Supplemental Online Content

This supplemental material has been provided by the authors to give readers additional information about their work.

eTable 1. Secondary Outcome Endpoints: changes from baseline assessment

Endpoint	Mean Change (range)	*P*-value
Epilepsy and Learning Disabilities Quality of Life - Modified		
Seizure severity		
Month 3.5 (n=45)	**−0.18 (−1.8, 1.2)**	**.011***
Month 6.5 (n=40)	**−0.19 (−1.2, 0.9)**	**.008***
Behavior		
Month 3.5 (n=45)	**−0.19 (−1.9, 0.8)**	**.012***
Month 6.5 (n=40)	**−0.21 (−1.0, 0.4)**	**.001***
Mood		
Month 3.5 (n=45)	**−0.11 (−0.8, 0.6)**	**.019***
Month 6.5 (n=40)	**−0.15 (−0.7, 0.4)**	**.001***
Sleep Disturbance Scale for Children		
Month 3.5		
Total score (n=45)	**−3.7 (−50, 27)**	**.047***
Initiating and maintaining sleep (n=45)	**−3.2 (−32, 13)**	**.035***
Sleep breathing (n=45)	0 (−35, 42)	1.00
Arousal/nightmares (n=45)	-0.4 (−35, 36)	.749
Sleep-wake transition (n=45)	−1.6 (−26, 29)	.406
Excessive somnolence (n=45)	-3.3 (−58, 32)	.101
Sleep hyperhidrosis (n=45)	-0.7 (−41, 18)	.642
Month 6.5		
Total score (n=37)	**−5.1 (−33, 24)**	**.012***
Initiating and maintaining sleep (n=38)	**−5.1 (−29, 12)**	**.006***
Sleep breathing (n=40)	0.4 (−14, 28)	.797
Arousal/nightmares (n=39)	**-1.7 (−12, 11)**	**.031***
Sleep-wake transition (n=39)	**−4.6 (−38, 25)**	**.030***
Excessive somnolence (n=40)	−3.6 (−23, 28)	.100
Sleep hyperhidrosis (n=40)	-2.8 (−47, 35)	.154
University of Washington Caregiver Stress Scale		
Month 3.5 (n=45)	−1.84 (−53.1, 19.5)	.230
Month 6.5 (n=40)	−0.45 (−16.6, 26.2)	.744

*Statistically significant change from baseline (bolded).

eTable 2. Qualitative evaluation of improvement or worsening associated with CBD transdermal gel (n = 43)

Category	Improvement/Positive Statements	n (%)	Worsening/Negative Statements	n (%)
Behavior/Cognition/Mood	Improved alertness	17 (40)	Decreased alertness	2 (5)
	Improved engagement/participation	15 (35)	--	
	Improved cognition	14 (33)	--	
	Attending school on time/more often	12 (28)	Attending school later/less frequently	1 (2)
	More energy/less fatigue	12 (28)	More fatigue/ less energy	2 (5)
	Improved concentration	10 (23)	--	
	Improved behavior	9 (21)	Worsened behavior	3 (7)
	Improved mood	8 (19)	--	
	Improved speech/communication	7 (16)	Worsened speech/communication	2 (5)
	Decreased aggression/violence	2 (5)	Increased aggression/violence	1 (2)
	Improved relationships	5 (12)	--	
	Short-term cognition improvement	1 (2)	--	
	--		Increased anxiety	1 (2)
Seizures	Reduction in frequency of seizures	16 (37)	Increase in frequency of seizures	3 (7)
	Reduced amplitude/intensity of seizures	9 (21)	--	
	Reduction in duration of seizures	9 (21)	--	
	Postictal state improvement	6 (14)	Increased postictal state	1 (2)
	Short-term reduction in frequency of seizures	3 (7)	--	
	Short-term reduction in amplitude/intensity of seizure	1 (2)	--	
	Less convulsive behavior	1 (2)	Change in seizure semiology	1 (2)
Other	Fewer hospital visits	4 (9)	--	
	Improved sleep	3 (7)	Negative impact on circadian rhythm	1 (2)
	Increased mobility	2 (5)	Decreased mobility	2 (5)
	Reduced injuries	2 (5)	--	
	Fewer migraine attacks	1 (2)	--	
	--		Difficulty in applying gel	11 (26)
	--		Negative reaction at gel application site	8 (19)
	--		Decreased appetite	1 (2)
	--		Eating difficulty	1 (2)
	--		Weight loss	1 (2)
Summary Measures	Improved social/interpersonal engagement and irritability[a]	33 (77)		
	Seizure improvements[b]	22 (51)		

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	Vitality[c]	23 (53)		
	Cognition/concentration[d]	20 (47)		
	School[d]	12 (28)		
	Any improvement	36 (84)	Any worsening	26 (60)

[a]Improved alertness, increased engagement/participation, improved speech/communication, behavior, mood, decreased aggression/violence.
[b]Reduction in frequency of seizures, reduced amplitude/intensity of seizures, reduction in duration of seizures, less convulsive behavior.
[c]Improved alertness, more energy/less fatigue, improved sleep.
[d]Improved cognition, improved concentration.

eFigure 1. Median percent reduction by seizure type from baseline to week 26
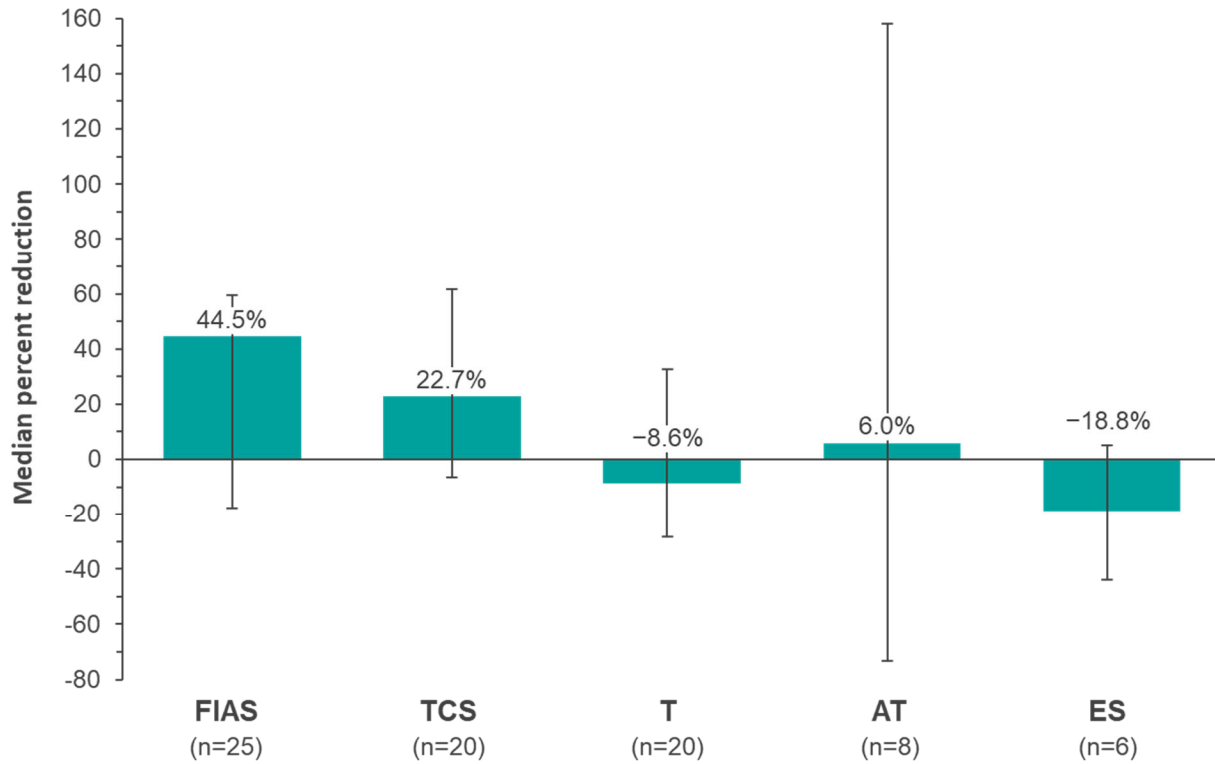
Median percent reduction from baseline to week 26 according to seizure type for seizure types occurring in 6 or more patients. The numbers of patients at each time point are shown under the graph. Error bars represent IQR. AT=atonic; ES=epileptic spasms; FIAS=focal impaired awareness; T=tonic; TCS=tonic-clonic seizures.

eFigure 2. Box plots of FIAS and TCS for each 28-day period
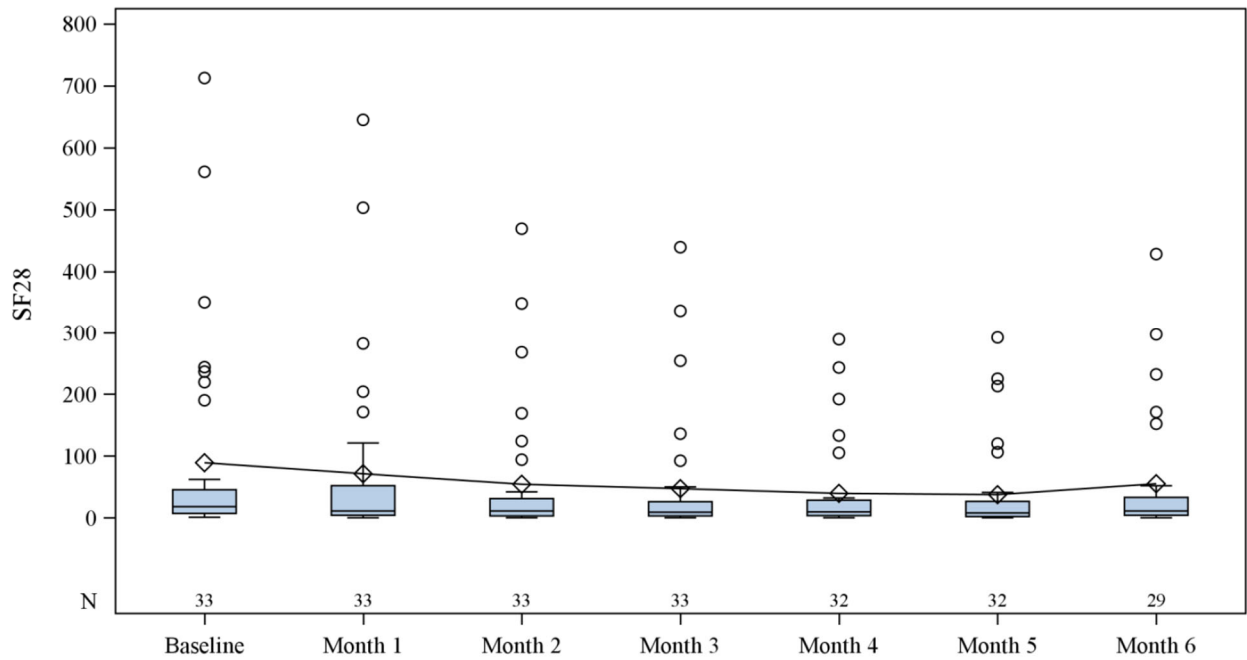
Box plots of FIAS and TCS monthly seizure frequency (SF28) for each 28-day assessment period. Boxes represent IQR with the horizontal line as the median and error bars representing 1.5 × IQR. Outliers are represented by circles. Diamonds represent mean values at each time point. The number of patients at each time point is shown above each month.

eFigure 3. Box plots (without outliers) of FIAS and TCS for each 28-day period
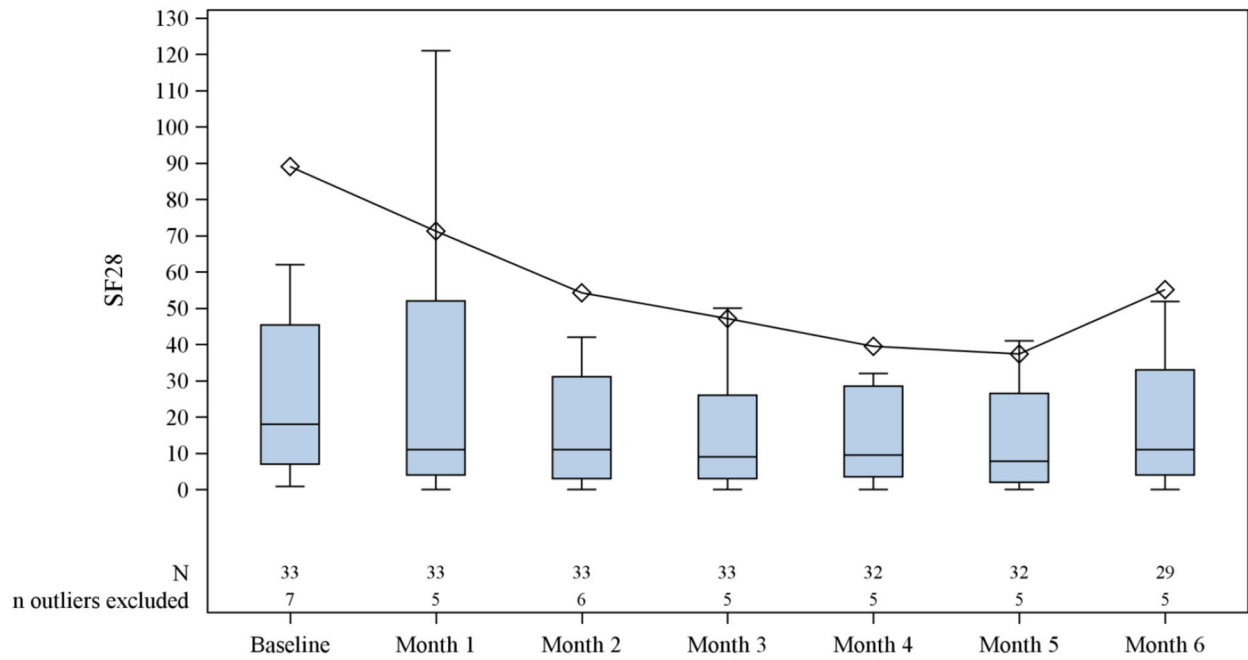
Box plots, without outliers, of FIAS and TCS monthly seizure frequency (SF28) for each 28-day assessment period. Boxes represent IQR with the horizontal line as the median and error bars representing 1.5 × IQR. Diamonds represent mean values at each time point. The numbers of patients at each time point and the numbers of outliers excluded per time point are shown above each month.