

Intensive Sleep Retraining: Conditioning Treatment for Primary Insomnia

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PROTOCOL NAME

Intensive Sleep Retraining (ISR): conditioning treatment for primary insomnia.

GROSS INDICATION

This is indicated for chronic primary (psychophysiologic) insomnia, with evidence of conditioning (learned insomnia) and/or behavioral contributors or maintaining factors.

SPECIFIC INDICATION

Initial data indicate that this treatment is effective for those with sleep onset, or sleep onset and maintenance insomnia. However, there is some support for a greater treatment effect with sleep onset difficulties.

CONTRAINDICATIONS

Specific contraindications include patients with a particular susceptibility to sleep deprivation (e.g., epilepsy or seizure disorders, bipolar disorder).

ISR treatment has to date only been applied to a carefully selected subsection of insomnia sufferers, with no evaluation of effectiveness for early morning awakening insomnia, circadian rhythm disturbances, or so-called “secondary” insomnia. However, if we assume that these co-morbid disorders may involve some conditioning factors in the sleep disturbance, ISR may prove to be applicable to a wider range of insomnia presentations.

RATIONALE FOR INTERVENTION

Conditioning factors are proposed to be involved in the precipitation and perpetuation of chronic insomnia. Learning theory suggests that insomnia may be a “learned” arousal or wakefulness response, or alternatively may be a “learned” absence of de-arousal associated with internal and external cues for sleep [1]. As such, the cues to produce a sleep-conducive state, and to aid the subsequent sleep experience, may then be less effective or absent.

Traditional behavioral therapies for insomnia often involve a gradual build-up of sleep debt in early weeks of treatment application, a heightened homeostatic drive that gradually enables more and more experiences of shorter sleep onsets at night. Rapid sleep onsets, occurring at increasing frequency with time, are thought to condition sleep-conducive cues in the bedroom environment.

ISR is proposed to act by using an acutely increased homeostatic drive to facilitate rapid sleep onsets in a series of sleep opportunities in a single treatment session. Thereby, conditioning treatment, as might occur with traditional behavioral therapies such as Stimulus Control Therapy (SCT [2]) and Sleep Restriction Therapy (SRT [3]), is applied in a shorter time frame.

STEP BY STEP DESCRIPTION OF PROCEDURES

The following procedures are a description of the ISR treatment that has been used in the research to date.

1. *Treatment preparation.* A pre-treatment night of sleep restriction allows an initial build-up of sleep pressure. This is set at a period of 5 hours time in bed, independent of sleep time, using an alarm to awaken. In addition, naps and caffeine are avoided in the 24 hours prior to treatment start.
2. *Treatment.*
 - a. Treatment occurs in the sleep laboratory in order to enable EEG sleep onset monitoring. Arrival in the laboratory is followed by the application of relevant EEG (C3-A2, C4-A1, O1-A2), EOG and EMG electrodes as per a standard 10–20 system.
 - b. Treatment “sleep trials” begin at 10:30 pm on night 1 of treatment.
 - c. A “sleep trial” involves the treatment recipient getting into bed in order to attempt to initiate sleep in a laboratory bedroom-simulation environment. (It may be advantageous to mimic the home environment as closely as possible, including bringing personal pillows, bedding, pyjamas, etc.).
 - d. Once settled in bed, just prior to a sleep trial start, an assessment of subjective sleepiness (Stanford Sleepiness Scale; SSS [4]) is completed.
 - e. The half-hourly sleep trials start with lights out, and an instruction to “get comfortable, lie still and allow yourself to fall asleep”, after which time the bedroom lights are extinguished.

- f. EEG monitoring in the adjacent sleep laboratory area allows measurement of sleep onset latency (SOL), and restriction of the amount of sleep obtained in any nap opportunity. Participants are awoken following 3 consecutive minutes of (any stage of) sleep, if obtained within each 20-minute nap opportunity.
 - g. Following each sleep trial, participants are asked whether they experienced and recognized sleep within the sleep trial. Feedback is then provided as to whether sleep was obtained according to the EEG, in order to facilitate some sleep–wake discrimination training. This is consistent with research data suggesting that individuals with insomnia are prone to report prior wakefulness following an awakening from sleep, and that feedback about sleep state may improve sleep in insomnia sufferers [5].
 - h. Following the end of each sleep trial treatment, recipients get out of bed and maintain quiet wakeful activities (i.e. reading, watching DVDs). Wakefulness is corroborated by on-line EEG. The laboratory remains a “time-free” environment throughout treatment.
 - i. Half-hourly trials are held throughout a 25-hour treatment period, resulting in a total of 50 opportunities to initiate sleep under sleep deprivation conditions.
3. *Post-treatment.*
- a. A post-treatment recovery sleep is limited to a period of 8 hours in bed in order to maintain circadian rhythmicity, and encourage the maintenance of some homeostatic sleep drive to encourage ongoing treatment response.
 - b. Daily sleep diaries are completed throughout the 2 weeks prior to treatment, and for at least 6 weeks immediately following ISR.

POSSIBLE MODIFICATIONS/VARIANTS

1. Research indicates that ISR, although rapidly efficacious on its own, tends to be more consistently effective when combined with follow-up Stimulus Control Therapy (SCT). This treatment may then alter some of the previously maintaining factors in patients’ insomnia – for instance, spending excessive amounts of time in bed. SCT has been implemented on the first post-ISR treatment day, with a series of five weekly sessions with a clinical psychologist.
2. One case series pilot study attempted to implement this conditioning treatment for a period of 36 hours, starting at 10:30 am [6]. However, sleep onsets were less likely to be obtained within the first treatment day, and the routine was therefore altered in future trials. To date, there is little evidence regarding the number of sleep trials or sleep onsets required for effective treatment.
3. Future research will attempt to examine the “type” of insomnia, and the sleep and psychological profiles of participants most likely to benefit from ISR treatment. For instance, there has been a trend for a greater treatment

effect with sleep onset disturbance over sleep maintenance difficulties. However, larger-scale investigations will need to be completed before these trends can be confirmed.

PROOF OF CONCEPT/SUPPORTING DATA/EVIDENCE BASE

The largest study to date of ISR was a randomized controlled trial involving 79 participants with chronic sleep onset insomnia (with or without sleep maintenance insomnia) [7]. Treatment groups were ISR, SCT, ISR plus SCT, and a sleep hygiene control (concurrently administered in other treatment groups). ISR was administered in a weekend treatment period, followed up with five weekly treatment sessions. Figure 13.1 illustrates the average heightened sleepiness levels and decreased sleep onset latencies across the 25-hour treatment period.

Figure 13.2 illustrates the effect of ISR on immediate mean post-treatment (daily) sleep variables of total sleep time and sleep onset latency in a pilot study. There is evidence of rapid and significant changes in these variables.

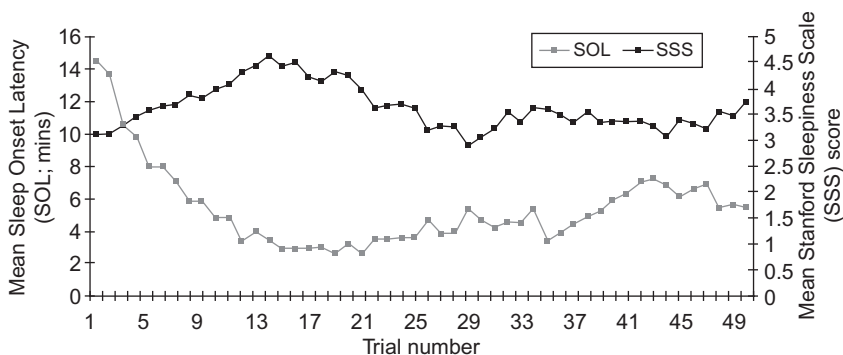


FIGURE 13.1 Mean Sleep Onset Latency (SOL) and Stanford Sleepiness Scale (SSS) scores at each sleep trial time throughout the ISR treatment procedure ($n = 39$).

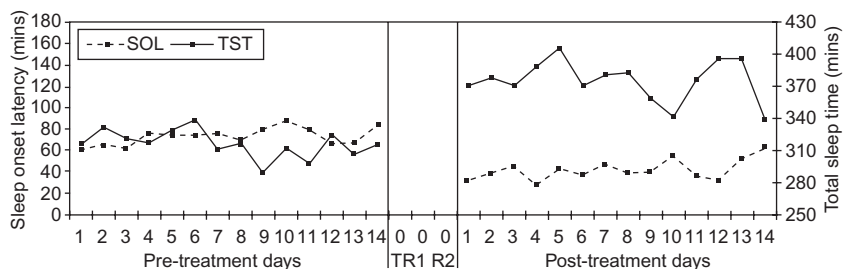


FIGURE 13.2 Mean daily Sleep Onset Latency (SOL) and Total Sleep Time (TST) immediately prior to, and following ISR T (treatment), R1 (recovery night 1) and R2 (recovery night 2). $N = 17$, ISR administered in isolation [8].

In the most recent larger RCT study, the active treatment groups (ISR, SCT, ISR + SCT) all resulted in significant improvements in sleep diary sleep onset latency and sleep efficiency, with moderate to large effect sizes, from pre-treatment to post-treatment. Wake time after sleep onset decreased significantly in the SCT and ISR + SCT groups. Total sleep time increased significantly in the ISR and ISR + SCT treatment groups. There were few statistically significant differences between active treatment groups, indicating a comparable treatment response.

In this largest trial, ISR was implemented with follow-up sleep hygiene recommendations addressing caffeine and other stimulants, exercise, alcohol, the bedroom environment, and a “wind-down” time prior to sleep. These instructions, also applied as a control treatment, showed little independent treatment effect. However, it has been suggested that the effectiveness of CBT treatments may be threatened if these factors are not concurrently addressed.

Trends indicated that the combination ISR+SCT group demonstrated the largest effect sizes for both sleep and daytime functioning variables, and resulted in a greater proportion of treatment responders, with 61 percent reaching “good sleeper” status (vs 38 percent with SCT, and 47 percent with ISR alone). Subjective (sleep diary) treatment gains achieved by post-treatment in the active treatment groups were largely maintained throughout follow up periods, up to 6 months.

In conclusion, Intensive Sleep Retraining is a brief, laboratory-based, conditioning treatment for chronic sleep onset insomnia, which results in very rapid improvements in sleep variables. The ISR treatment response seems to be comparable to other traditional behavioral therapies, and when used in combination may speed up and enhance the response to these therapies.

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