

Study protocol for the cannabidiol youth anxiety pilot study (CAPS): A 12-week open label pilot study of cannabidiol for anxiety disorders

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Background Affecting up to 15% of youth, anxiety disorders are among the most prevalent psychiatric conditions in adolescents [1]. Current evidence-based treatments for anxiety disorders in this age group include cognitive behaviour therapy (CBT) and/or medication. However, treatment resistance is a significant problem in children and adolescents with anxiety. Based on the most recent meta-analytic evaluations, only around 50% of children and adolescents remit from their anxiety disorders with CBT or pharmacological intervention [2, 3]. Therefore, there is a clear need to develop and explore novel therapeutic agents for the management of anxiety disorders in this age group. The aim of the present study is to test the feasibility, safety, tolerability and therapeutic effects of 12-week treatment with cannabidiol (CBD) to reduce anxiety severity in young people who do not respond to standard treatment.

Methods This is a single-centre, 12-week open label trial of CBD in patients (n=30) aged 12-25 (inclusive) who do not respond to evidence-based standard treatment for anxiety disorders (i.e., CBT or CBT plus SSRIs/SSNRIs). All patients included into the study will receive CBD on a fixed-flexible schedule, beginning with 200mg of CBD per day, which can be adjusted up to 800mg/day for participants who tolerate CBD. A background intervention of bi-weekly CBT sessions will be offered to all participants. The primary outcome is anxiety severity, measured with the Overall Anxiety Severity and Impact Scale (OASIS), at week 12. Secondary outcomes will include absence of an anxiety disorder diagnosis, depressive symptoms, social and occupational functioning, plasma levels of CBD and its metabolites and study withdrawal due to adverse events. The trial will be conducted at federally funded youth mental health services (headspace). (ANZCTR identifier: ACTRN12617000825358p)

Conclusions Data from this study will provide the first evidence of the potential safety, tolerability and efficacy of CBD for anxiety disorders in youth. Results from this study will be used to inform further evaluations of CBD for anxiety disorders in larger studies.

References

1. AIHW (2011) Young Australians: their health and wellbeing. Australian Institute of Health and Welfare (AIHW): Canberra, pp 1-262.
2. James *et al.* (2015) *The Cochrane Database of Systematic Reviews* **18**;(2): CD004690.
3. Strawn *et al.* (2015) *Depress Anxiety* **32**