Supplementary File 2. World Health Organisation Trial Registration Data Set	
Primary registry and trial identifying number	Australian and New Zealand Clinical Trials Registry (ANZCTRN12619000714189)
Secondary identifying numbers	UTN: U1111-1231-0849
Date of registration in primary registry	13 May, 2019
Source(s) of monetary or material support	The Lambert Initiative for Cannabinoid Therapeutics, The University of Sydney
Primary sponsor	The Woolcock Institute of Medical Research 431 Glebe Point Road Glebe NSW 2037 Australia
Contact for public queries	Miss Anastasia Suraev (cansleep@woolcock.org.au)
Contact for scientific queries	Dr Camilla Hoyos (camilla.hoyos@sydney.edu.au)
Public title	A single-dose, double-blind, placebo-controlled, randomised, crossover study of an oral cannabis-based medicine (ETC120) on sleep, cognition, and next-day function in adults with chronic insomnia disorder
Scientific title	A single-dose, double-blind, placebo-controlled, randomised, crossover study of an oral cannabis-based medicine (ETC120) on sleep quality and quantity in adults with chronic insomnia disorder
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Insomnia disorder
Intervention(s)	*Active comparator*: oral solution containing 10 mg Δ_9-tetrahydrocannabinol (THC) and 200 mg cannabidiol (CBD) in medium-chain triglycerides (MCT) oil
	Placebo comparator: matching oil solution containing no active ingredients
Key inclusion and exclusion criteria	*Ages eligible for study*: 35 to 60 years inclusive *Sexes eligible for study*: Both *Accepts healthy volunteers*: No
	Inclusion criteria: Adult patient (35 to 60 years) diagnosed with chronic insomnia disorder

	Exclusion criteria: Shift worker, medical condition or medication that is the cause of the insomnia (including other sleep disorder), use of any modality of treatment for insomnia including CBT in the past 3 months, history of drug and alcohol abuse/dependency, history of major psychiatric disorder except clinically managed depression.
Study type	Interventional *Allocation*: randomized controlled trial. Crossover: double blind (participant, investigator, outcomes assessor) *Primary purpose*: Treatment Phase I/Phase 2
Date of first enrolment	August 2019
Target sample size	20
Recruitment status	Recruiting
Primary outcome(s)	Change in total sleep time (TST) and wake after sleep onset (WASO) measured in minutes from in-laboratory overnight PSG
Key secondary outcomes	Sleep microarchitecture metric measured using high-density EEG and source modelling; next-day neurobehavioural functioning (including cognition, alertness and simulated driving performance)