

Moderate Trial

Eligibility Criteria:

(a) Inclusion criteria

1. Males & Females aged 18-70 years.
2. Able to give informed written consent.
3. Literacy in English.
4. Symptoms of Insomnia Disorder as diagnosed by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria for Insomnia Disorder specifically: Difficulty initiating or maintaining sleep or waking up too early for at least 3 nights per week, for at least 3 months, with adequate opportunity and circumstances for sleep and at least one daytime impairment related to the sleep difficulty.¹ Assessed by telephone screening interview.²
5. Insomnia Severity Index scale scores of 15 or more.³
6. Never previously treated with CBT-I or Armodafinil.
7. At least one month hypnotic free and willing to not take hypnotics for the duration of the trial.
8. Female patients with the ability to fall pregnant must use a medically accepted method of barrier contraception throughout the 14 weeks of the study.

Moderate trial

Exclusion criteria

1. Pregnancy or lactation - during the face-to-face screening visit the patients will be asked by a medical practitioner whether they are breastfeeding or whether there is any chance they could be pregnant (see also inclusion criteria #8). If patients are not well established in their use of medically acceptable contraception in the opinion of the medical practitioner then the participant will be asked undertake a urine based pregnancy test to rule out pregnancy. The investigators will provide the urine-based test kit to the potential participant.
2. Patients with moderate-severe skin allergies and/or eczema. Any history of clinically significant cutaneous drug reaction or a history of clinically significant hypersensitivity reaction, including multiple allergies or drug reactions.
3. Past or present seizure disorder; a history of psychosis, depression or mania; current mood disorder; or a clinically significant head trauma (eg, brain damage).
4. History of a suicidal ideation, or a history of a suicide attempt, or is currently a suicidal risk.
5. History of significant aggression or violence or exhibits homicidal ideation or violent intentions.
6. Active, clinically significant gastrointestinal, cardiovascular, hepatic, renal, hematologic, neoplastic, endocrine, neurologic, immunodeficiency, pulmonary, dermatologic, or other major clinically significant disorder/disease.
7. Any history of left ventricular hypertrophy or mitral valve prolapse.
8. A clinically significant deviation from normal in ECG, physical examination, or vital sign.
9. Use of any medication known to induce metabolism via cytochrome P450 system (CYP450) 3A4/5 within 14 days prior to the baseline visit.
10. Use of any medication known to interact with Armodafinil within 5 half lives of the baseline visit.
11. Shift workers who rotate to night shift.
12. Drug addiction or alcoholism.
13. Severe unstable Psychiatric disorders.
14. Sleep disorders (other than untreated insomnia) and an apnea-hypopnea index >15 if suspected for sleep apnea.
15. Severe cognitive impairment that does not allow patients to consent or follow treatment instructions.
16. Recent time-zone travel (within last 1 month).
17. Any other conditions that contraindicate Armodafinil or SRT in the opinion of the Principal Investigator (Medical Practitioner).
 - a. Liver function tests exceeding the 95% confidence limits of normal which in the opinion of the medical PI contraindicate armodafinil