



Rt Hon Matt Hancock MP
Secretary of State
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

13 May 2021

Dear Matt Hancock

I am writing on behalf of Drug Science and the parents of 21 children with severe treatment resistant epilepsy who are currently getting significant respite from medical cannabis.

This letter details the recent analysis we have conducted that reveals the remarkable efficacy of this medication.

Given that the parents are currently being forced to pay an unsustainable amount of personal money each month (in excess of £1200 per month), we ask that you use these findings to facilitate access to this highly effective treatment on the NHS.

Yours truly,

A handwritten signature in purple ink, appearing to be "David Nutt", written over a horizontal line.

Prof David Nutt DM FRCP FRCPsych FMedSci DLaws
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Chair Drug Science

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The study and findings [a full report available if required]

We assessed a case-series of 21 of patients using Bayesian analysis to determine effectiveness and likelihood of successful outcome in individuals using whole-plant cannabis medicines to treat their conditions.

This was a retrospective, open-label study using reports from carers and clinicians involved in the management of the children's care. We investigated how treatment with whole-plant medical cannabis has led to changes in seizure frequency, anti-epileptic drug (AEDs) use, psychiatric and behavioural morbidities, cost and other demographic details. We also documented doses of CBD and THC in each.

The primary objective was to assess the impact of this treatment on seizure frequency, and we use a Bayesian statistical model to predict likelihood of effective treatment in similar patient groups. The study was approved by Imperial College Research Ethics Committee (20IC5830 ICREC Committee (01/05/2020).

Findings

From the 21 patients enrolled in the study there was an 84% reduction in seizure frequency across the cohort with no significant adverse events. We also showed a reduction in the use of AEDs from seven to one following initiation of treatment. Our Bayesian analysis indicated a 96% likelihood of successful treatment response, defined by a significant reduction in seizure frequency in patients with similar aetiologies.

Interpretation

Whole-plant medical cannabis products are an effective and safe medicine for reducing seizure frequency in children suffering with intractable epilepsies. We encourage specialist physicians to prescribe for such patients within the NHS and for regulatory bodies to adapt their recommendations and permit greater access for these medicines.

Epileptic Aetiologies

The patients presented with a range of epileptic aetiologies including predefined syndromes, rare genetic disorders and undiagnosed epileptic encephalopathies. There represented; 4 with genetic aetiologies (PCDH19 mutation, NARS2 mutation, chromosome deletion, undiagnosed genetic mutation), 3 with Lennox-Gastaut syndrome, two with Dravets syndrome, 2 with Doose syndrome, 2 with CDKL5 deficiency disorder, 1 with West syndrome, 1 with Rett Syndrome, 1 with Aicardi syndrome, 1 with CFC syndrome, 3 with undiagnosed refractory epilepsies.

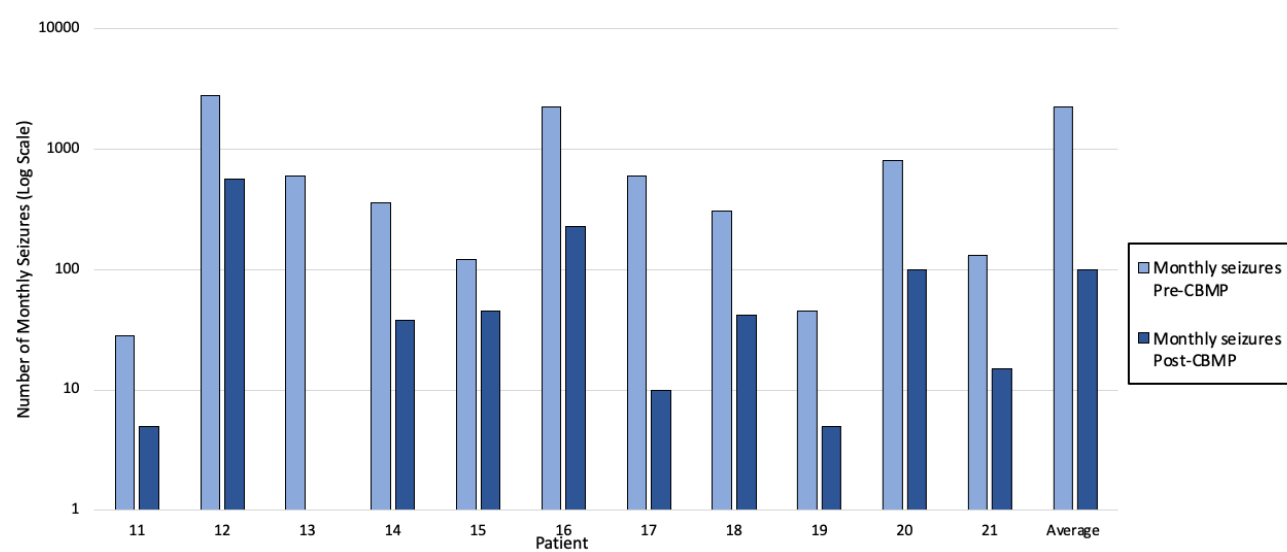
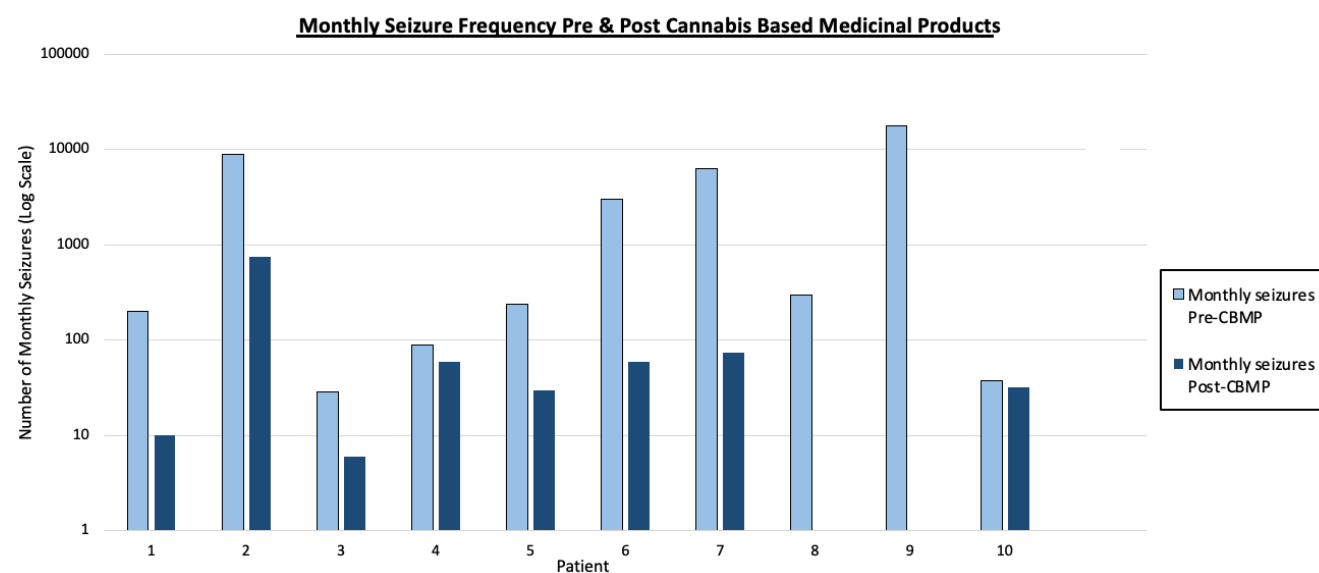
Medication [full details available on request]

Patients reported an average of 7 (\pm 4.58) anti-epileptic drugs prior to initiation of CBMP which reduced to an average of 1 (\pm 1.23) per patient with 7 patients managing to completely wean off all AEDs. The most common secondary intervention in the cohort was a ketogenic diet (N=7) prior to initiation of CBMP which was not effective in any patient and was subsequently discontinued. Three patients had a current vagal nerve stimulation implant.

6/7 of the patients using Epidyolex had failed to respond to this NICE recommended CBMP for treatment resistant epilepsy with the single responsive participant indicating that addition of yellow oil whole-plant extract contributed to an additional 20% decrease in seizure frequency (patient 14).

Seizure frequency and Bayesian analysis

Figures show the findings [note y axis is a log10 scale]. On average, there was an 84% reduction in monthly seizure frequency across the cohort [about 30 x fewer seizures per month] and three participants managed to achieve complete seizure freedom. The data shows 21 successes and no failures over 21 trials. This gives a posterior distribution for ϑ with $p(\vartheta \geq 0.90) = 0.90$ and a mean of 0.96. As the patients were not the subject of randomisation from a population, the best we can confidently say is that there is a 96% chance that each further patient from a similar cohort will experience a reduction in seizures.



Dose of CBMP

All patients were using whole-plant cannabis products which contain a range of terpenes, flavonoids and minor phytocannabinoids. We are currently in process of analysing the respective components of each medication in this study which we plan to report on. For this study we are only able to report on the respective doses of THC and CBD. For THC dosage, patients consumed an average (SD) of 8.9 (\pm 6.8) mg of THC a day and for CBD 276.3 (\pm 153.3) mg of CBD daily. The average cost of CBMPs across our cohort came to £1239.38 per month.

Other symptoms

Parents and carers reported significant improvements in health and wellbeing of their children following initiation of CBMPs. Particularly, these improvements were noted in sleep, eating, behaviour and cognition. A subset of eleven of such changes are analysed in (Schlag et al, 2021 (in press) – available on request).