

Title. Is restriction of time in bed central to the efficacy of sleep restriction therapy for insomnia? results from a randomised, controlled, dismantling trial comparing sleep restriction with bedtime consistency

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Introduction. Sleep restriction therapy (SRT) is considered to be the chief ingredient of CBT for insomnia yet it remains unclear how this component exerts its therapeutic effects. Theoretical models posit that mild sleep deprivation, created by time in bed reduction, is needed to overcome arousal, obviate sleep effort and enhance the consolidation and predictability of sleep. To isolate the role of time in bed restriction we specifically designed a trial to compare SRT with a novel intervention, called 'Bedtime consistency therapy' (BCT), which involves prescription and monitoring of a regular - but not restricted - time in bed.

Materials and methods. Fifty-six participants (17 male, mean age = 41.11 ± 9.08) with insomnia disorder were randomised to four weeks of SRT (n = 27) or BCT (n = 29). Treatment arms were matched for therapist time and number of sessions. The primary outcome, insomnia severity, was obtained by the Insomnia severity index (ISI) at baseline, 4 (post-treatment) and 12 weeks post-randomisation. Secondary outcomes included quality of life (measured by the Glasgow sleep impact index; GSII), depression and anxiety (measured by the hospital anxiety and depression scale; HADS) and cognitive complaints (measured by the British Columbia cognitive complaints Inventory; BC-CCI). Sleep continuity variables were assessed continuously during baseline (2 weeks) and treatment (4 weeks) through sleep diary and actigraphy. A linear mixed effects regression model was fitted with outcomes at 4 and 12 weeks for questionnaire measures, and early (weeks 1-2) and late (week 3-4) treatment for continuous diary and actigraphy measurement. Linear mixed-model analyses were conducted with fixed

effects of time and group. Random effects were run to account for between-subject variation and centred baseline was included as covariate.

Results. Average time in bed during the entire treatment phase was significantly lower in the SRT group (427 ± 63.5 min) compared to the BCT group (499 ± 61.4 min, $p < .001$). Analysis of the ISI revealed a significant group difference at both 4 ($p < .005$) and 12 ($p < .005$) weeks. The estimated adjusted mean difference was -3.51 (95% CI: $-5.6, -1.43$) and -3.37 (95% CI: $-5.46, -1.29$) respectively, indicating that participants in the SRT group reported lower levels of insomnia severity at 4 (SRT: 7.65 ± 3.22 , BCT: 11.2 ± 4.86) and 12 weeks (SRT: 6.5 ± 4.01 , BCT: 9.9 ± 7.72). Significant between-group differences were also found at 12 weeks for sleep-related quality of life, in favour of SRT ($p < .005$). No group differences were observed for cognitive complaints, anxiety or depression. Diary-reported sleep onset latency was significantly lower in the SRT group versus BCT at late treatment ($p < .05$), and for wake-time after sleep onset during both early and late treatment ($p < .05$). Superiority of SRT over BCT was also supported by actigraphic measures of sleep initiation ($p < .05$) and maintenance ($p < .05$).

Conclusions. We systematically show that time in bed restriction demonstrates superior efficacy to bedtime consistency in isolation. Our results underscore the centrality of the bedtime restriction component to SRT and pave the way for future analyses of mechanism of action.