

## Circadian phase tailored light therapy in primary chronic insomnia. A randomised control trial study

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**Background:** Although insomnia and circadian rhythm disorders are distinctive diseases, extreme chronotypes and desynchronised circadian phase may contribute to insomnia disorder pathophysiology. Our study aims to investigate the effects of a tailored light therapy protocol on sleep and mood parameters in patients with primary chronic insomnia (PCI).

**Methods:** Twenty-four drug-free PCI patients (M/F: 7/9; mean age 49.06 (11.86) years) were investigated for subclinical mood related symptoms (STAY, Beck, Fatigue severity scale), subjective chronotype (MEQ), subjective nocturnal sleep parameters (PSQI, ISI, SCI), 7-day/night actigraphy and circadian phase (by in-home salivary Dim Light). The measurements were compared before and after a single-blind 5-weeks tailored light therapy versus sham protocol (Luminette/Sham group: 12/12 patients).

**Results:** Sixteen patients completed the protocol (Luminette/Sham: 8/8 patients). In Luminette group 43% patients showed a DLMO time shift in accordance to light delivery time.

Sham group failed to present an analogous shift. In Luminette group sleep efficiency (SE) remained stable after active light treatment with respect to pre treatment condition (SE pre median 84.95% [76.25-88.59], SE post mean 85.12%  $\pm$  3.76) while in the Sham group it showed a decremental trend (SE pre median 85.78% [77.25-89.5], SE post mean 81.22%  $\pm$  7.91). Insomnia severity index (ISI) mean score improved nearly significantly in the Luminette group (pre mean 16.38 $\pm$ 5.48, post mean 11.5 $\pm$ 6.05) but not in the sham group. Anxiety (STAY mean score) significantly improved in the Luminette group (pre mean 42.14 $\pm$ 14.08, post mean 35.88 $\pm$ 12.67), while remained stable in the sham group.

**Conclusions:** Light therapy protocol tailored on the circadian phase proved to improve both sleep and mood in drug-free patients with primary chronic insomnia.