BMJ Open Supplementary Material 1

SPIRIT Item2b: WHO Trial Registration Data Set

Data Category	Information
Primary registry and trial identifying number	Australian New Zealand Clinical Trial Registry https://www.anzctr.org.au Trial ID: ACTRN12620001080910
Date of registration in primary registry	20 October 2020
Secondary identifying numbers	2019/552
Source(s) of monetary or material support	School of Psychology, The University of Sydney
Primary sponsor	The University of Sydney
Secondary sponsor(s)	N/A
Contact for public queries	A/Prof Ben Colagiuri PhD, +61 2 9351 4589, ben.colagiuri@sydney.edu.au
Contact for scientific queries	A/Prof Ben Colagiuri PhD, +61 2 9351 4589, ben.colagiuri@sydney.edu.au
Public Title	Open-label placebo for insomnia (OPIN)
Scientific Title	Open-label placebo for insomnia (OPIN): a cohort multiple randomised controlled trial in adults with moderate or severe insomnia
Countries of recruitment	Australia

Health condition(s) or problem(s) studied	Insomnia
Intervention(s)	Active comparator: open-label placebo (OLP) capsules Placebo comparator: conventional (deceptive) placebo (CP) capsules
Key inclusion and exclusion criteria	Inclusion criteria: adult (≥ 18 years), self-reported insomnia symptoms with score on Insomnia Severity Index (ISI) ≥ 10 Exclusion criteria: sleep disorder other an insomnia, severe medical or psychiatric comorbidity, current regular (≥ 1/week) administration of sleep medication, current psychological treatment for sleep, currently pregnant, planning to conceive within 3 months, breastfeeding or 1-year post-partum, regular night shift work
Study type	Cohort multiple randomised controlled trial Allocation: randomised Intervention model: parallel assignment Masking: Open-label placebo arm (both participant and investigator are aware of treatment allocation, conventional placebo arm (participant is blind but investigator aware of treatment allocation) Primary purpose: Intervention outcome
Date of first enrolment	
Target sample size	267
Recruitment status	Not yet recruiting

Primary outcome(s)	Determine whether OLP is associated with reductions in self-reported insomnia symptoms measured with the Insomnia Severity Index (ISI), compared to CP and no treatment.
Key secondary outcomes	Improvements in objective and subjective sleep parameters, daytime fatigue, anxiety, depression and stress, expectancy, treatment satisfaction and self-reported side effects; clinically significant improvements in insomnia in OLP, relative to CP and no treatment; rate of uptake of OLP relative to CP; predictors of uptake and placebo effect