia MJ. *Chest*. 2014;146(5):1387-1394.

Differentiating Narcolepsy Type 1 and Type 2 from IH

NT1

NT2

IH



IH = idiopathic hypersomnia; REM = rapid eye movement

*CSF hypocretin-1 is also known as orexin-A

Differential Diagnosis

- EDS
 - OSAS
 - Sleep deprivation/poor sleep hygiene
 - Depression
 - Substance/drug intake
 - Idiopathic hypersomnia
 - Kleine-Levin syndrome
 - Poor sleep hygiene
 - Periodic Limb Movement Disorder
 - Circadian rhythm abnormality
 - Behavioral symptoms of EDS (irritability, poor attentiveness, aggression, hallucinations)
- Cataplexy
 - Typical cataplexy
 - To be videoed if possible
 - Seizure, hypotension, psychogenic
- Hallucinations
 - Schizophrenia
 - Night terrors
 - Panic attacks

Diagnosing Narcolepsy

- Careful clinical history
- Sleep diary
- +/- Actigraphy
- Overnight sleep study/daytime MSLT
- Maintenance of Wakefulness Test (MWT)
- CSF hypocretin-1 levels



Self-Report Measures Can Be Used in Clinical Practice

Epworth Sleepiness Scale (ESS)

- The ESS is the most frequently used, validated self-report assessment of a patient's sleepiness¹
- On a 4-point scale, patients rate their likelihood of falling asleep during 8 different situations (reading, driving, etc.)²
- The ESS can also be used to monitor the progression of or improvement in sleepiness over time³

Swiss Narcolepsy Scale (SNS)

- The SNS is a validated self-report assessment of a patient's sleepiness
- On a 5 item, 5-point scale, patients rate the frequency of individual symptoms (EDS and cataplexy)
- The SNS has a high sensitivity and specificity in identifying NT1⁴ (particularly compared to ESS)
- Each answer is weighted by a positive or negative factor; score of < 0 is suggestive of narcolepsy with cataplexy
- A two-item short form version (sSNS) also available demonstrating discriminative power for NT1⁵



Subjective measures rely on patients to accurately report their own sleepiness; however, they are⁴:

- Practical for monitoring progression or improvement in EDS
- Simple to administer

1. Miglis MG, Kushida CA. *Sleep Med Clin.* 2014;9(4):491-498. 2. Johns MW. *Sleep.* 1991;14(6):540-545.

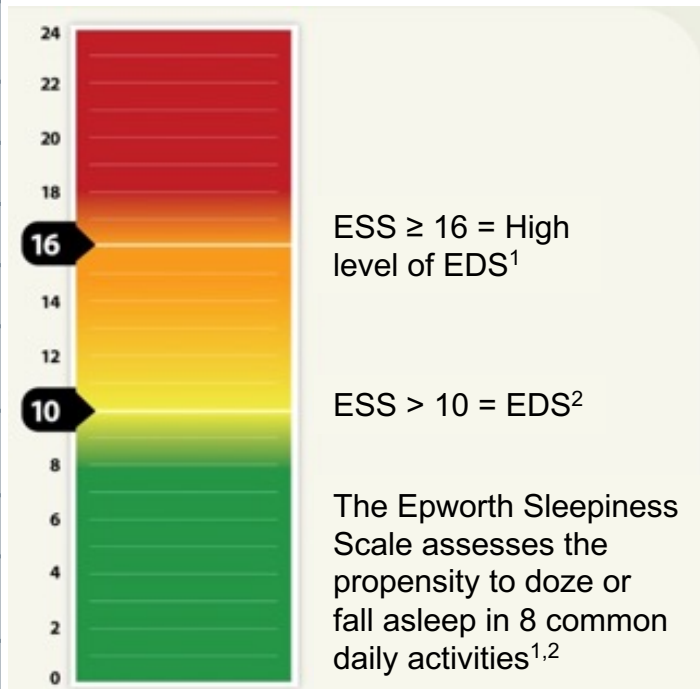
3. Ahmed IM, Thorpy MJ. *Sleepiness: Causes, Consequences and Treatment.* 2011.

4. Sturzenegger C, et al. *Clin Transl Neurosci.* 2018;2(2):34. 5. Bargiotas P, et al. *J Neurol.* 2019;266(9):2137-2143.

Measuring the Severity of EDS: Epworth Sleepiness Scale

0 = would never doze; 1 = slight chance of dozing; 2 = moderate chance of dozing; 3 = high chance of dozing

Situation	Chance of Dozing
Sitting and reading	
Watching television	
Sitting inactive in a public place	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking with someone	
In a car, while stopped for a few minutes in traffic	
Total scores range from 0–24 Total Score:	



Mean ESS scores lower in OSA (9 ± 5) than narcolepsy 17 ± 4 ^{3,4}

1. Johns MW. *Sleep*. 1991;14(6):540-545. 2. Johns MW. *Sleep*. 1991;20:844-848. 3. Lipford MC, et al. *J Clin Sleep Med*. 15(1):33-38. 4. Luca G, et al. *J Sleep Res*. 2013;22(5):482-495.

Swiss Narcolepsy Scale

Q1: How often are you unable to fall asleep?

Q2: How often do you feel bad or not well rested in the morning?

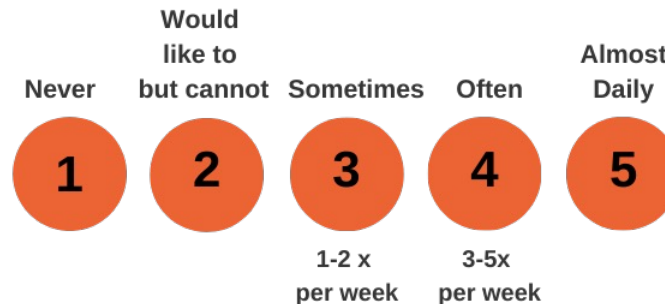
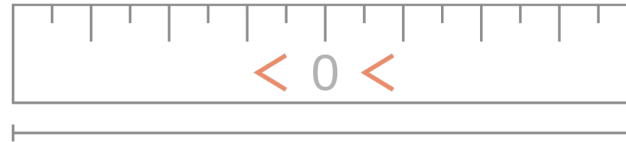
Q3: How often do you take a nap during the day?

Q4: How often have you experienced weak knees/buckling of the knees during emotions like laughing, happiness, or anger?

Q5: How often have you experienced sagging of the jaw during emotions like laughing, happiness, or anger?



< 0 = narcolepsy
> 0 = non-narcoleptic
hypersomniac



Score
 $(6 \times Q1) + (9 \times Q2) - (5 \times Q3) - (11 \times Q4) - (15 \times Q5) + 20$

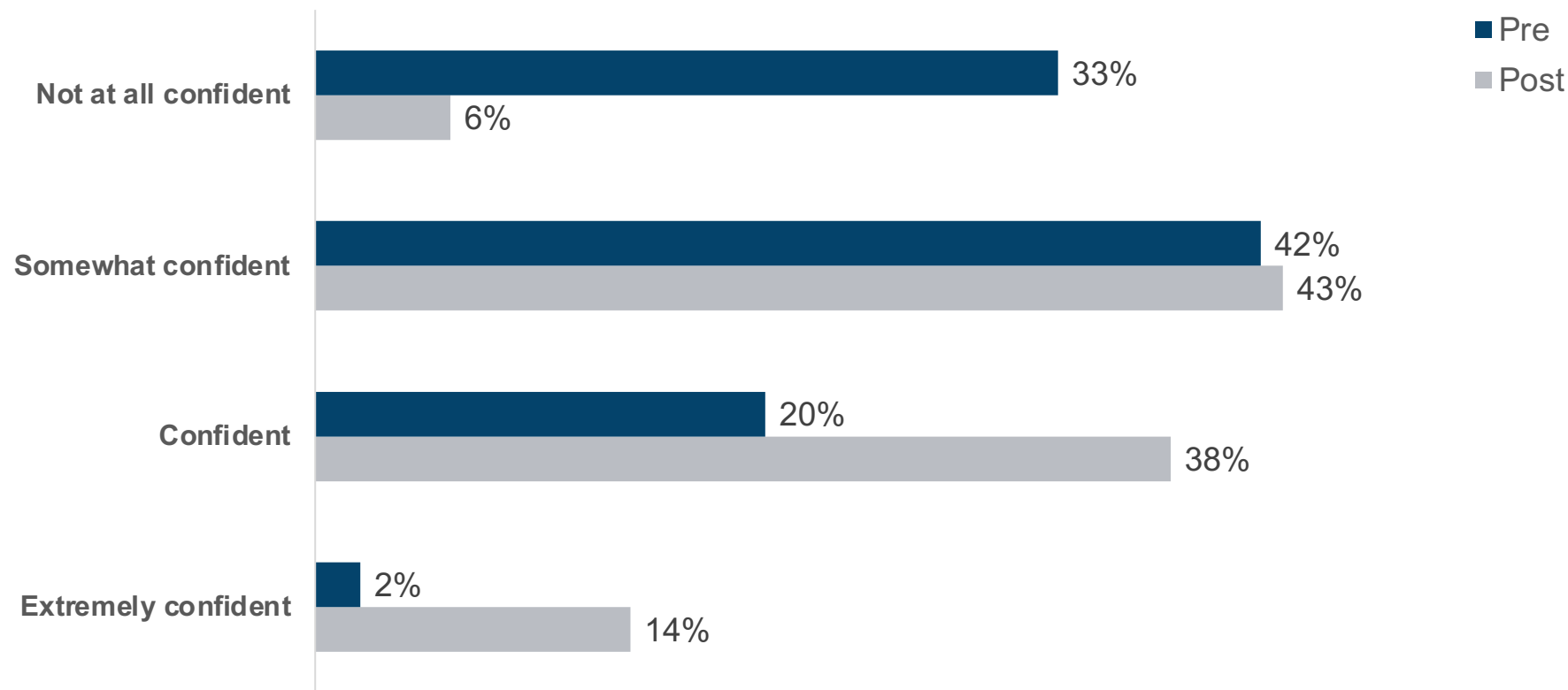
- Inability to fall asleep: +6
- Unrefreshed in the AM: +9
- Napping at noon: -5
- Knee buckling (during cataplexy): -11
- Jaw sagging (during cataplexy): -13

Audience Response

Now, how confident are you in your ability to accurately diagnose narcolepsy?

- A. Extremely confident
- B. Confident
- C. Somewhat confident
- D. Not at all confident

Now, how confident are you in your ability to accurately diagnose narcolepsy?



Results recorded on April 6, 2022

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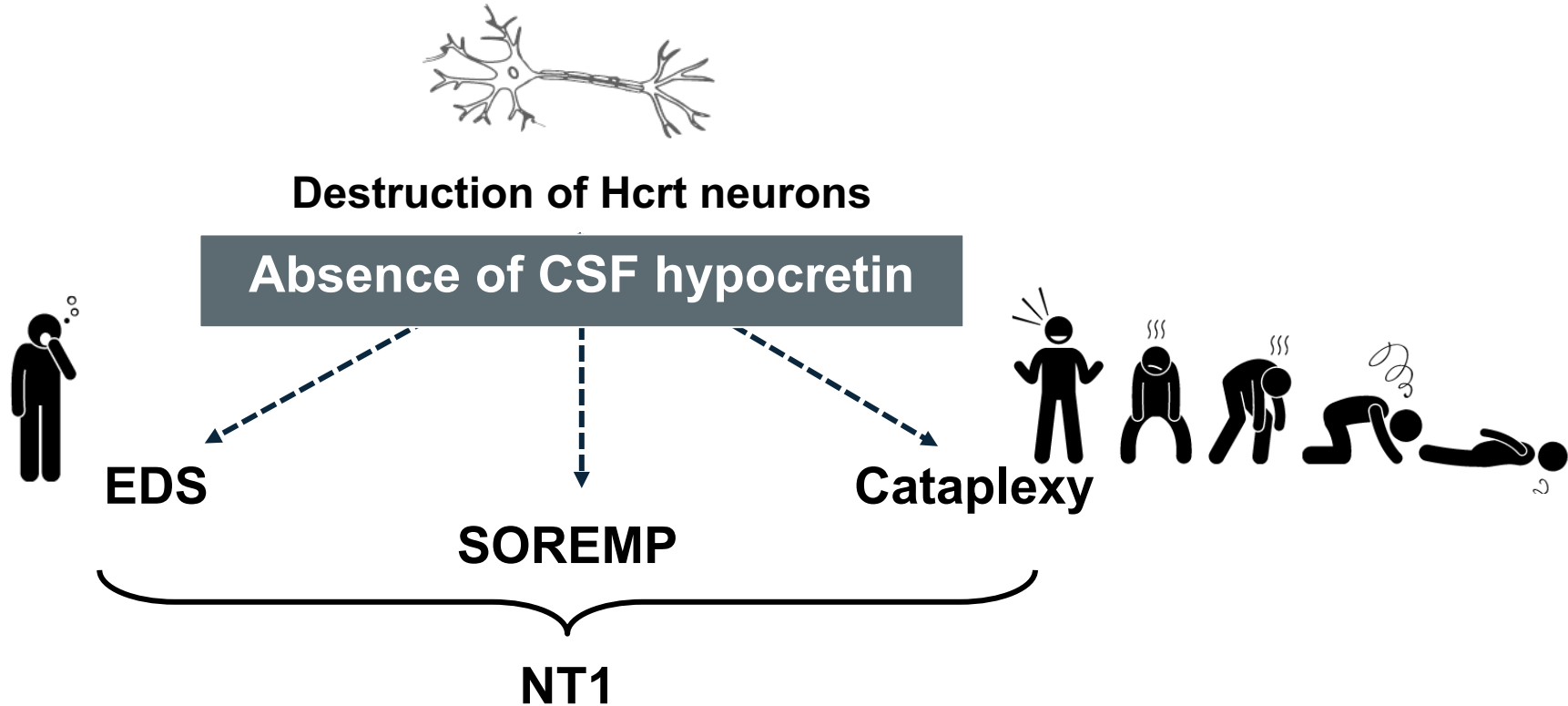


Learning Objective **2**

Differentiate the clinical,
functional, and psychosocial
impact of NT1 versus NT2.



Neurobiology of NT1: Loss of Orexin/Hypocretin Neurons



Hcrt = hypocretin

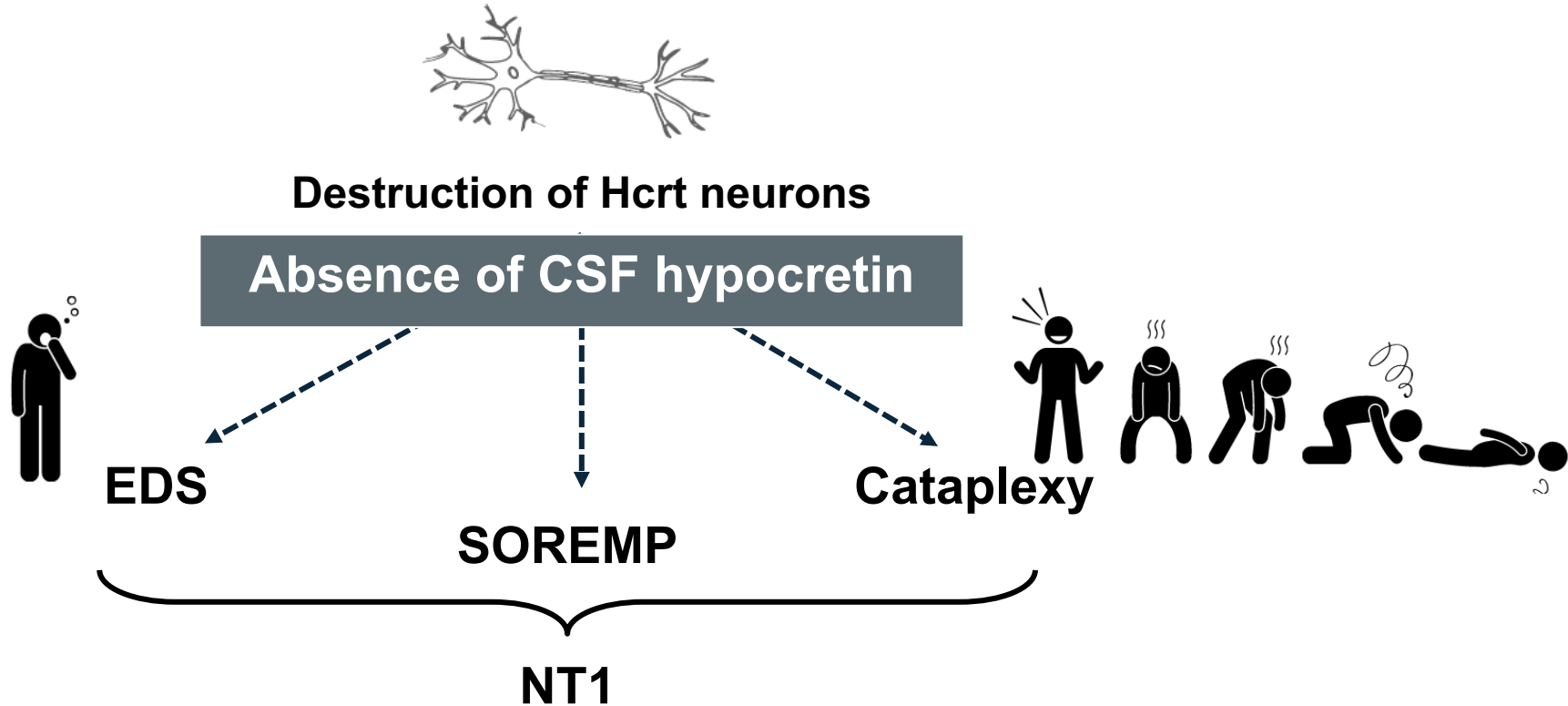
Sakuri T, et al. Orexin (hypocretin) and narcolepsy. In: *The Genetic Basis of Sleep and Sleep Disorders*. 2013.

Audience Response

How often do you consider the differential impact of narcolepsy type 1 versus narcolepsy type 2?

- A. 0% of the time
- B. 1%-25% of the time
- C. 26%-50% of the time
- D. 51%-75% of the time
- E. 76%-100% of the time

Neurobiology of NT1: Loss of Orexin/Hypocretin Neurons



Hcrt = hypocretin

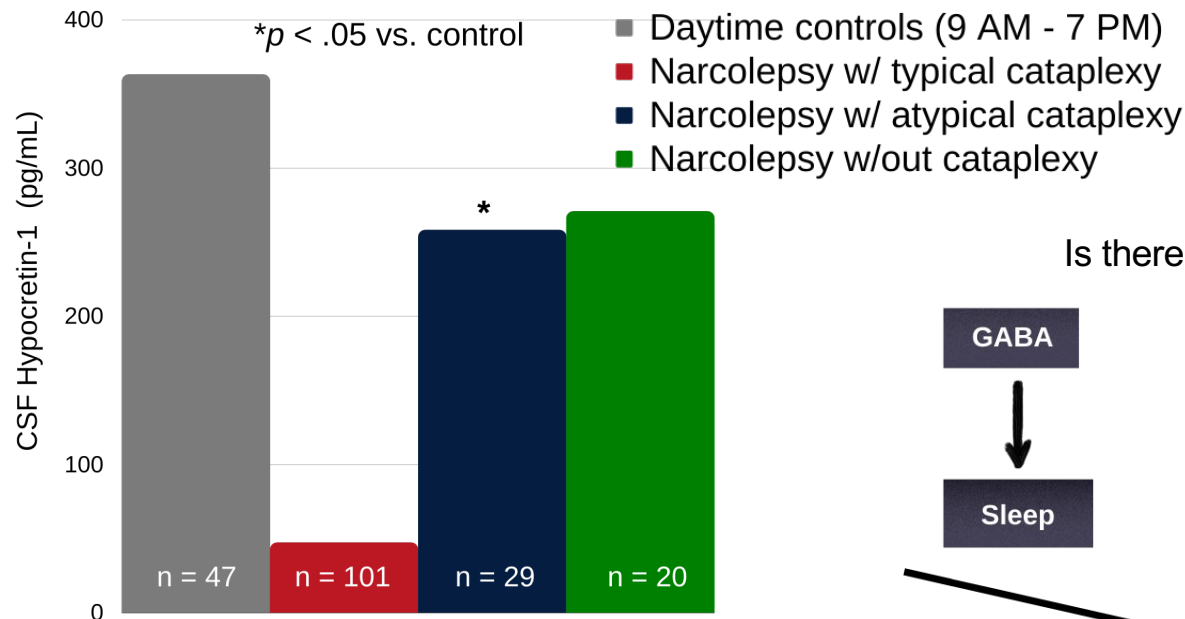
Sakuri T, et al. Orexin (hypocretin) and narcolepsy. In: *The Genetic Basis of Sleep and Sleep Disorders*. 2013.

Neurobiology of NT2: Pathology of Lateral Hypothalamus?

- Sleep-wake instability with high REM sleep propensity
 - Partial lesion of Hcrt neurons? Increased activity of MCH neurons
- Circadian disturbances to explain the high REM sleep propensity

No association between MCH, histamine, and hypocretin levels, EDS, SOREMPs, cataplexy

NT2: Problem with phenotyping and stability of NT2. Unclear pathophysiology? No identified specific biomarker



Is there biological dysfunction?



5HT = serotonin; DA = dopamine; GABA = gamma-aminobutyric acid; HA = histamine; MCH = melanin concentrating hormone; NE = norepinephrine

Peyron C, et al. *Sleep Med.* 2011;12(8):768-772. Barateau L, et al. *Sleep.* 2021;zsab012.

Disturbed Nocturnal Sleep by the Numbers

N = 57 with NT1¹



Sleep Apnea 43% loud snoring
21% experience apneas
20% awakening with dyspnea during the night



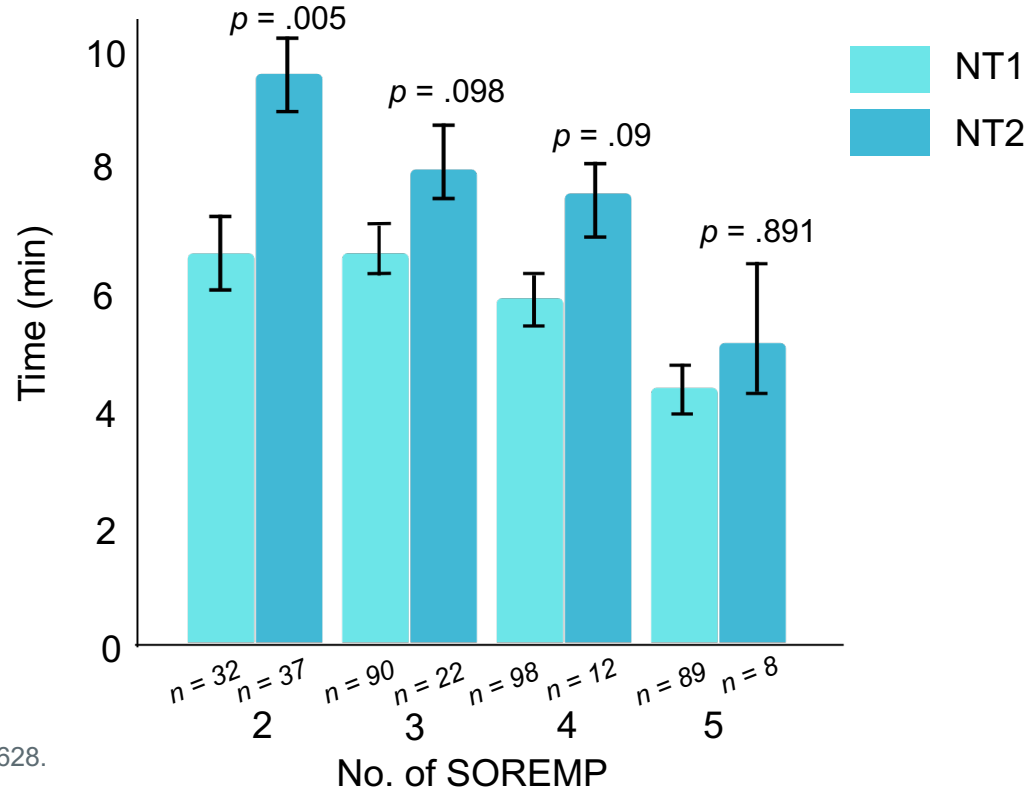
Waking Up 50% felt unrefreshed
17 ± 28 minutes to get up in the morning
24% experienced sleep drunkenness

Sleep 71% unable to sleep without awakening
31% got up at night to eat

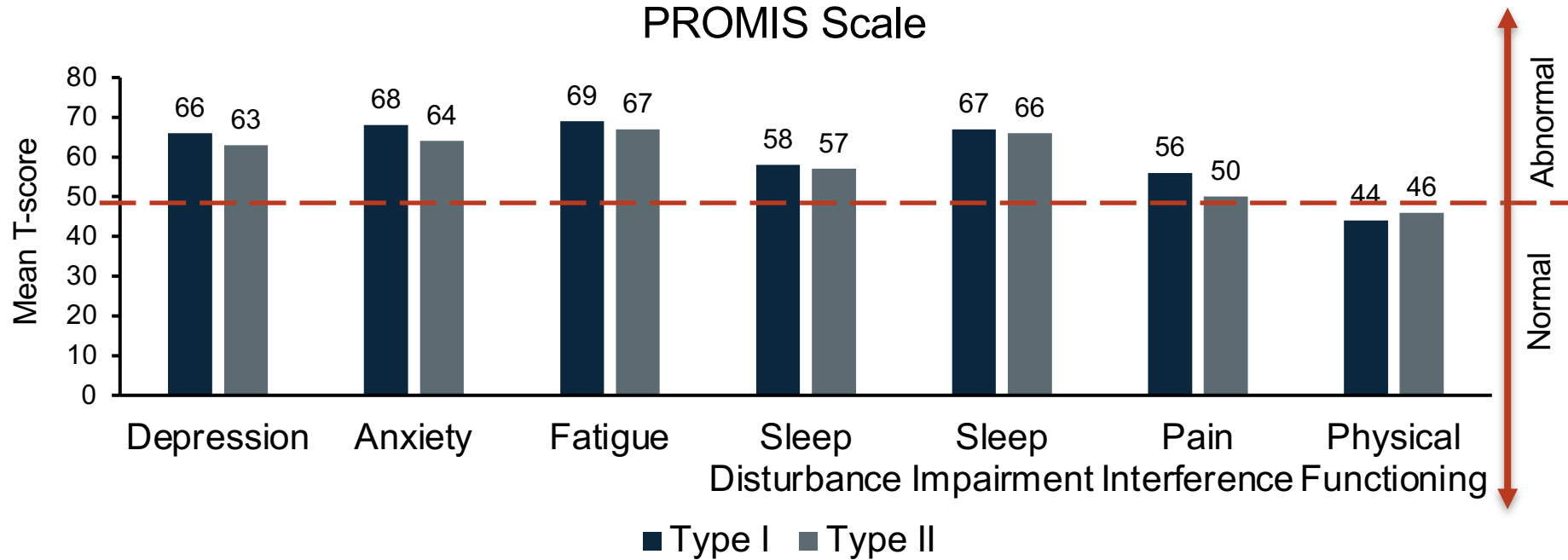


In a sample of 248 patients with NT1, disturbed nocturnal sleep severity was associated with higher scores on the Narcolepsy Severity Scale, higher sleepiness, anxiety/depressive symptoms, autonomic dysfunction, and worse quality of life.²

Comparison of REM Sleep Latency in NT1 vs. NT2



Health-Related Challenges Associated with Narcolepsy by Subtype



PROMIS = Patient-Reported Outcomes Measurement Information System

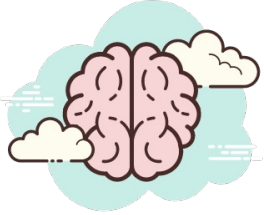
Ong JC, et al. *Behav Sleep Med.* 2021;19(2):145-158.

Baseline Characteristics of Patients with Narcolepsy

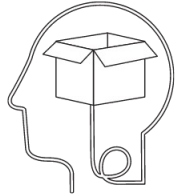
Variable	Patients with Narcolepsy (n = 59)
MWT sleep latency, min, mean (SD)	8.7 (6.2)
ESS	17.2 (2.8)
Baseline CGI-S, n (%)	
Moderately ill	17 (28.8)
Markedly ill	21 (35.6)
Severely ill	12 (20.3)
Extremely ill	8 (13.6)
% at least moderately ill	98.3
FOSQ-10 total, mean (SD)	11.4 (2.9)
SF-36v2	
Physical Component Summary, mean (SD)	46.1 (9.8)
Mental Component Summary, mean (SD)	44.8 (9.5)
WPAI:SHP (employed patients)	
% Work time missed, mean (SD)	14.9 (26.0)
% Impairment while working, mean (SD)	48.4 (23.9)
% Overall work impairment, mean (SD)	61.5 (22.5)
% Activity impairment, mean (SD)	65.8 (21.5)
EQ-VAS total score, mean (SD)	69.4 (20.3)

CGI-S = Clinical Global Impressions Scale; EQ-VAS = EuroQol Visual Analogue Scale; FOSQ = Functional Outcomes of Sleep Questionnaire; WPAI:SHP = Work Activity and Impairment Questionnaire: Specific Health Problem

Impact of Narcolepsy on HRQoL and Psychosocial and Work Functioning



Brain fog



Memory problems



Impaired
critical thinking



Falling asleep
throughout the day



Employment: frequent job
changes, job loss,
absenteeism / presenteeism



Strain on
relationships



Worsened
HRQoL



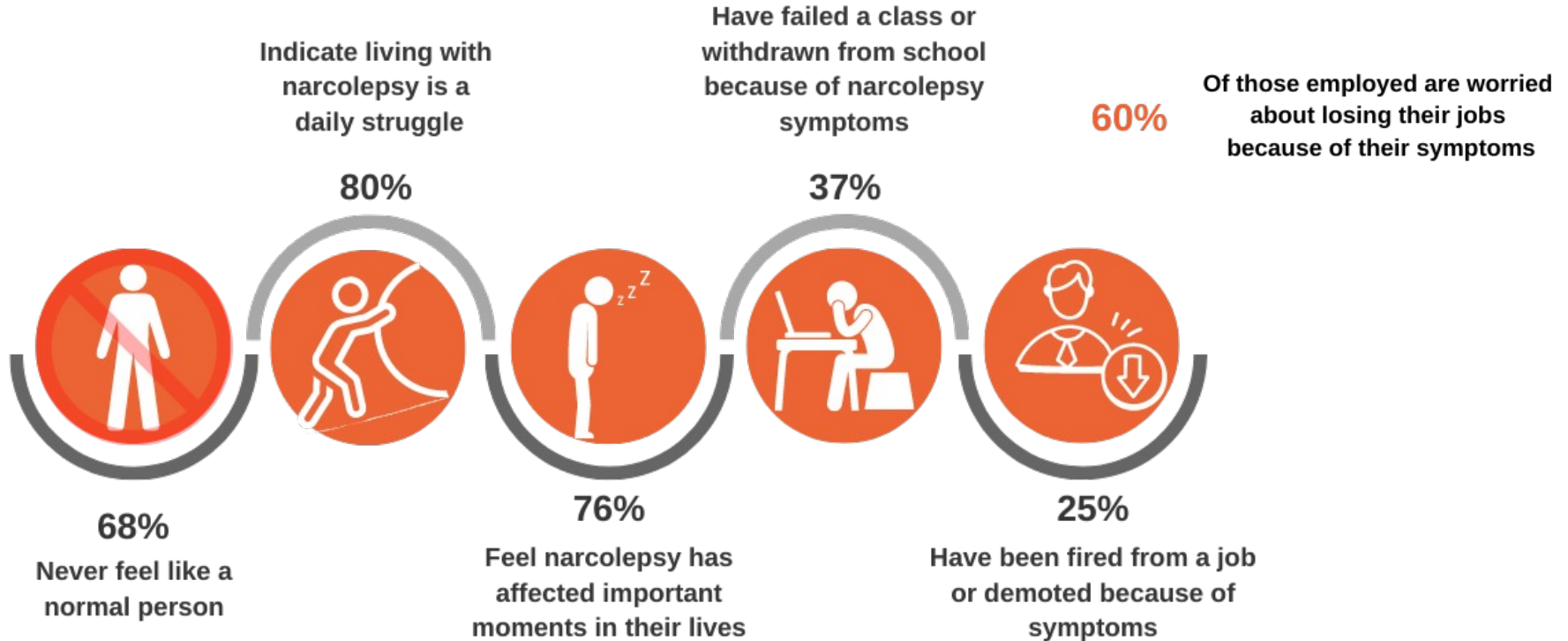
Increased risk of
accidents while driving

HRQoL = health-related quality of life

Emsellem HA, et al. *Sleep Med.* 2020;67:128-136. Bellebaum C, et al. Memory and cognition in narcolepsy. In: *Narcolepsy*. 2016. pp. 233-243.
McCall CA, et al. *Ther Clin Risk Manag.* 2020;16:1099-1108.

Living with Narcolepsy: The Patient Perspective

In a survey of 200 individuals living with narcolepsy:

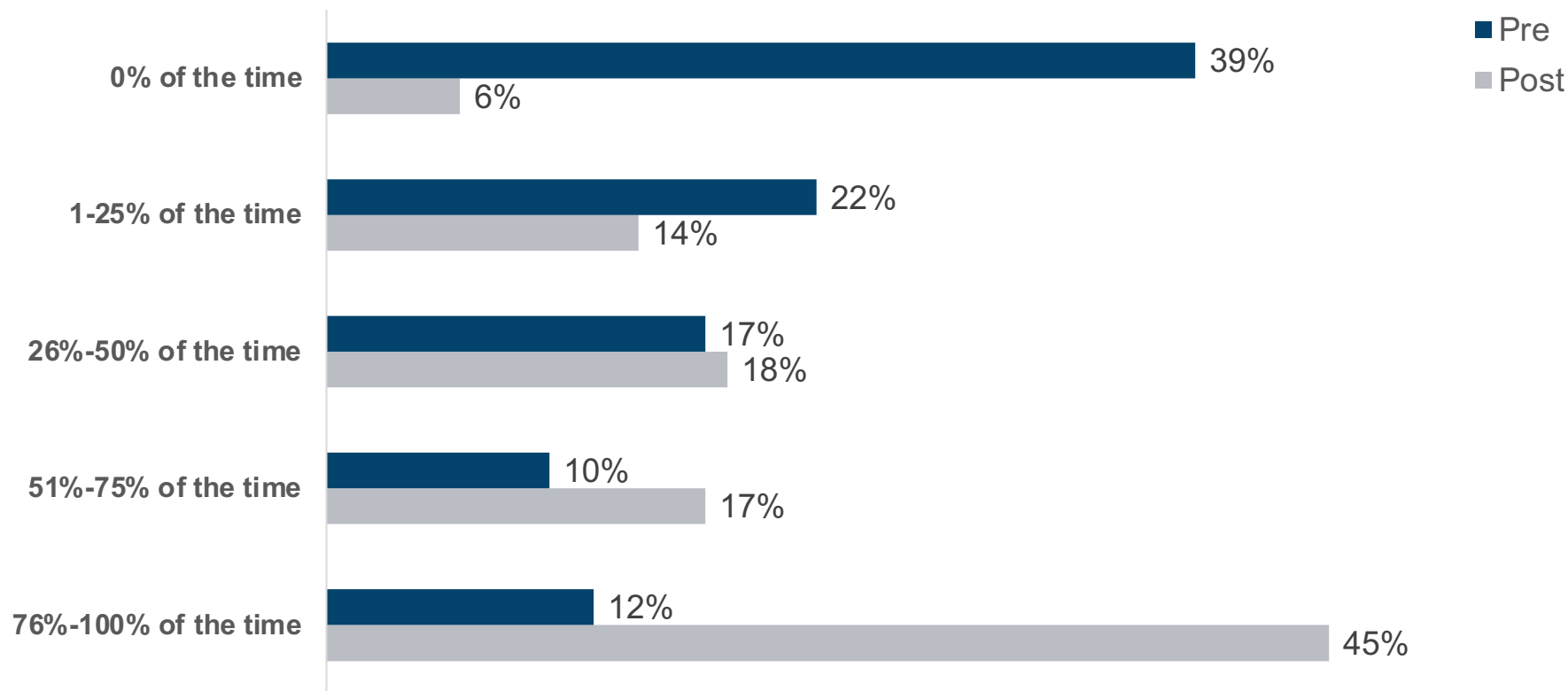


Audience Response

Now, how often will you consider the differential impact of narcolepsy type 1 versus narcolepsy type 2?

- A. 0% of the time
- B. 1%-25% of the time
- C. 26%-50% of the time
- D. 51%-75% of the time
- E. 76%-100% of the time

Now, how often will you consider the differential impact of narcolepsy type 1 versus narcolepsy type 2?



Results recorded on April 6, 2022

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Learning
Objective **3**

Evaluate the latest safety and efficacy data on novel and emerging strategies to reduce the burden and impact of EDS and cataplexy in adults with narcolepsy.



Audience Response

How confident are you using the latest clinical evidence to develop an effective treatment plan to reduce the burden and impact of EDS in adults with narcolepsy?

- A. Extremely confident
- B. Confident
- C. Somewhat confident
- D. Not at all confident

Treatment Goals in Narcolepsy

1. Reduce EDS
2. Control cataplexy
3. Control nightmares and hallucinations, sleep paralysis, and disturbed nocturnal sleep (DNS)
4. Improve psychosocial dysfunction and quality of life
5. Improve safety of patient and public
6. Optimize risk/benefit of pharmacotherapies

FDA-Approved Treatments for Narcolepsy

Drug	MOA	Dose	EDS	Cataplexy	Adults	Children
Modafinil	Dopamine (DA) reuptake inhibitor	100-400 mg	X		X	
Armodafinil	DA reuptake inhibitor	50-250 mg	X		X	
Solriamfetol	DA-norepinephrine (NE) reuptake inhibitor	75-150 mg	X		X	
Pitolisant	Histamine H3 antagonist/inverse agonist	8.9-35.6 mg	X	X	X	
Sodium oxybate (SXB) / lower sodium oxybate (LXB)	GABA _B agonist	4.5-9.0 g (twice-nightly dosing)	X	X	X	X
Amphetamines / Methylphenidate	Sympathomimetic; enhance DA, NE, serotonin	Varies			X	X

Amphetamines and methylphenidate are approved for narcolepsy but not specifically cataplexy or EDS.

Barateau L, et al. *Ther Adv Neurol Disord*. 2019;12:1756286419875622.

Safety Considerations for FDA-Approved Treatments for EDS and Cataplexy in Narcolepsy

Drug	Schedule	Common AEs (≥ 5%)
Modafinil / Armodafinil	IV	Anxiety, back pain, diarrhea, dizziness, dyspepsia, headache, insomnia, and nausea
Solriamfetol	IV	Anxiety, decreased appetite, headache, insomnia, and nausea
Pitolisant	–	Anxiety, insomnia, and nausea
SXB / LXB	III	Anxiety (adults), decreased appetite, diarrhea (adults), dizziness, enuresis (peds), headache, hyperhidrosis (adults), parasomnia (adults), vomiting, and weight decrease (peds)
Amphetamines / Methylphenidate	II	Dry mouth, upset stomach, loss of appetite, weight loss, headache, dizziness, tremors, tachycardia, elevated blood pressure, insomnia, mood changes

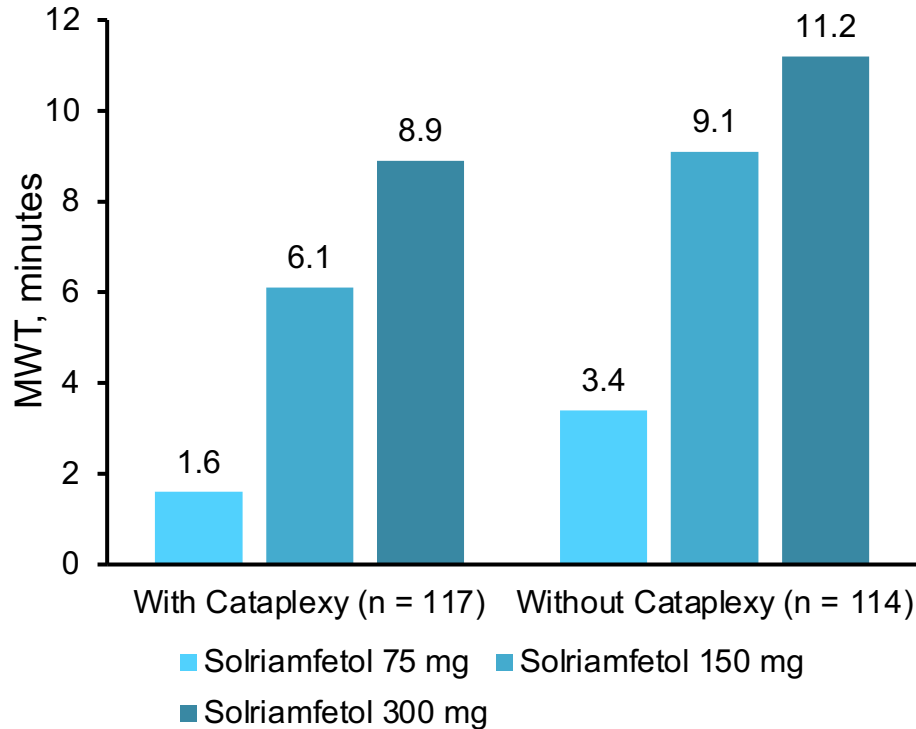
AEs = adverse events
 Drugs@FDA Website.

Safety: Other Considerations

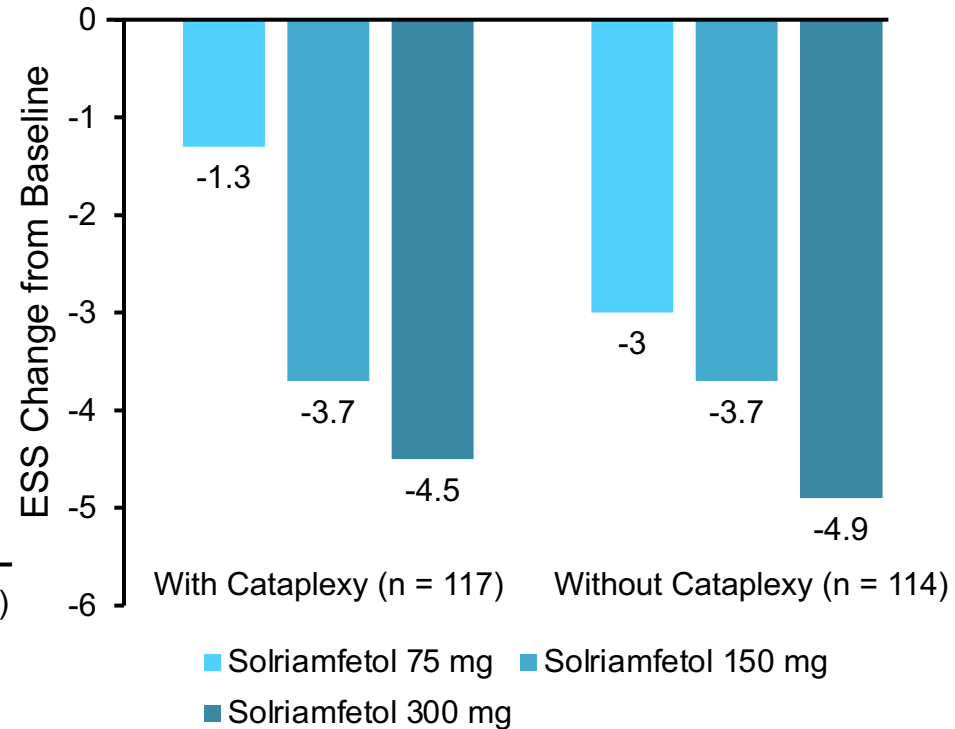
Agent	Additional Considerations
Modafinil/ Armodafinil ^{1,2,3}	<ul style="list-style-type: none"> • May reduce effectiveness of hormonal contraceptive agents • May increase heart rate and diastolic and systolic blood pressure • Allergic reactions and rashes
Solriamfetol ^{4,5,6}	<ul style="list-style-type: none"> • Precautions regarding blood pressure and heart rate increases • No effect on birth control
Pitolisant ^{3,7,8}	<ul style="list-style-type: none"> • May reduce effectiveness of hormonal contraceptives • No clinically relevant effects on vital signs, laboratory findings • May increase QTc intervals • Not a controlled substance
SXB / LXB ^{9,10}	<ul style="list-style-type: none"> • High sodium formulation may be contraindicated in patients at risk for CVD events • May decrease body mass index • Common, early onset AEs are generally of short duration and decrease over time • LXB formulation may be ideal in those with CVD risks
Amphetamines / Methylphenidate ³	<ul style="list-style-type: none"> • Schedule II controlled substance • High potential for abuse • Serious cardiovascular events (such as sudden deaths, stroke, myocardial infarction)

1. Volkow ND, et al. *JAMA*. 2009;301(11):1148-1154. 2. Black JE, et al. *J Clin Sleep Med*. 2010;6(5):458-466. 3. Drugs@FDA Website.
4. Meskill GJ, et al. *Sleep*. 2020;43(Suppl 1):A291. 5. Zomorodi K, et al. *J Clin Pharmacol*. 2019;59(8):1120-1129. 6. Carter LP, et al. *JPsychopharmacol*. 2018;32(12):1351-1361. 7. Scart-Gres C, et al. *Sleep*. 2019;42(Suppl 1):A244-245. 8. Setnik B, et al. *Sleep*. 2020;43(4):zsz252.
9. Husain AM, et al. *J Clin Sleep Med*. 2020;16(9):1469-1474. 10. Dauvilliers Y, et al. *Sleep*. 2020;43:A286.

Solriamfetol: Efficacy in Narcolepsy—MWT and ESS

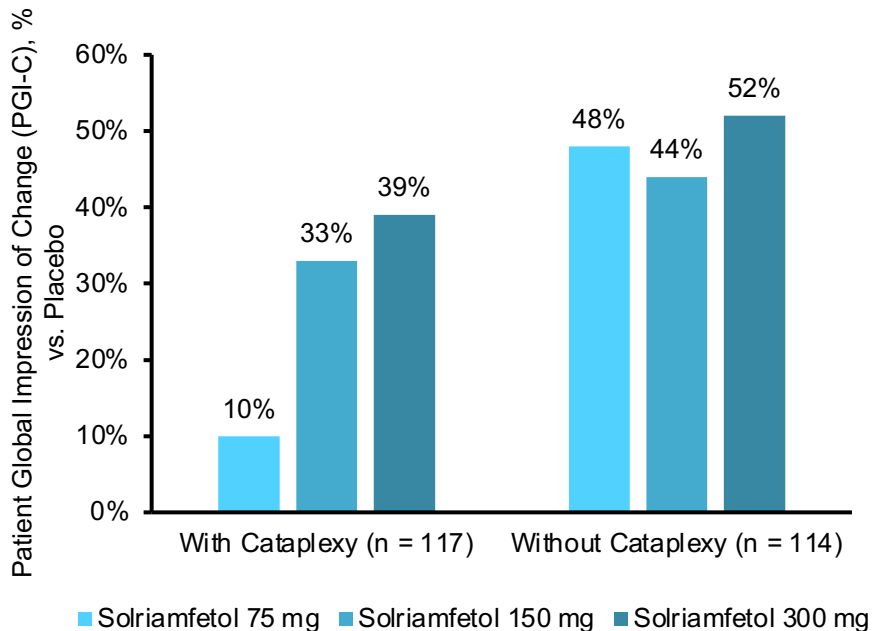


MWT: with cataplexy ($p < .05$; 150 and 300 mg);
without cataplexy ($p < .001$; 150 and 300 mg)

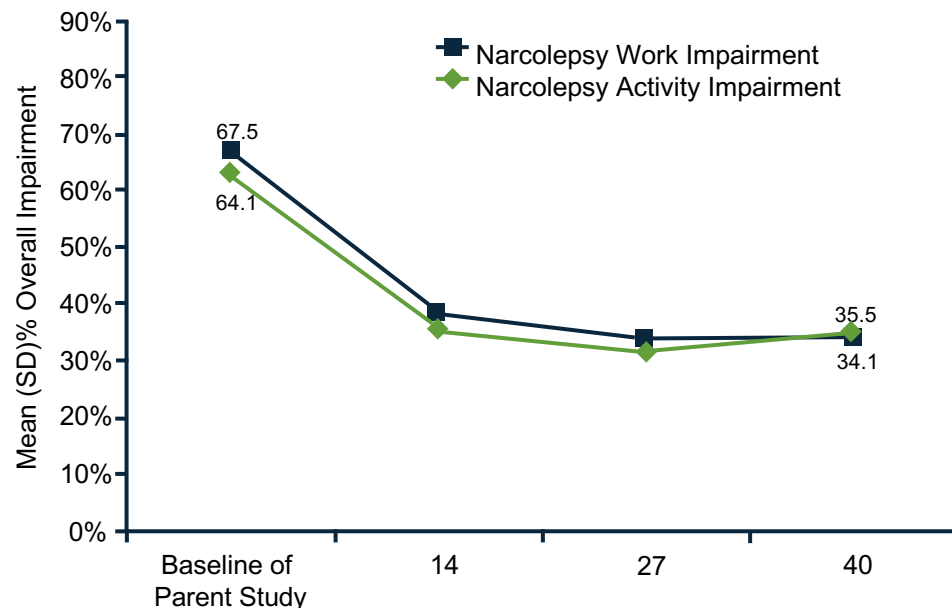


ESS: with cataplexy ($p < .01$; 150 and 300 mg);
without cataplexy ($p < .05$; all doses)

Solriamfetol: Efficacy in Narcolepsy—PGI-C and Work Productivity and Activity Impairment (WPAI)



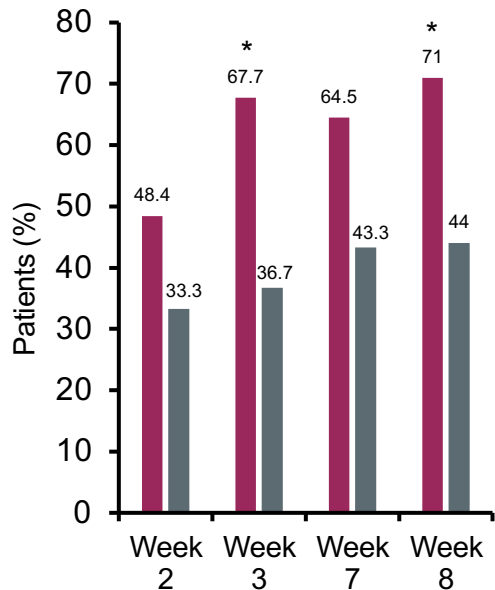
PGI-C: with cataplexy ($p < .05$; 150 and 300 mg); without cataplexy ($p < .001$; all doses)



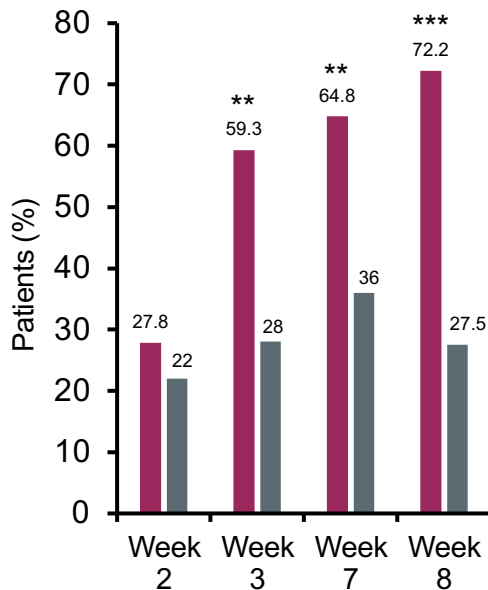
Pitolisant: Efficacy in Narcolepsy—Reducing ESS Scores and Cataplexy Attacks

ESS score reduction of ≥ 3

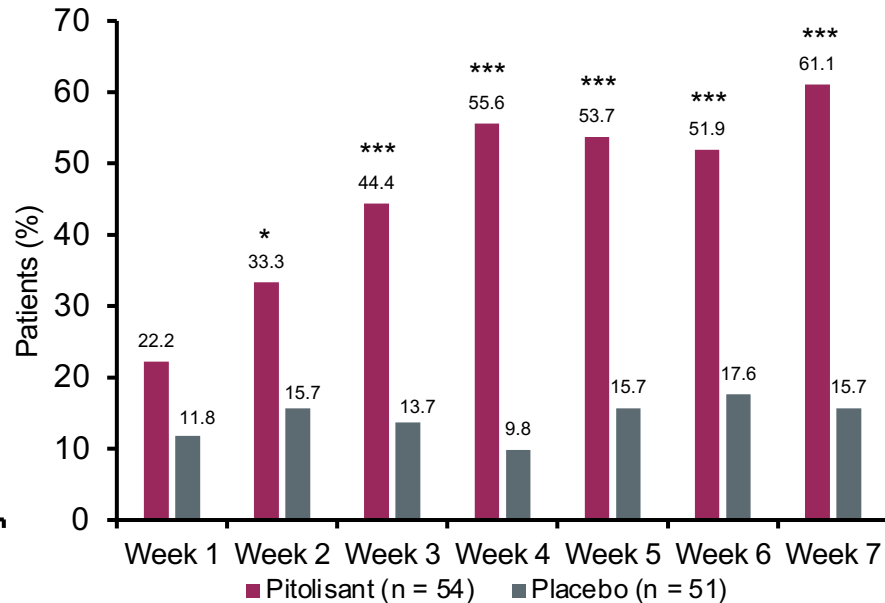
HARMONY 1



HARMONY CTP



$\geq 50\%$ reduction in the weekly rate of cataplexy attacks



■ Pitolisant (n = 31)

■ Placebo (n = 30)

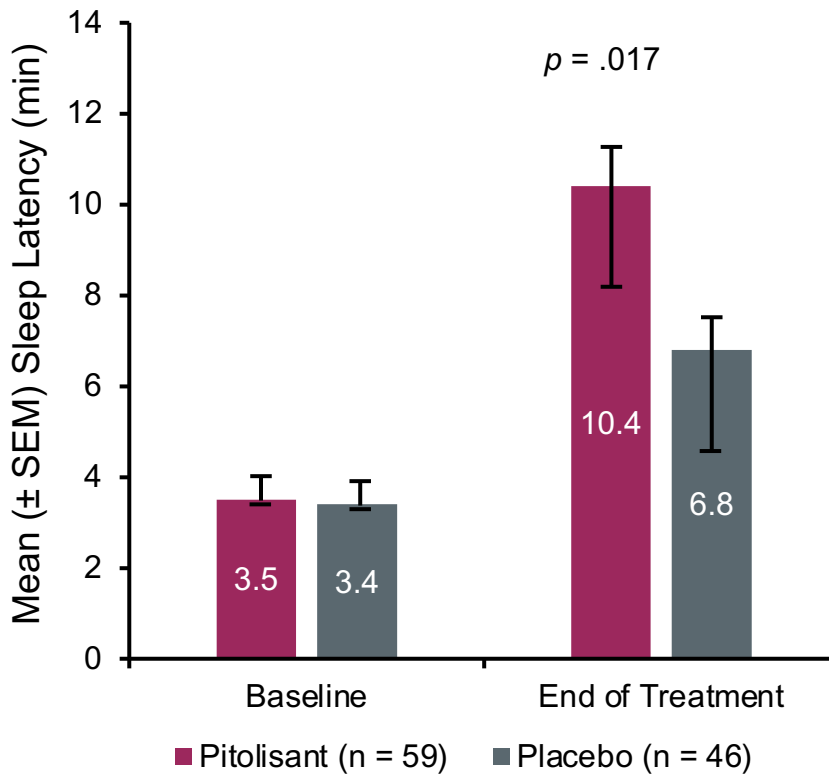
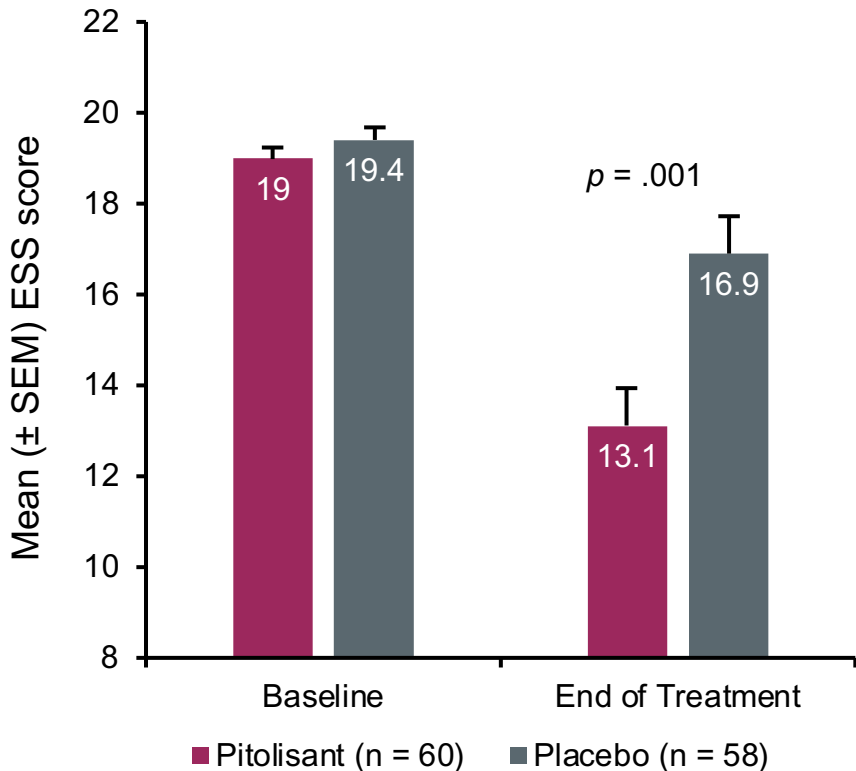
■ Pitolisant (n = 54)

■ Placebo (n = 51)

* $p < .05$ vs placebo; ** $p < .01$ vs placebo; *** $p < .001$ vs placebo

Watson NF, et al. *CNS Drugs*. 2021;35(12):1303-1315.

Pitolisant: Efficacy in Narcolepsy with High EDS Burden—ESS and Sleep Latency

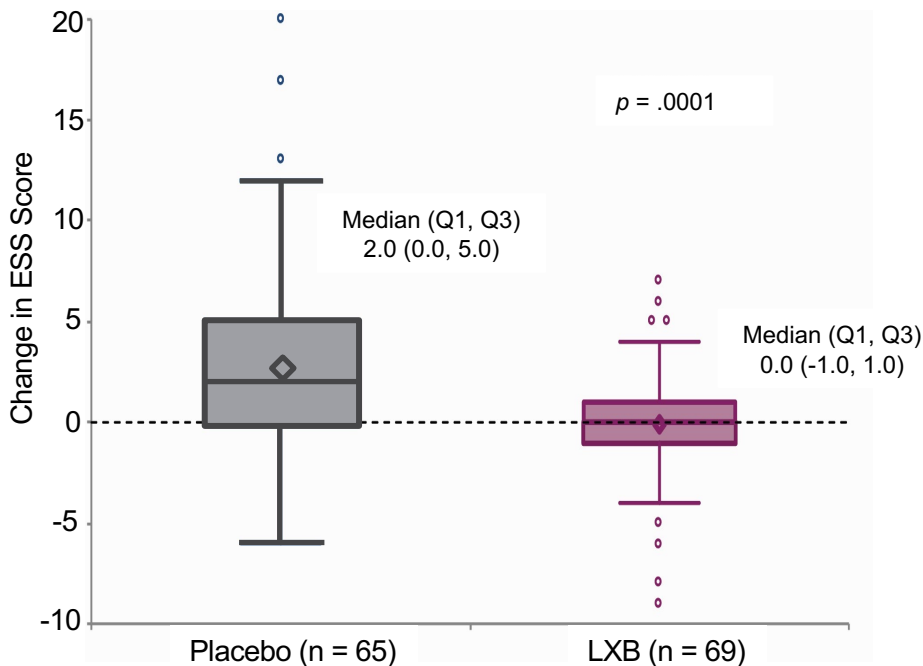


Inclusion criteria: baseline score of ≥ 16 on the ESS and baseline sleep latency of ≤ 8 min on the MWT

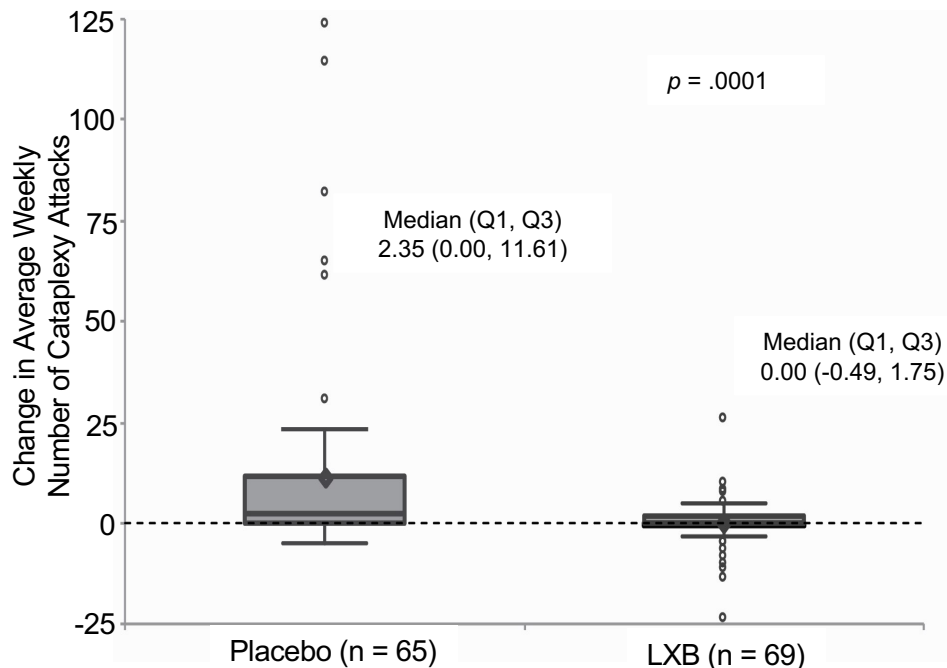
SEM = standard error of measurement

Davis CW, et al. *Sleep Med.* 2021;81:210-217.

Twice-Nightly Lower Sodium Oxybate: Efficacy in Narcolepsy— Change in ESS Score and Weekly Cataplexy Attacks

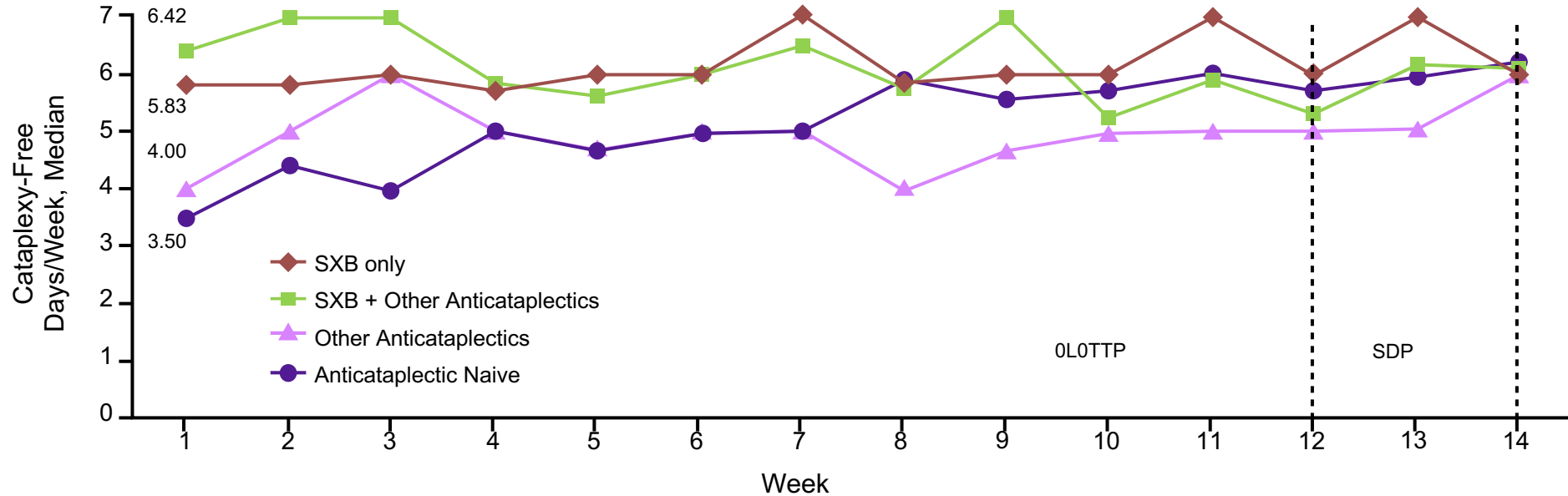


Change in the ESS score from the end of the stable-dose period to the end of the double-blind randomized withdrawal period



Change in weekly number of cataplexy attacks from the stable-dose period to the double-blind randomized withdrawal period

Twice-Nightly LXB: Efficacy on Cataplexy-Free Days/Week



- At the end of SDP (when all participants were on a stable, optimized dose of LXB), median (Q1, Q3) cataplexy-free days/week were: SXB only, 6.0 (3.5, 7.0); SXB + other anticatataplectic(s), 6.1 (1.4, 7.0); other anticatataplectic(s), 6.0 (2.6, 7.0); anticatataplectic naive 6.2 (4.0, 7.0)

Challenges with Current Therapies

- Safety

- Comorbidities can impact treatment selection

- Adherence

- Good adherence seen in only **55%** of patients taking wake-promoting medication; 13% intermediately and 32% poorly adherent
- **27%** of patients taking SXB do not take it according to the prescribed schedule

- Dosing:

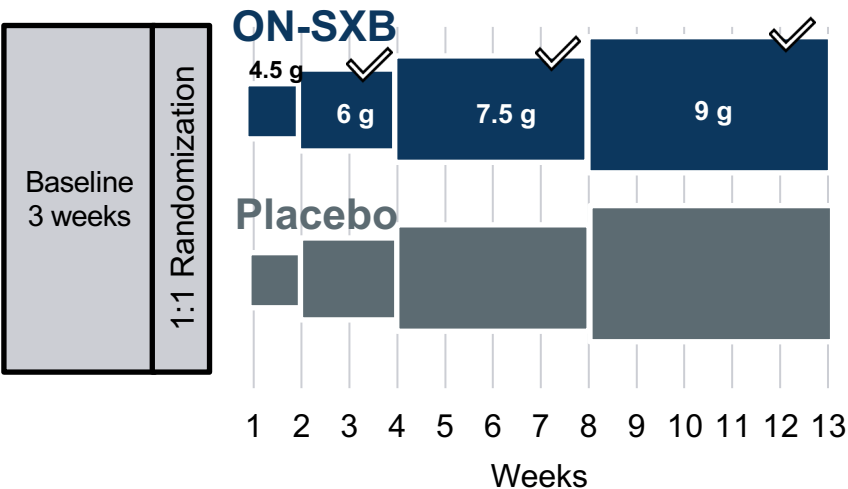
- Customization needed
- SXB/LXB have twice-nightly dosing
 - 50% at bedtime, 50% 2.5 – 4 hrs later



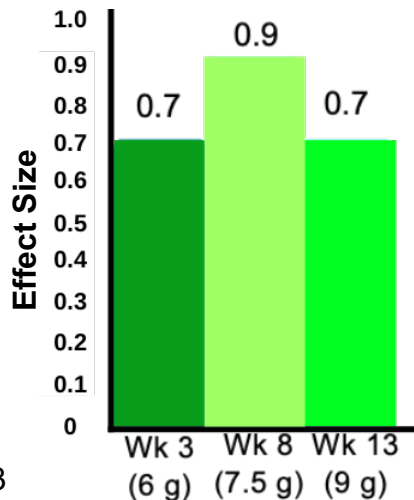
FT-218[†]: Efficacy in Narcolepsy—MWT

Study Design

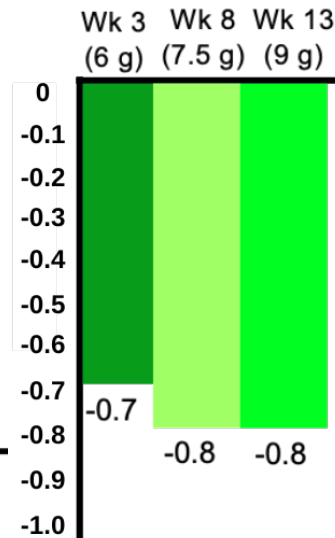
✓ Safety and efficacy assessment



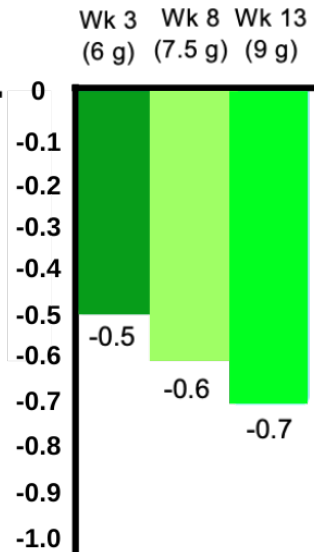
MWT



NCA



ESS



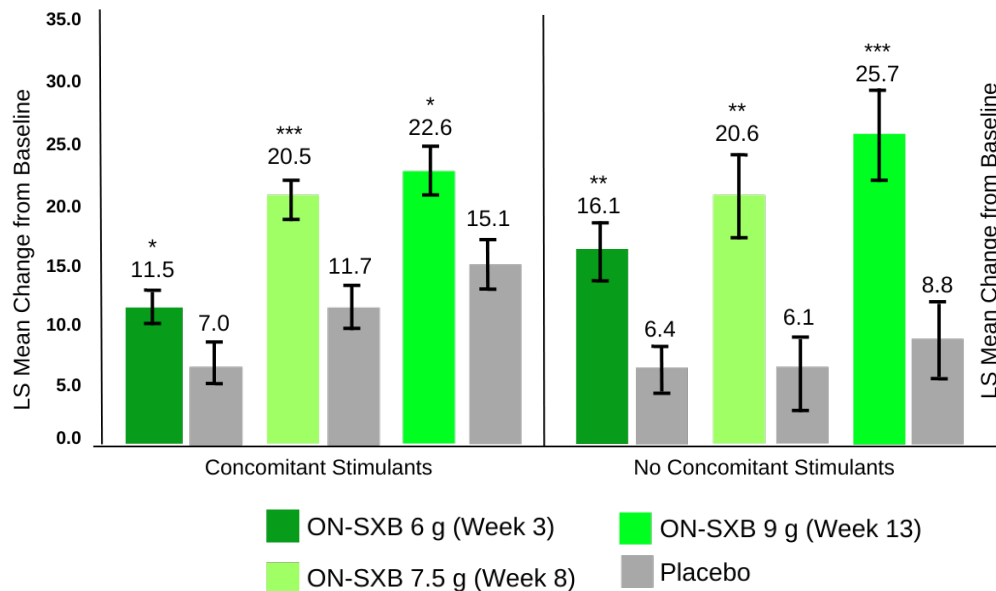
[†]FT-218 is not FDA-approved for the treatment of cataplexy or EDS associated with narcolepsy.

NCA = number of cataplexy attacks (weekly); ON-SXB = once-nightly sodium oxybate (FT218); Wk = week

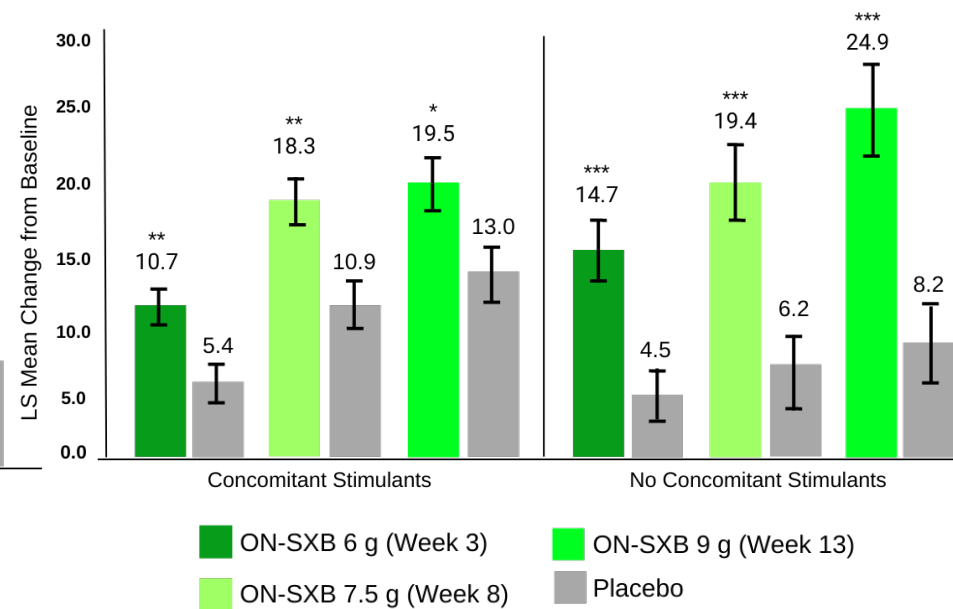
Thorpy MJ, et al. Presented at World Sleep 2022. March 11-16, 2022. Rome, Italy. Poster 172.

FT-218:† Patient-Reported Outcomes—Sleep Quality and Refreshing Sleep

Refreshing Nature of Sleep



Sleep Quality



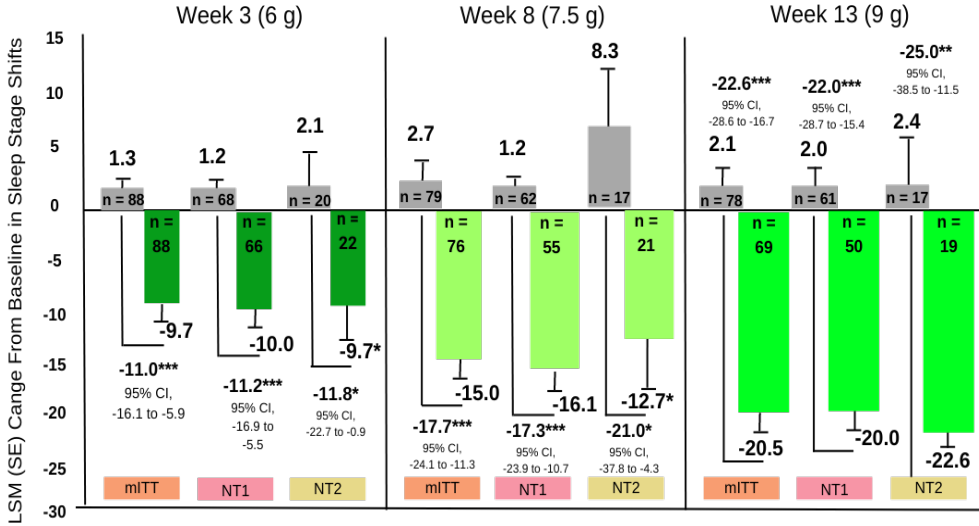
†FT-218 is not FDA-approved for the treatment of cataplexy or EDS associated with narcolepsy.

* $p < .05$, ** $p < .01$, *** $p \leq .001$. Error bars represent the standard error.

Thorpy MJ, et al. Presented at World Sleep 2022. March 11-16, 2022. Rome, Italy. Poster 127.

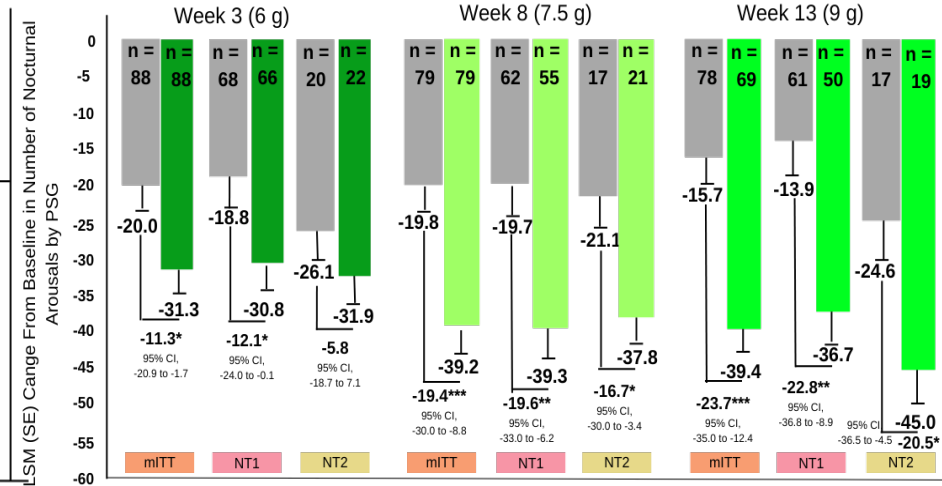
FT-218:† Efficacy by Narcolepsy Type

Change From Baseline in Sleep Stage Shifts by Narcolepsy Type



■ ON-SXB 6 g (Week 3) ■ ON-SXB 7.5 g (Week 8) ■ ON-SXB 9 g (Week 13) ■ Placebo

Change From Baseline in Nocturnal Arousals by Narcolepsy Type



■ ON-SXB 6 g (Week 3) ■ ON-SXB 7.5 g (Week 8) ■ ON-SXB 9 g (Week 13) ■ Placebo

†FT-218 is not FDA-approved for the treatment of cataplexy or EDS associated with narcolepsy.

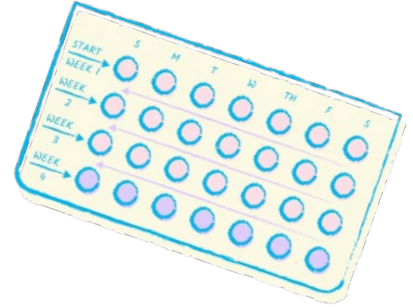
* $p < .05$, ** $p < .01$, *** $p < .001$

Dauvilliers Y, et al. Presented at World Sleep 2022. March 11-16, 2022. Rome, Italy. Poster 156.



Personalizing Treatment Selection for Patients with Narcolepsy

- Patient's needs and preferences
- Severity of EDS
- Comorbidities
- Cardiovascular Risk
- Polypharmacy, including use of oral contraceptives
- Convenience of use: dosing regimen
- Adherence
- Carryover effects

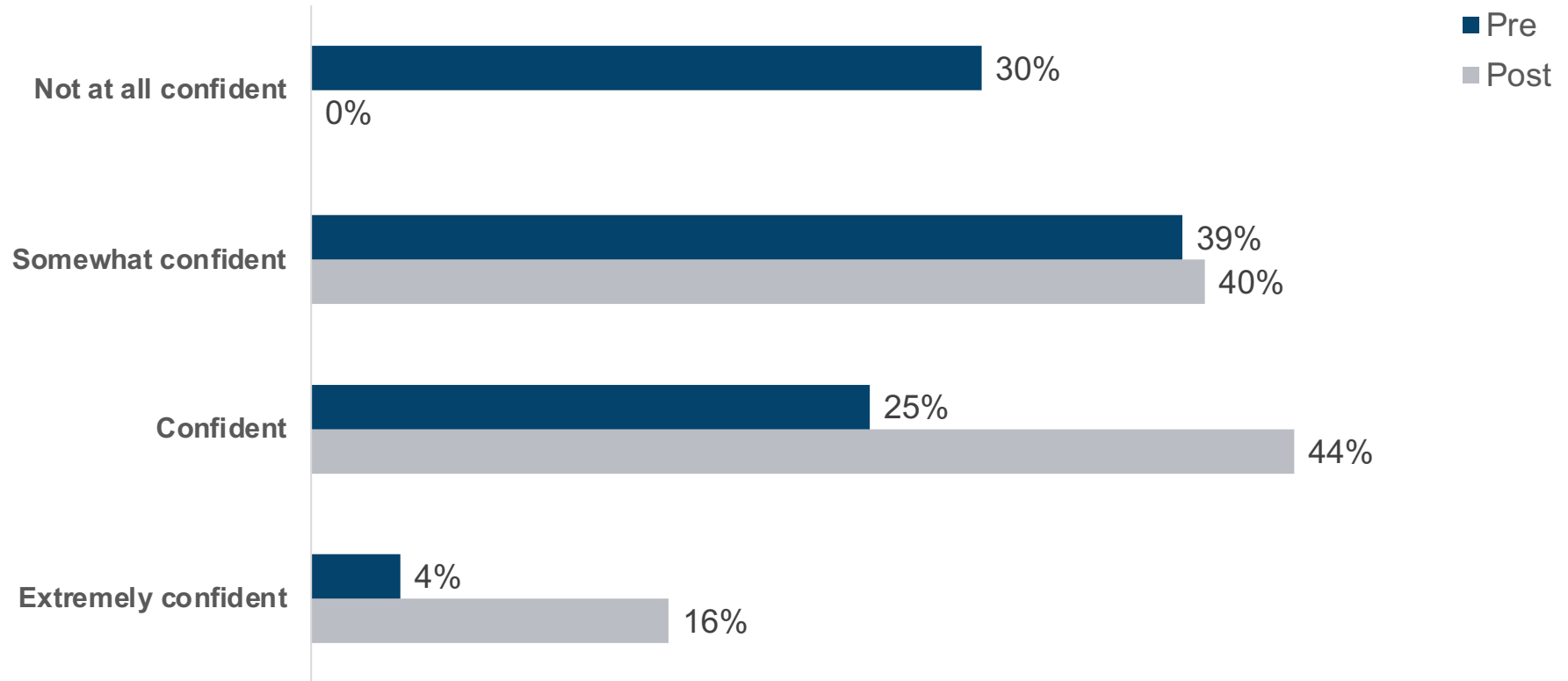


Audience Response

Now, how confident are you using the latest clinical evidence to develop an effective treatment plan to reduce the burden and impact of EDS in adults with narcolepsy?

- A. Extremely confident
- B. Confident
- C. Somewhat confident
- D. Not at all confident

Now, how confident are you using the latest clinical evidence to develop an effective treatment plan to reduce the burden and impact of EDS in adults with narcolepsy?



Results recorded on April 6, 2022

Conclusions

- The diagnosis of narcolepsy is challenging and laden with missed diagnoses, misdiagnosis, and considerable diagnostic delays.
- EDS and REM dissociative symptoms exert a profound negative impact on quality of life and functioning.
- Disturbed nocturnal sleep is a common complaint in patients with narcolepsy and should be assessed for efficacy of treatment.
- Treatment options for narcolepsy are expanding and include therapies that offer more ideal dosing strategies for patients.

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

- Use ICSD-3 diagnostic criteria to accurately diagnose NT1 and NT2
- Assess the presence, quality of life impact, and efficacy of treatment on EDS, REM dissociative symptoms, and importantly, disturbed nocturnal sleep in patients with narcolepsy
- Use the latest clinical data to develop personalized treatment plans, consider:
 - Updated clinical parameters
 - Newly approved and emerging narcolepsy medications

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Questions & Answers





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