

Supplemental File 1: Inclusion and Exclusion Criteria for Study Participation.

Inclusion Criteria

Participants selected for the study must meet the following criteria:

1. Age between 12 months and 18 years
2. Parent/ legal guardian informed consent obtained
3. Clinical and EEG (sleep recording within 12 months of study enrollment) characteristics of Dravet Syndrome and confirmatory genetic mutation result
4. Medication-resistant epilepsy – with failure to achieve seizure control with at least 2 appropriate AEDs at therapeutic doses
5. Clinically apparent seizures (excluding myoclonic and absence) occurring at least twice per week
6. Agreed diary compliance and clinical compliance with current prescribed therapy
7. Concomitant AED medication dosing stable during 4 week pre-intervention period. Ketogenic diet regime and VNS device settings must be stable for 3 months prior to pre-intervention period.
8. Ability to tolerate administration of medication orally or via percutaneous feeding tube (PEG).
9. Negative urinary pregnancy test for all female participants of child bearing age
10. Was never on Cannabinoid therapy or have not been treated with Cannabinoid products for at least last 60 days (confirmed by negative urine test for Tetrahydrocannabinol (THC), only for those who had been treated with CBD).

Exclusion Criteria

Children may not be included in the study if:

1. Under 12 months, over 18 years
2. Co-morbid renal, liver or cardiac disease
3. Any evidence of underlying inborn error of metabolism (mitochondrial disease)
4. No clinically apparent seizures, or less than 1 per week
5. Previous significant drug reaction (i.e. Stevens Johnson Syndrome, Significant angioedema causing airway compromise)
6. Any known or suspected family history of schizophrenia or other psychotic illness, or known schizophrenia in a first degree relative
7. Known sensitivity or allergic reaction to cannabinoids.
8. Currently taking any Cannabinoid products.
9. Any planned surgical or other intervention or travel during the intervention period.
10. Any inability to understand/speak English.