A Randomized Controlled Trial Investigating the Effects of a Special Extract of Bacopa monnieri (CDRI 08) on Hyperactivity and Inattention in Male Children and Adolescents: BACHI Study Protocol (ANZCTR12612000827831).


Abstract
Clinical diagnoses of Attention Deficit Hyperactivity Disorder (ADHD) and the use of prescription medications for its treatment have increased in recent years. Current treatments may involve the administration of amphetamine-type substances, a treatment path many parents are apprehensive to take. Therefore, alternative pharmacological treatments are required. Few nutritional or pharmacological alternatives that reduce ADHD associated symptoms (hyperactivity and inattention) have been subjected to rigorous clinical trials. Bacopa monnieri is a perennial creeping herb. CDRI 08 is a special extract of Bacopa monnieri which has been subjected to hundreds of scientific studies and has been shown in human randomized controlled trials (RCTs) to improve memory, attention, and mood. It is hypothesised that chronic administration of CDRI 08 will improve attention, concentration and behaviour in children with high levels of hyperactivity and/or inattention. This paper reports the protocol for the first 16-week, randomized, placebo-controlled, double-blind, parallel groups trial examining the efficacy and safety of CDRI 08 in male children aged 6-14 years with high levels of inattention and hyperactivity. The primary outcome variable will be the level of hyperactivity and inattention measured by the Conners' Parent Rating Scale (CPRS). Secondary outcome variables include cognition, mood, sleep, and EEG.

TRIAL REGISTRATION:
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