

Optimal Sleep Using NeurOptimal®-Insomnia Studies

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Objectives

- To describe the role of sleep in normal health and well-being
- To discuss the link between sleep and optimal performance
- To understand the role of NeurOptimal® in facilitating sleep

Overview: Normal Sleep

- Sleep may be the most powerful biological drive
- Sleep is an active and cyclic process
- Sleep drive is composed of two interacting factors and modulated by a third
- Sleep need decreases across development
- Sleep loss (and gain) accumulates: concept of sleep debt (and accrual)

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When there's a huge sleep debt, you can sleep anywhere—any time—as evidenced by these forest fire fighters.

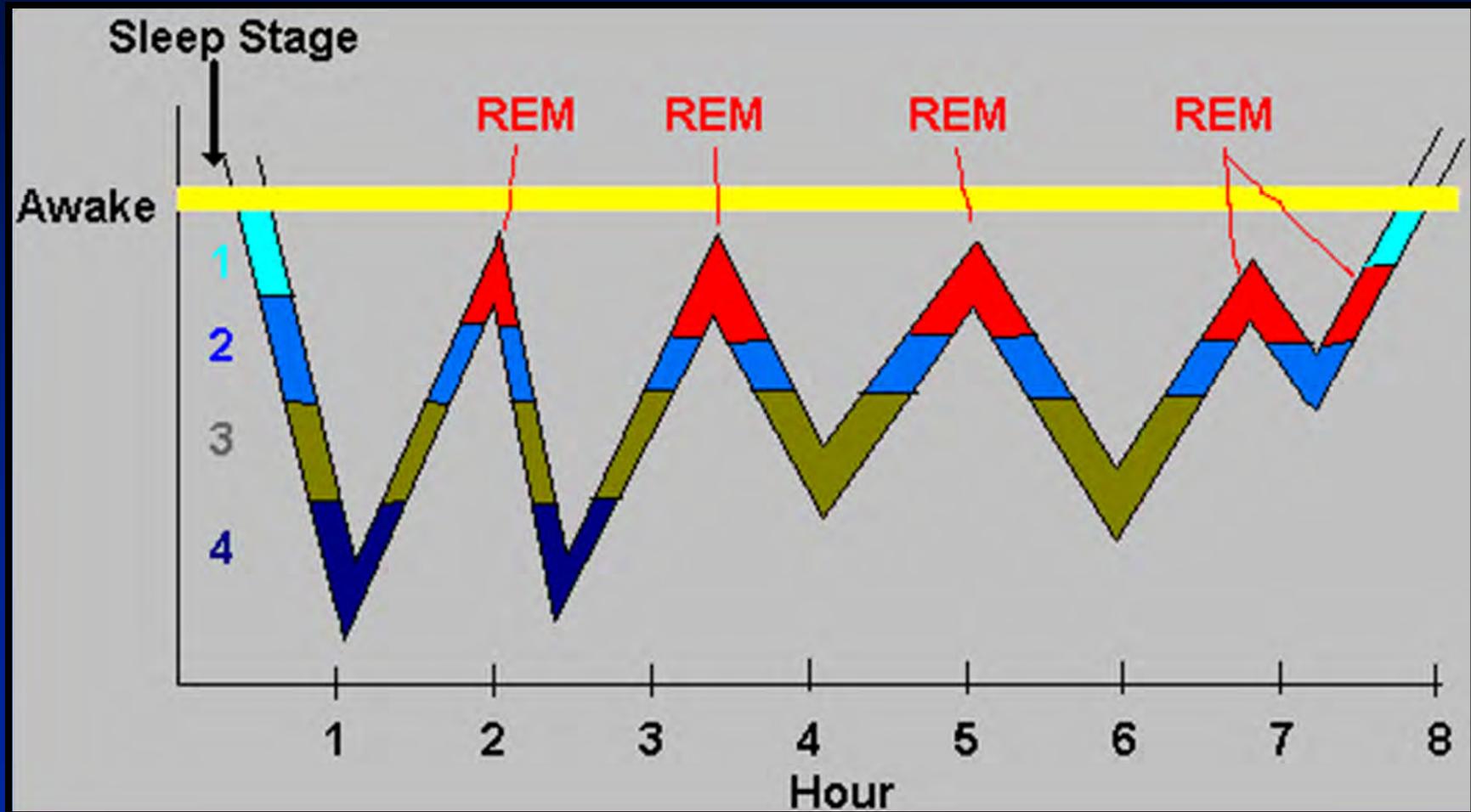


from Dinges (2001)

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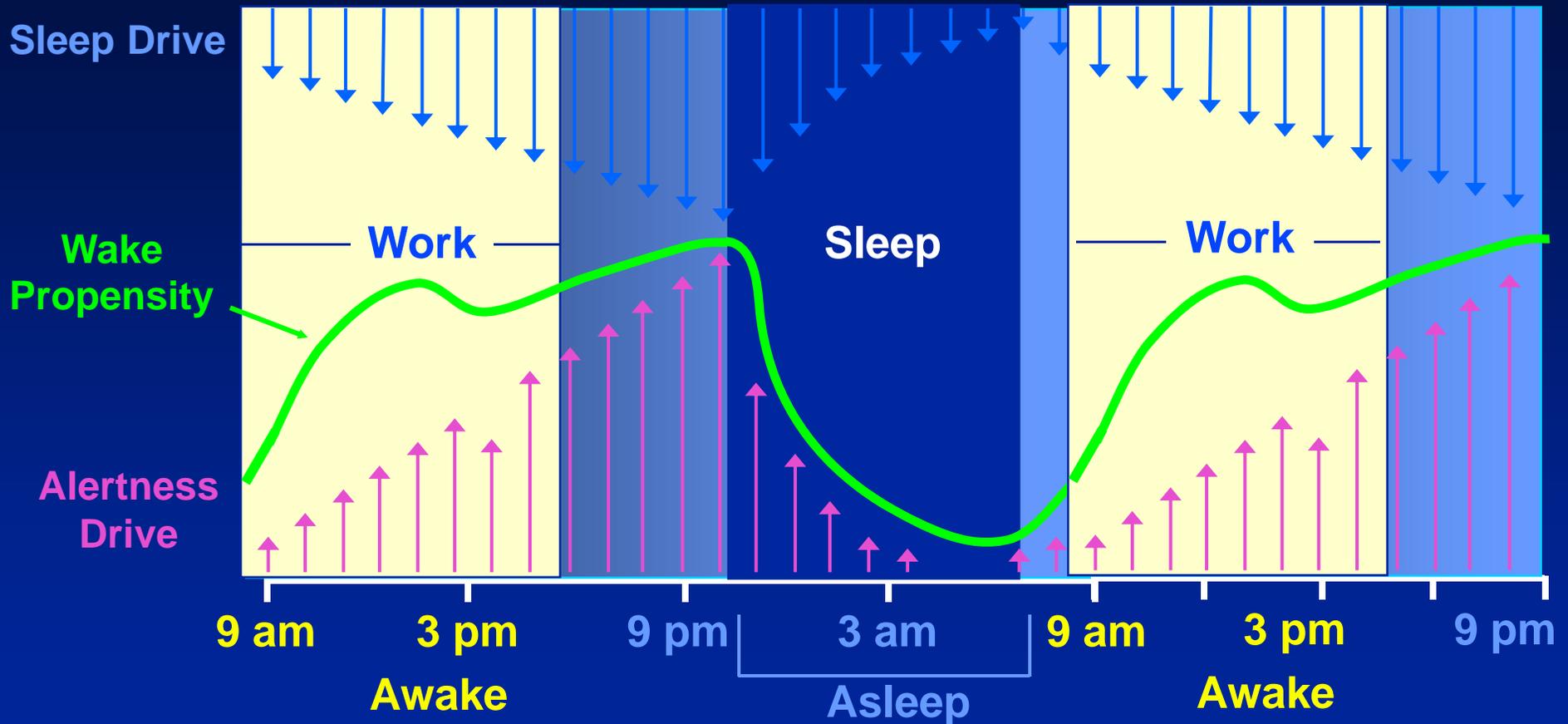
Overview: Normal Sleep

- Pressure for Slow Wave Sleep (deep sleep) is greatest
 - Growth hormone is released primarily during this stage
 - Body protects for need by entering early in sleep period
 - Will rebound markedly in recovery sleep
- REM (dream) sleep also important
 - Data supports crucial role in memory consolidation and learning
 - Early awakenings curtail REM percentage
 - Recovery sleep also demonstrates rebound
 - Stress increases need for REM
- *In fact, most recent studies indicate the need of BOTH types of sleep for optimal learning and insight*

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The Interacting Influence of Sleep Drive and Circadian Drive on Alertness



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Developmental Sleep Needs



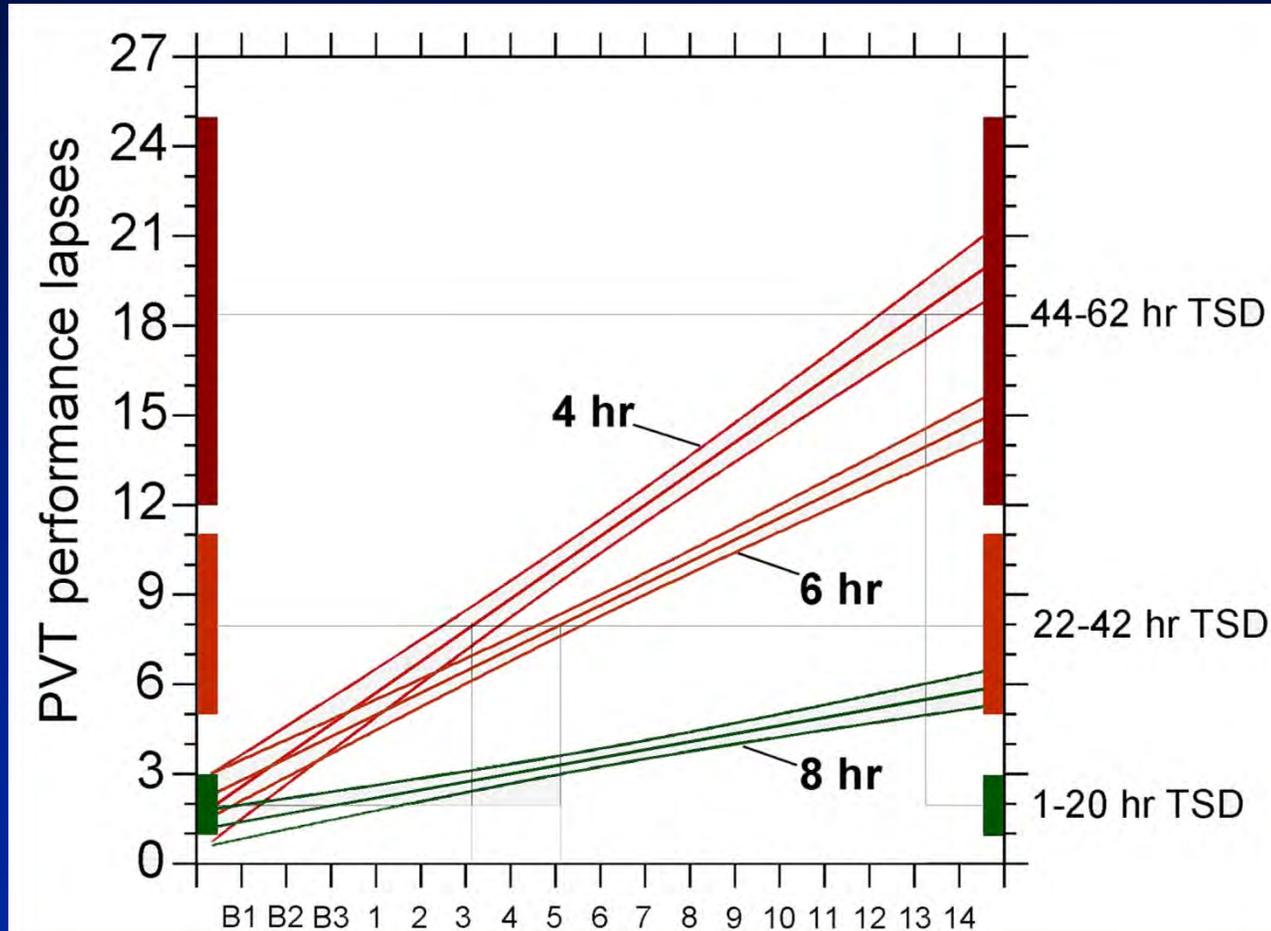
- 6 months: 13-14 hrs
- Toddlers: 12-14 hrs
- Preschooler: 11-12 hrs
- 6-7 yrs: 10-11 hrs
- 7-11 yrs: 9-10 hrs
- 12-20+ yrs: 8.5-9 hrs
- Adults 7-8 hrs



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Sleep Loss Accrues



= 2 nights without sleep

= 1 night without sleep

= 0 night without sleep

Functions of Sleep

- Learning, declarative memory and emotional processing during REM sleep
- Immune restoration and surveillance—NREM
- Body growth and maintenance—metabolic as well as somatic—NREM
- Overall executive function and well-being—REM & NREM

Sleep is primarily a physiologic process that restores both somatic and neuronal integrity—“a daily (nightly) tune up”

**What can go wrong or, what is
Insomnia?**

Insomnia

Insomnia is a *subjective complaint* (symptom) of one or more of the following:

- Inability to initiate or maintain sleep
- Inadequate sleep quality
- Insufficient amount of sleep

Cognitive-Behavioral Perspective on Insomnia

- **Predisposing factors** - personality factors, physiologic arousal, genetic predisposition, etc.
- **Precipitating factors** - situational stress, acute injury, bereavement, etc.
- **Perpetuating factors** - any form of compensatory strategies a patient used to cope with insomnia

Cognitive-Behavioral Perspective on Insomnia

Perpetuating factors

- **Behavioral** = napping, spending too much time in bed, variable schedule, ingesting caffeine or alcohol later than usual, exercising or working too late
- **Cognitive** = catastrophic thoughts, maladaptive beliefs, overblown consequences

Progression of Transient to Chronic Insomnia ("Learned Insomnia")

Transient insomnia occurs
during period of stress



Frustration
in waiting for sleep



Worry
about daytime functioning



Delayed sleep onset
disrupts sleep



**Cycle
becomes
chronic,
continuing
after
resolution
of original
stress**

Cognitive-Behavioral Treatment of Insomnia

- Most common cognitive-behavioral therapies (CBT) are:
 - Sleep hygiene education
 - Stimulus control
 - Sleep restriction
 - Relaxation therapy
 - Cognitive therapy
- Most behavioral sleep medicine clinicians use a multi-modal approach - combining the techniques above.

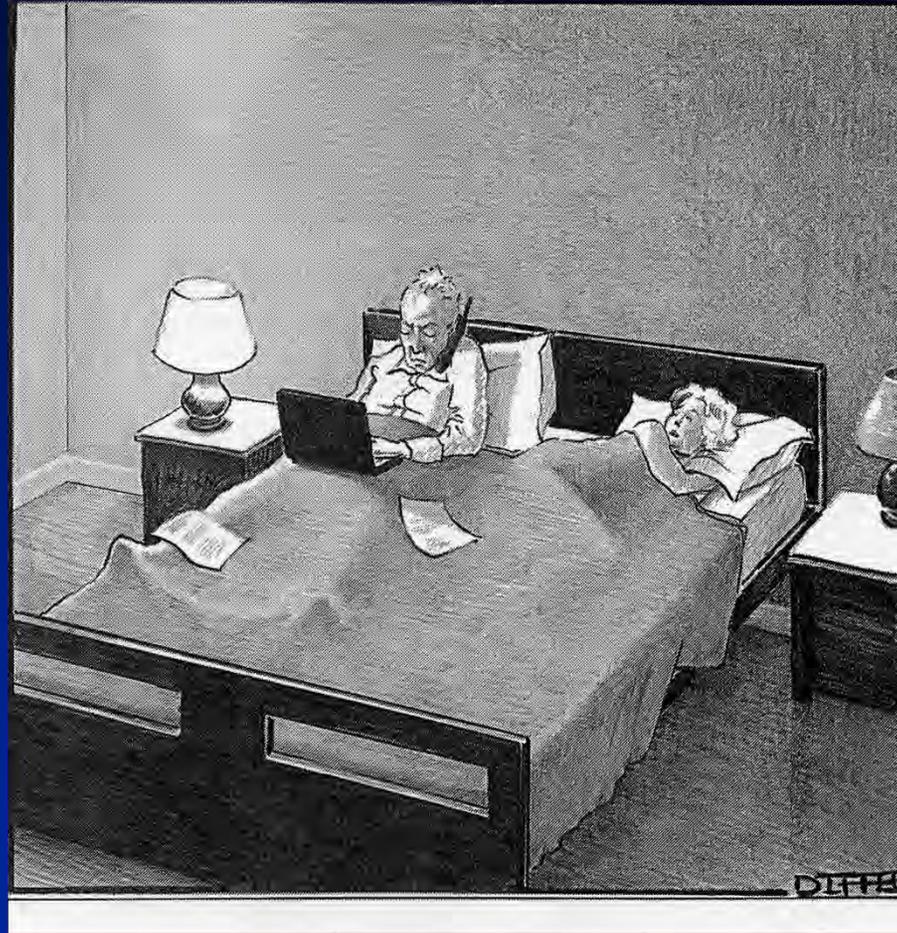
Cognitive-Behavioral Treatment of Insomnia

- Therapeutic regimen - usually therapy requires 6-8 weeks of, in most cases, face-to-face meeting with the provider. Sessions last 30-90 minutes.
- Stimulus control and sleep restriction are implemented during the first 2-3 sessions. Additional sessions are used to upwardly titrate sleep time
- Adjunctive therapies such as cognitive therapy and relaxation training occur during the balance of the sessions to help prevent relapse.

Sleep Hygiene Education

- Addresses a variety of behaviors that may influence the quality and quantity of sleep. Common suggestions include:
 - Keep regular bed and **wake** times
 - Exercise regularly
 - Make bedroom a comfortable temperature and free of noise, light, e-gizmos, especially TVs and PCs
 - Keep bedroom for sleep (sex), not work!
 - Cut down on caffeine and tobacco products
 - Avoid alcohol, especially in the evening
 - Avoid TV/radio news in evening
 - Don't go to bed hungry

Val and Sue During the Early Days



“You’re sleep-working again, dear.”

Cognitive Therapy

- Based on the observation that people with insomnia have negative thoughts and beliefs about their condition and its consequences.
- Challenging these beliefs can decrease anxiety and arousal associated with insomnia.
- Cognitive restructuring focuses on catastrophic thinking and the belief that poor sleep will have devastating consequences.
- These beliefs are challenged with evidence collected by the patient of how often these horrible consequences have occurred (not often).

Benzodiazepines/Agonists

- These agents are efficacious in the short-term management of insomnia-to prevent escalation to chronic insomnia
- Unless added behavioral management the danger is long-term need for meds
- Long-term hypnotic use efficacy needs further study
- Frequency and severity of adverse effects are much lower in the newer benzodiazepine receptor agonists (but still present!)

Relaxation Training

- Relaxation training specifically targets the physiological arousal experienced by the patient.
- Any technique (progressive muscle relaxation, deep breathing, autogenic training) with which the patient is comfortable can be used. It may need to be practiced out of bed because of 'performance anxiety'.
- Biofeedback – any technique that aids anxiety reduction (heart rate variability, galvanic skin response, skin temperature)

Insomnia Study

- Current Therapies for Insomnia
 - Chronic Insomnia affects approximately 11.76%, or 32 million of the adults in the US
 - Treatment in the real world clinic insomnia population is limited by:
 - Access to skilled clinicians who provide Cognitive Behavior Therapy
 - Successful CBT requires sustained patient motivation
 - Limited long-term efficacy of pharmacologic agents, and risks of adverse effects.
 - Need for more therapies that provide long term efficacy in patients with chronic insomnia.

Background

- Neurofeedback For Insomnia
 - Chronic Psychophysiological Insomnia is likely related to underlying hyperarousability.
 - NeurOptimal provides physiologic training independent of patient cognition or motivation.
 - Early studies in neurofeedback showed highly significant benefit for patients with insomnia, but so far this modality has not been used in standard clinical practice.

Method

■ Retrospective Analysis of Insomnia Real World Management

- Retrospective analysis of sleep logs in 18 consecutive patients diagnosed with Chronic Psychophysiologic Insomnia

→ Difficulty initiating and/or maintaining sleep on at least 4/7 nights for at least 6 consecutive months

- Standard Insomnia treatment strategies were provided: sleep restriction, stimulus control, sleep hygiene, and pharmacologic treatment as would normally occur.
- Neurofeedback sessions were provided twice weekly, 30 min. per session.

Results

Mean age: 50 ± 17 yrs, range 24-91 yrs
Gender: M- 8; F-10
sessions: 15

Sleep Aids Used:

Ambien (A), Elavil (E), Lunesta (L), Clonazepam (C),
Estazolam (S), Benadryl (B), Tylenol PM (T), Restoril
(R), OTC-over the counter sleep aid

Table 1 Participant Demographics

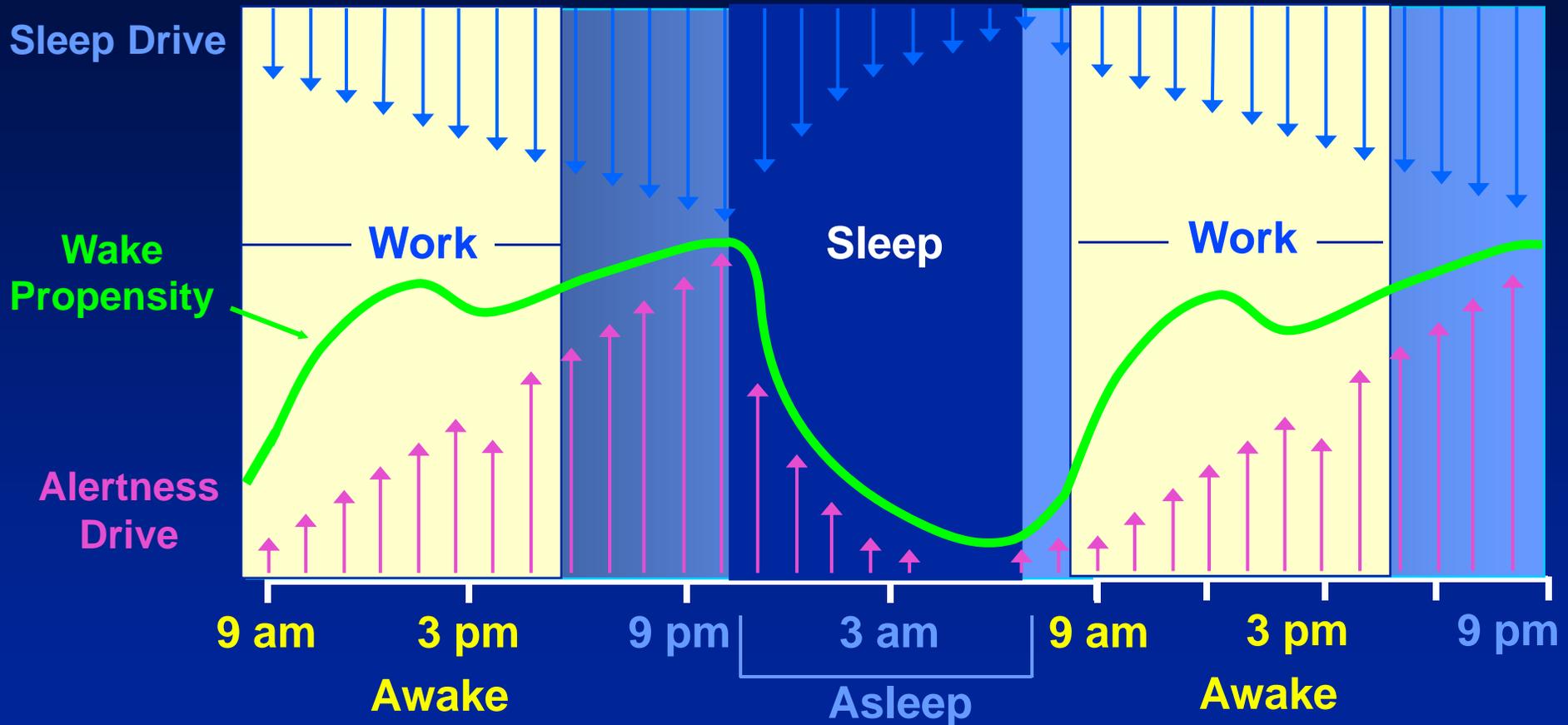
| Sub # | Age | sex | Insomnia duration (years) | Prev. Med | Curr. Med | Co-morbidity | # of NF | Sleep restriction | Sleep Hygiene | Relaxation Response | Stimulus control |
|-------|-----|-----|---------------------------|-----------|--------------|---|---------|-------------------|---------------|---------------------|------------------|
| 1 | 91 | M | 5.5 | A, E | L, R | Depression | 23 | Y | Y | Y | |
| 2 | 79 | F | >10 | A | L | PLM, OSA, hypothy. | 19 | Y | Y | | Y |
| 3 | 59 | M | 10 | A,L | L | OSA | 15 | Y | Y | Y | |
| 4 | 62 | F | 6 | A,B | C,L, S | Anxiety, Depression | 19 | Y | Y | Y | |
| 5 | 24 | F | 1 | OTC | - | Anxiety | 7 | | Y | | |
| 6 | 39 | M | 1 | - | - | - | 11 | Y | Y | Y | |
| 7 | 53 | F | 8 | L,A,B,T | - | Hypothyroid. | 4 | Y | Y | Y | |
| 8 | 51 | M | 1 | L | L(pm) | - | 6 | Y | Y | | Y |
| 9 | 39 | F | 1 | M | A, Alp | Anxiety | 15 | | Y | | Y |
| 10 | 54 | M | 30 | K,A,Zo | K,Zo | Anxiety, Panic attacks | 27 | | Y | Y | |
| 11 | 34 | F | 2 | L,A, Zo | Alp,Te | Anxiety, | 15 | | Y | | |
| 12 | 52 | M | 1 | Wellbut | A | OSA, Bruxism | 13 | | Y | Y | |
| 13 | 59 | F | 29 | L,A,E | C | Anxiety, Depression | 4 | | Y | Y | |
| 14 | 43 | F | 3+ | A,Zolof | Zolof | Anxiety | 10 | | Y | Y | |
| 15 | 46 | F | 2 | L | A | Anxiety | 5 | | Y | Y | |
| 16 | 20 | M | 8 | Xyrem | Lexa,Zy pre. | Anxiety, Depression, OCD, Lyme, Tension | 4 | | Y | | |
| 17 | 55 | M | >10 | - | Neuron | Mild OSA, RLS, PLM | 30 | | Y | | |
| 18 | 47 | M | 14 | Zolof | L | OSA | 14 | | Y | | |

Table 2.

Sleep Log Data (mean \pm SD)

| Sleep Parameters | Pre-NF | Post-NF | % Change | p value |
|------------------------------|-----------------|-----------------|----------|---------|
| Total sleep time (hrs) | 5.7 \pm 1.3 | 6.6 \pm 0.8 | +15.8.9% | <0.005 |
| Sleep efficiency (%) | 75 \pm 11 | 90 \pm 6 | + 20.0% | <0.001 |
| Wake after sleep onset (hrs) | 1.1 \pm 0.8 | 0.4 \pm 0.3 | - 63.6% | <0.001 |
| Sleep onset latency (mins) | 47.2 \pm 33.5 | 20.8 \pm 25.1 | - 55.9% | <0.005 |

The Interaction of Sleep Drive and Circadian Drive on Alertness

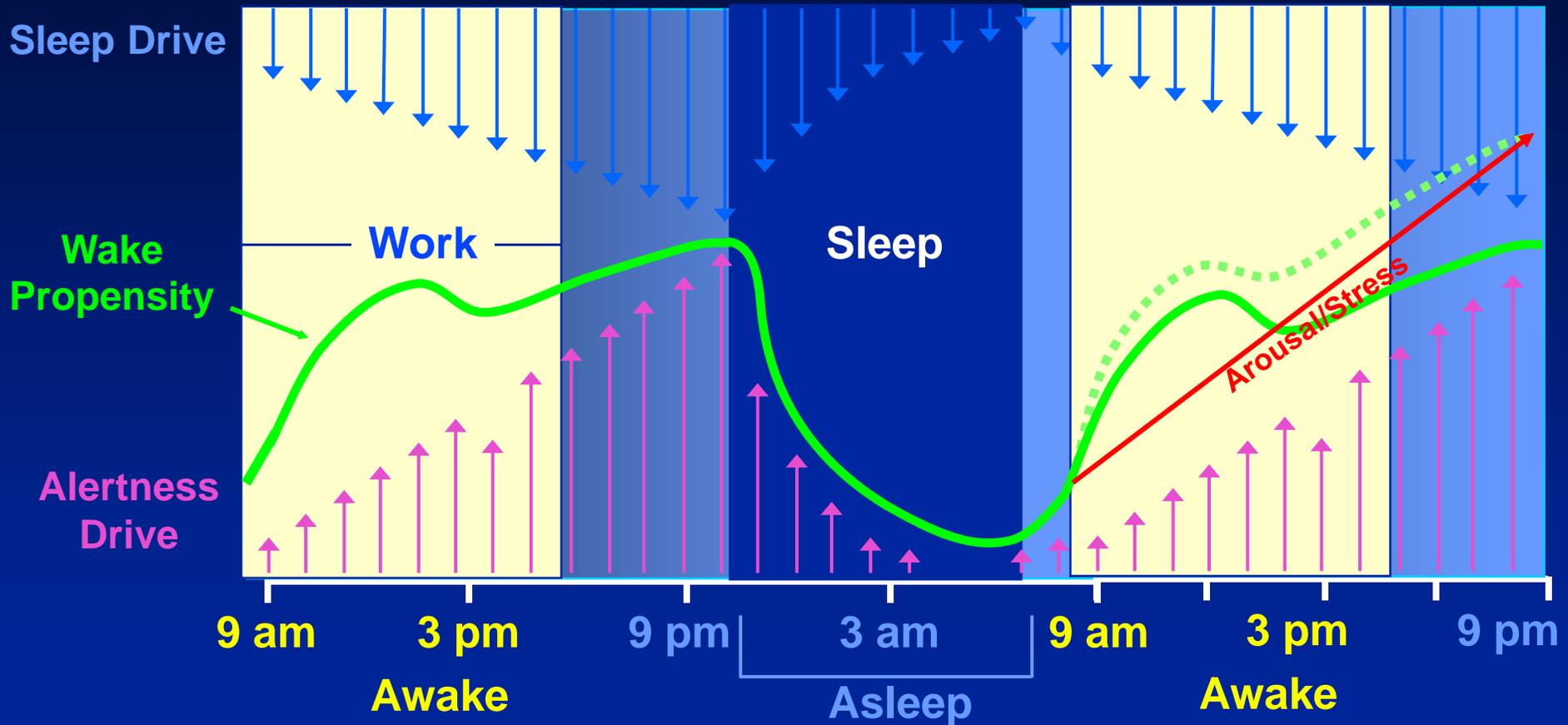


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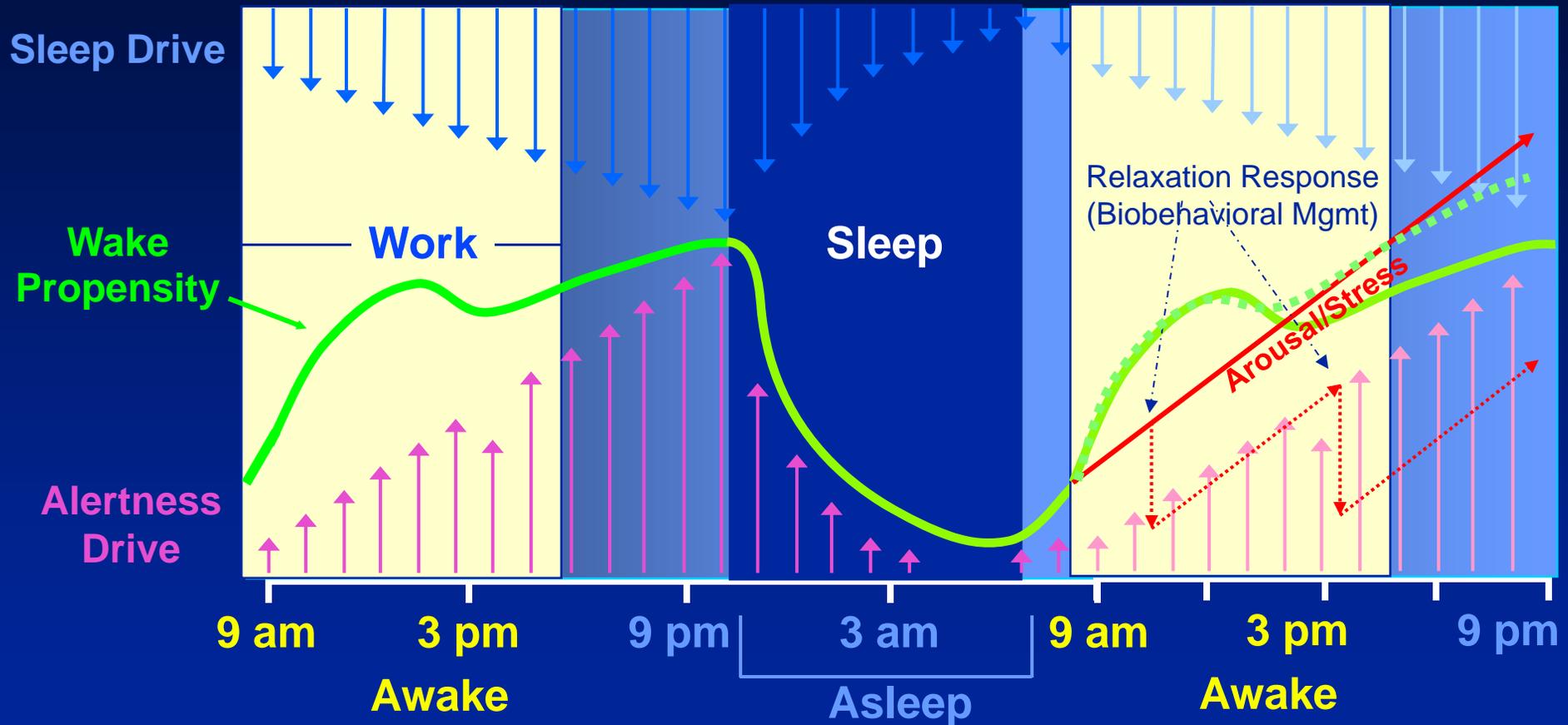
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The Impact of Arousal/Stress on Alertness



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The Impact of the Relaxation Response on Arousal/Stress and Alertness

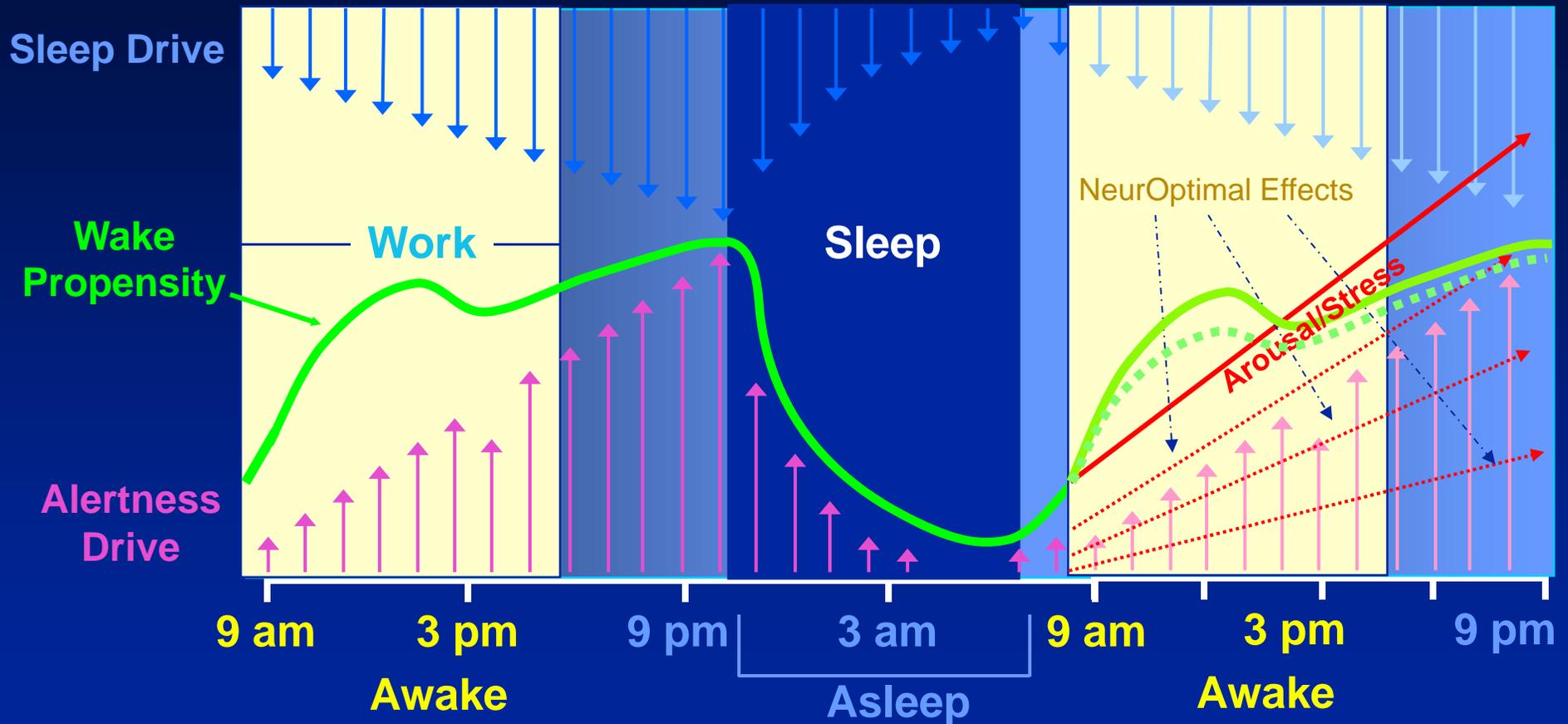


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The Effect of NeurOptimal on Arousal/Stress and Alertness

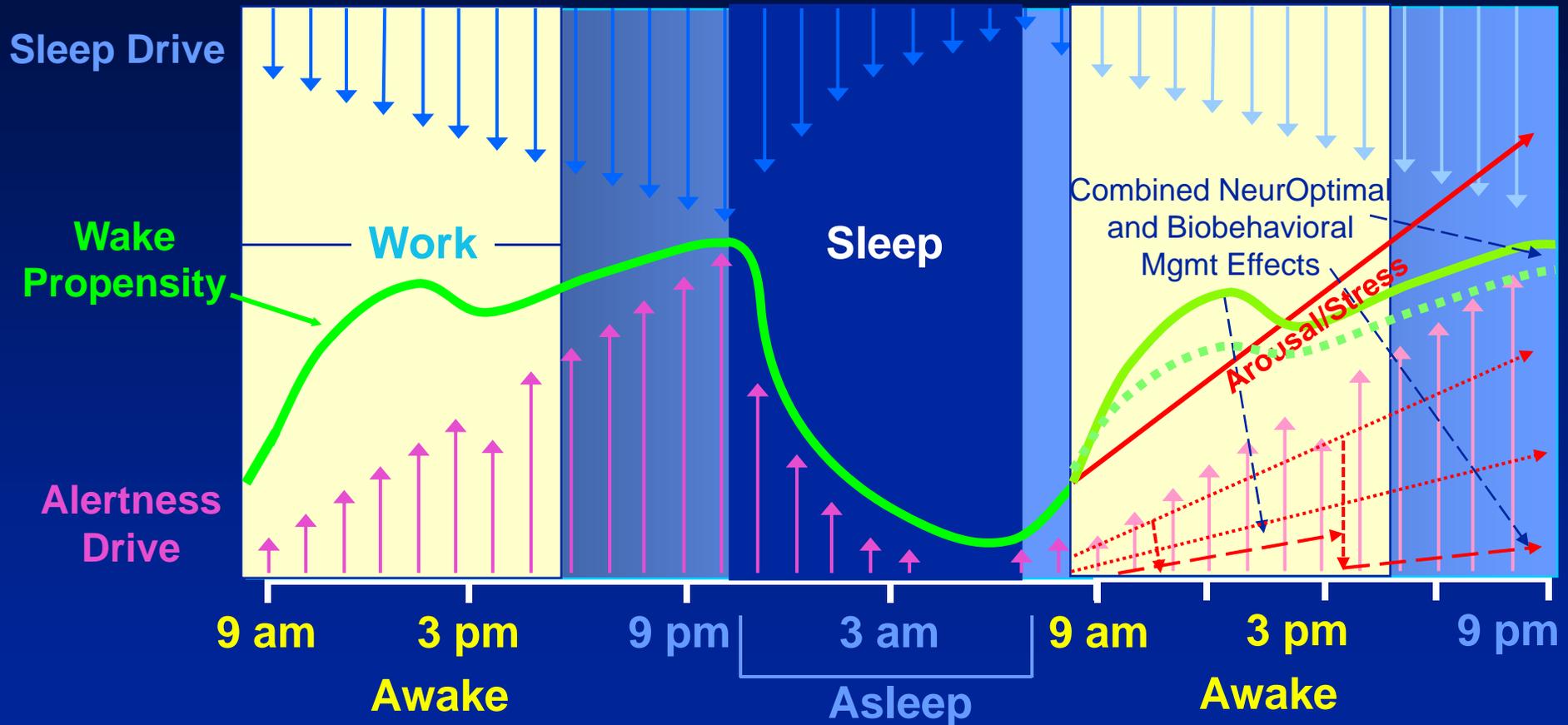


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The Combined Effects of NeurOptimal and BioBehv Mgmt on **Asl/Stress** and **Alertness**



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SUMMARY

- Sleep is an active process controlled by 3 major, interacting, drives
- Sleep need varies across the lifespan
- Chronic, partial sleep loss for any reason is cumulative and has negative consequences
- Primary Insomnia is an arousal/stress disorder
- Biobehavioral Management provides coping skills and techniques for managing extrinsic factors
- NeurOptimal training improves adherence to CBT sleep strategies, reduces physiological arousal *and improves sleep*

INNOVATION:

**Cognitive-Behavioral Therapy
for CPAP Adherence (CBT-C)**

CPAP Adherence

- No clear field standard
 - Too few studies to define amount of adherence needed to treat common sequelae
- Average patient uses CPAP about 5 hours per night
- Most clinicians generally recommend CPAP use for more than 4-5 hours per night on \geq 70% of all nights

CPAP Adherence

Average subjective use reported (based on six prospective compliance studies) was at least six hours per night BUT *objective* use was 5 ± 0.46 hours per night.

Reeves et al. Am J Respir Crit Care Med 1995; 151: 443

Kribbs et al. Am Rev Rrespir Dis 1993; 147:887

Reeves-Hoche, et al. Am j Respir Crit Care Med 1994; 149: 149

Engleman et al. Thorax 1994; 49:263

Rauscher et al. Chest 1993; 103: 1675

Meurice et al. Chest 1994; 105: 429

CPAP Adherence

- Review performed of past 50 years of adherence to ALL medical treatments
 - Lowest in sleep disorders
 - CPAP compliance: 65%
 - Overall average for all medical disorders: 75%
- Adherent patients tend to gradually increase duration of nightly CPAP use

CBT for CPAP Adherence (CBT-C)

- **Therapeutic regimen** - usually therapy requires **1-2 weeks** of face-to-face meeting with the provider. Sessions last **30-90 minutes (consider PAP-NAP)**.
- Most likely CBT-C would include:
 - **CPAP education** – already indicated
 - **Stimulus control** – decrease negative associations
 - **Sleep restriction** – increase Sleep Pressure
 - **Cognitive therapy** – change negative cognitions
 - **Relaxation therapy** – enhanced desensitization
- New CBT-C to include:
 - **NeuroOptimal/Biofeedback**

CBT-C ---What we have seen

- **Therapeutic regimen** - usually therapy requires **2-4 weeks** of face-to-face meeting with the provider. Sessions last **30-90 minutes (consider PAP nap)**.
- CBT-C includes:
 - CPAP education – already indicated
 - Stimulus control – decrease negative associations
 - Sleep restriction – increase Sleep Pressure
 - **Cognitive therapy – change negative cognitions**
 - Relaxation therapy – enhanced desensitization
- **New CBT-C includes:**
 - **NeuroOptimal while using CPAP**