

Tuberous Sclerosis Complex–Associated Neuropsychiatric Disorders (TAND) Outcomes Following Adjunctive Cannabidiol Treatment: 6-Month Intermediate Analysis of the EpiCom Trial

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Objective

- To investigate behavioural and other co-occurring outcomes after initiation of treatment with adjunctive cannabidiol (CBD) in patients with tuberous sclerosis complex (TSC)-associated seizures. Here, we present the prespecified 6-month intermediate analysis of EpiCom



Conclusions

- In this intermediate analysis, reductions in behavioural outcomes scores as measured on the TAND-SQ, ABC, CBCL, and ABCL were reported after 26 weeks of CBD initiation
- Additionally, reduction in severity of behavioural outcomes as measured on the CareGI-S and CGI-S scales were reported by caregivers and clinicians after 26 weeks
- Safety profile was consistent with previous studies
- Participants currently enrolled in the study are continuing treatment through 52 weeks; final results are expected late in 2026

First presented at the American Epilepsy Society Annual Meeting, 2025.

References: 1. Vanclooster S, et al. *J Neurodev Disord*. 2022;14(1):13. 2. de Vries PJ, et al. *J Neurodev Disord*. 2023;15(1):32. 3. European Medicines Agency. Epidyolex® 100 mg/ml oral solution: summary of product characteristics, 2026. Available from: https://www.ema.europa.eu/en/documents/product-information/epidyolex-epar-product-information_en.pdf (Accessed 19 August 2026). 4. Electronic Medicines Compendium (eMC). Epidyolex® 100 mg/ml oral solution: summary of product characteristics, 2026. Available from: <https://www.medicines.org.uk/emc/product/10761/smpc/print> (Accessed 19 August 2026). 5. US Food and Drug Administration. Epidyolex® Prescribing Information, 2026. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/210365s024s029a030bl.pdf (Accessed 19 August 2026). 6. van Eeghen AM, et al. Poster presented at TSC International Research Conference, June 26–28, 2025, Bethesda, MD, USA (P-7). **Support and Acknowledgements:** This study was sponsored by Jazz Pharmaceuticals, Inc. The authors would like to thank all of the study investigators, study staff, patients, and caregivers for their participation in this research. Writing and editorial assistance were provided to the authors by Arun Sharma, PhD, of Syneco Health, US, and Lahoor Basha, PharmD, of Syneco Health, UK, and funded by Jazz Pharmaceuticals, Inc., in accordance with Good Publication Practice (GPP) 2022 guidelines. **Disclosures:** All authors met the ICMJE authorship criteria and had full access to relevant data and information. Neither honoraria nor payments were made for authorship. AVE has consulted for and received research support from Jazz Pharmaceuticals, Inc.; her institution has received research support from Jazz Pharmaceuticals, Inc., ForWishdom, and the European Commission/ERN ITHACA. SMLW has consulted for, conducted studies funded by, or received honoraria for services provided to Jazz Pharmaceuticals, Inc. SR, MD-B, and JS are employees of Jazz Pharmaceuticals, Inc., and hold stock and/or stock options in the company. KW and LM-R are employees of Jazz Pharmaceuticals, UK Ltd., and hold stock and/or stock options in the company. TD is an employee of Jazz Pharmaceuticals, Inc. Gentium Srl, and holds stock and/or stock options in the company. PJdV was a member of a study steering committee for three phase 3 trials in TSC sponsored by Novartis, was on the scientific advisory group of the TOSCA international disease registry sponsored by Novartis, and has provided consultancy to Jazz Pharmaceuticals, Inc. Epidyolex® is approved in the EU for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, in patients ≥2 years of age; it is additionally approved in the EU for the adjunctive treatment of seizures associated with tuberous sclerosis complex in patients ≥2 years of age. **Clinical trial ID:** NCT05864846.



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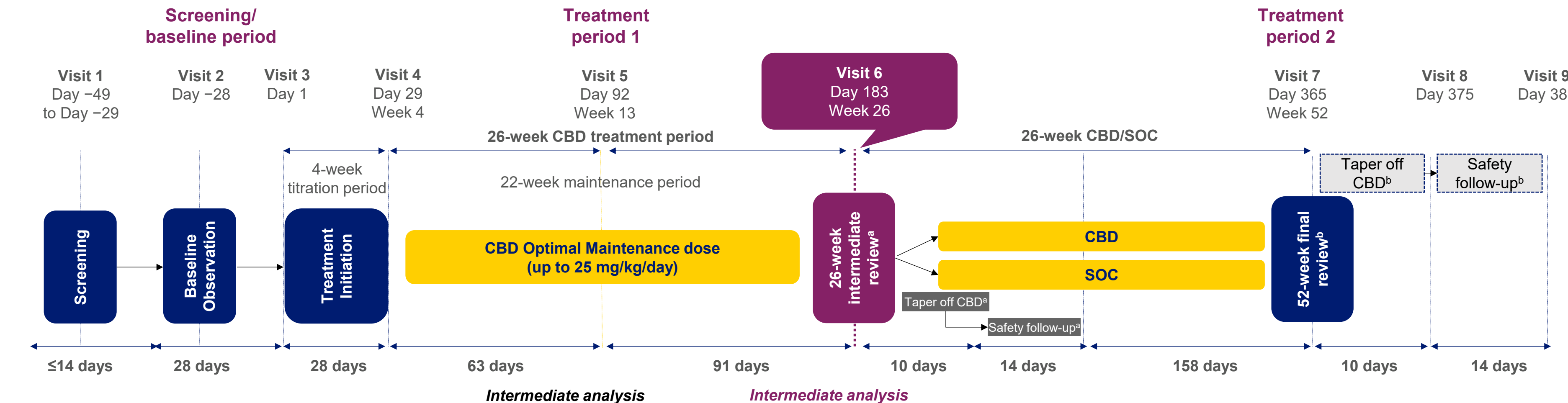
Introduction

- Approximately 90% of people with tuberous sclerosis complex (TSC) experience TSC-associated neuropsychiatric disorders (TAND; **Figure S1**), which substantially impact their quality of life. However, treatment options remain limited.^{1,2} **Supplementary material** can be accessed by scanning the poster QR code
- A plant-derived, highly purified pharmaceutical formulation of cannabidiol (CBD; Epidyolex® [EU]/Epidiolex® [US], 100 mg/mL oral solution) is approved for the treatment of seizures associated with TSC^{3–5}
- Anecdotal reports from the TSC community of patients, caregivers, and healthcare professionals have suggested benefits with CBD treatment in behavioural (eg, calm or relaxed behaviour) and neuropsychological symptoms (eg, increased attention span, awareness, and concentration)⁶
- EpiCom (**E**pilepsy **C**omorbidity; NCT05864846) is an interventional, multicentre, open-label, single-arm, phase 3b/4 study evaluating behavioural and other co-occurring outcomes following adjunctive CBD treatment in participants with TSC-associated seizures⁹

Methods

- Eligible participants aged 1 to 65 years (2–65 years in the United Kingdom, Canada, and Poland) with TSC-associated seizures and experiencing moderate/severe behavioural challenges on the Caregiver Global Impression of Severity (CareGI-S) scale were enrolled (**Table S1**)
- After a screening and baseline period of up to 49 days, participants receive CBD ≤25 mg/kg/day (based on response and tolerability) in addition to standard of care (SOC) for 26 weeks (Treatment period 1); includes a 4-week titration period and a 22-week maintenance period, after which, participants choose to continue either CBD with SOC or SOC alone for an additional 26 weeks (Treatment period 2) (**Figure 1**)
- This 6-month intermediate analysis includes enrolled participants (n=79) who completed Treatment period 1 (Visit 6) as of April 2025 (n=28)
 - Safety analysis set: all enrolled participants who received ≥1 dose of CBD; full analysis set: participants with ≥1 postbaseline assessment available (n=62)
- Key endpoints evaluated at the 26-week intermediate analysis were:
 - Most problematic behaviour (MPB), TAND Self-Report Quantified Checklist (TAND-SQ), Aberrant Behaviour Checklist (ABC), CareGI-S, Clinician Global Impression of Severity (CGI-S), Child and Adult Behaviour Checklist (CBCL/ABCL), seizure outcomes, treatment-emergent adverse events (TEAEs), and serious adverse events (SAEs)
 - Data were analysed using standard descriptive statistics for continuous variables, including 95% CI for mean and median changes
- The EpiCom study was conducted with Epidyolex®/Epidiolex®, and results do not apply to other CBD-containing products

Figure 1. Study design

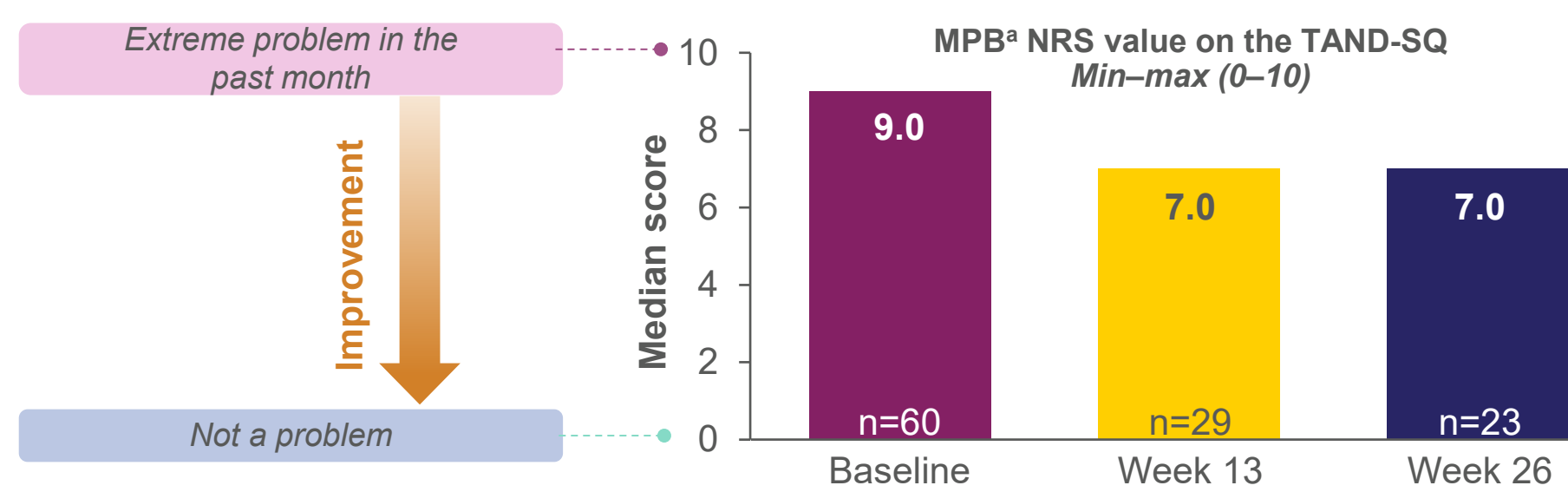


*Participants who decide to discontinue CBD after the 26-week intermediate review visit but remain on study will form the SOC treatment arm. These participants will taper off CBD and complete a safety follow-up. *Participants who decide to discontinue CBD after the 52-week final review visit will taper off CBD and complete a safety follow-up. For participants who wish to remain on CBD after the study, the 52-week final review visit is the last study visit. CBD, cannabidiol; SOC, standard of care.

Results

- At the time of this analysis, 79 participants were enrolled, 39 had completed Week 13, and 28 were eligible for Week 26 analysis; 10 participants discontinued the study
- Patient demographics and baseline characteristics are shown in **Table S2**

Figure 2. Most problematic behaviour (MPB) scores



MPB^a NRS value on the TAND-SQ
Min–max (0–10)
Median score
Baseline (n=60) 9.0
Week 13 (n=29) 7.0
Week 26 (n=23) 7.0

*MPB is a novel endpoint uniquely personalised to the patient and defined as the single behaviour identified by the caregiver as most troublesome for the participant based on the TAND-SQ checklist. Behaviours are scored 0–10 (0 = not a problem; 10 = extreme problem in the past month). MPB, most problematic behaviour; NRS, numerical rating scale; TAND, tuberous sclerosis complex-associated neuropsychiatric disorders; TAND-SQ, TAND Self-Report, Quantified Checklist.

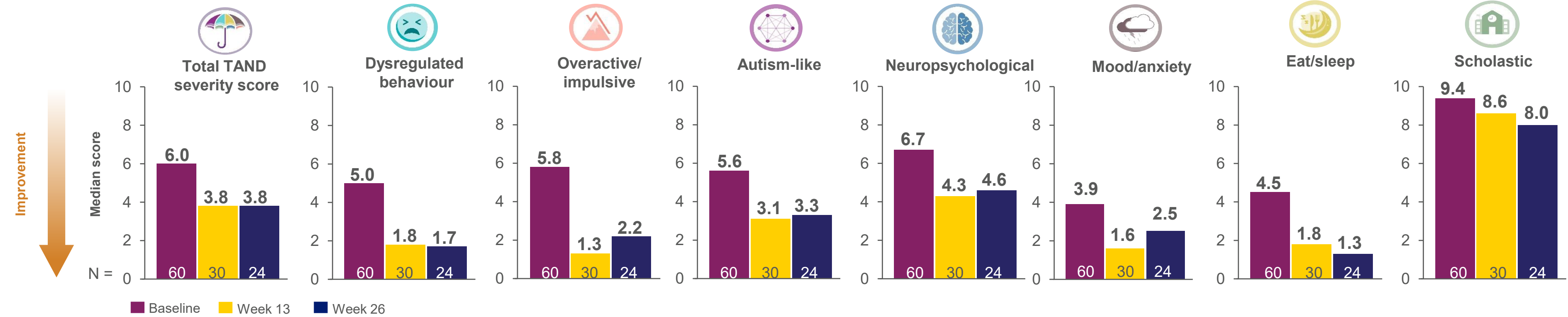
- At baseline (n=60), the median MPB numerical rating scale (NRS) value was 9.0, suggesting severe TAND problems; aggressive outbursts (23%) and anxiety (11%) were the most identified MPBs at baseline
- At Week 26 (n=23), median (95% CI) change from baseline in MPB NRS was –2.0 (–3.0, –1.0), suggesting an improvement in behavioural outcomes from baseline in participants who completed 26-week CBD treatment (**Figure 2**; **Table 1**)

Table 1. Change from baseline in most problematic behaviour (MPB) scores

	Baseline ^b (n=60), median	Change from baseline at Week 13 (n=29), median (95% CI) ^c	Change from baseline at Week 26 (n=23), median (95% CI) ^c
MPB ^a NRS value on TAND-SQ	9.0	–2.0 (–4.0, –1.0)	–2.0 (–3.0, –1.0)

*MPB is a novel endpoint uniquely personalised to the patient and defined as the single behaviour identified by the caregiver as most troublesome for the participant based on the TAND-SQ checklist. Behaviours are scored 0–10 (0 = not a problem; 10 = extreme problem in the past month). *At baseline, prospective participants must have had an MPB score of ≥6 (at least a moderate behavioural problem) on TAND-SQ to be eligible. *95% CI for the median change from baseline was calculated using the distribution-free method. MPB, most problematic behaviour; NRS, numerical rating scale; TAND, tuberous sclerosis complex-associated neuropsychiatric disorders; TAND-SQ, TAND Self-Report, Quantified Checklist.

Figure 3. TAND Self-Report, Quantified Checklist (TAND-SQ) scores



Min–max of the total TAND severity score and TAND cluster severity scores: 0–10. N numbers differ between the graph and table due to the potential for missing data at baseline and/or visits. TAND, tuberous sclerosis complex-associated neuropsychiatric disorders; TAND-SQ, TAND Self-Report, Quantified Checklist.

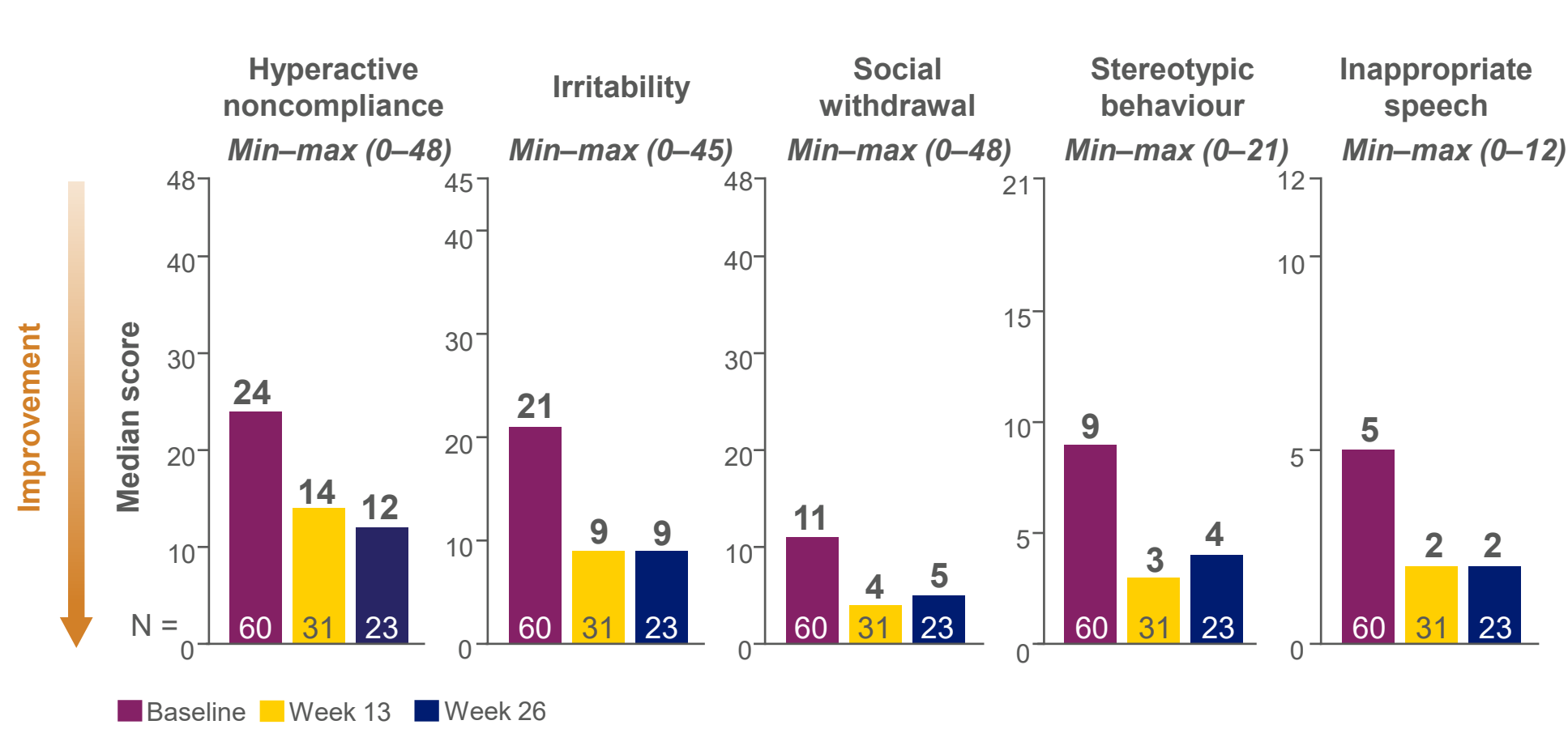
Table 2. Change from baseline in TAND Self-Report, Quantified Checklist (TAND-SQ) scores

	Baseline (n=60), median	Change from baseline at Week 13 (n=29), median (95% CI) ^a	Change from baseline at Week 26 (n=23), median (95% CI) ^a
Total TAND severity score	6.0	–1.4 (–2.0, –0.8)	–1.4 (–2.2, –0.2)
Dysregulated behaviour	5.0	–2.0 (–3.0, –0.7)	–0.7 (–2.7, 0.0)
Overactive/impulsive	5.8	–2.0 (–3.0, –0.3)	–1.3 (–3.3, 0.0)
Autism-like	5.6	–1.7 (–2.5, –0.1)	–0.8 (–2.0, 0.0)
Neuropsychological	6.7	–1.4 (–2.7, –0.3)	–0.6 (–3.6, 0.7)
Mood/anxiety	3.9	–1.0 (–2.0, –0.3)	–0.8 (–2.0, 0.0)
Eat/sleep	4.5	–0.5 (–2.0, 0.0)	–2.0 (–3.5, 0.0)
Scholastic	9.4	–0.3 (–1.0, 0.0)	–0.3 (–1.8, 0.0)

- A reduction in severity scores was reported across all TAND-SQ clusters and all timepoints, with the exception of scholastic; the greatest reduction from baseline to Week 26 (median [95% CI]) was seen in eat/sleep (–2.0 [–3.5, 0.0]) and overactive/impulsive (–1.3 [–3.3, 0.0]) scores (**Figure 3**; **Table 2**)

*95% CI for the median change from baseline was calculated using the distribution-free method. N numbers differ between the graph and table due to the potential for missing data at baseline and/or visits. CI, confidence interval; TAND, tuberous sclerosis complex-associated neuropsychiatric disorders; TAND-SQ, TAND Self-Report, Quantified Checklist.

Figure 4. Aberrant Behaviour Checklist (ABC) subscale scores



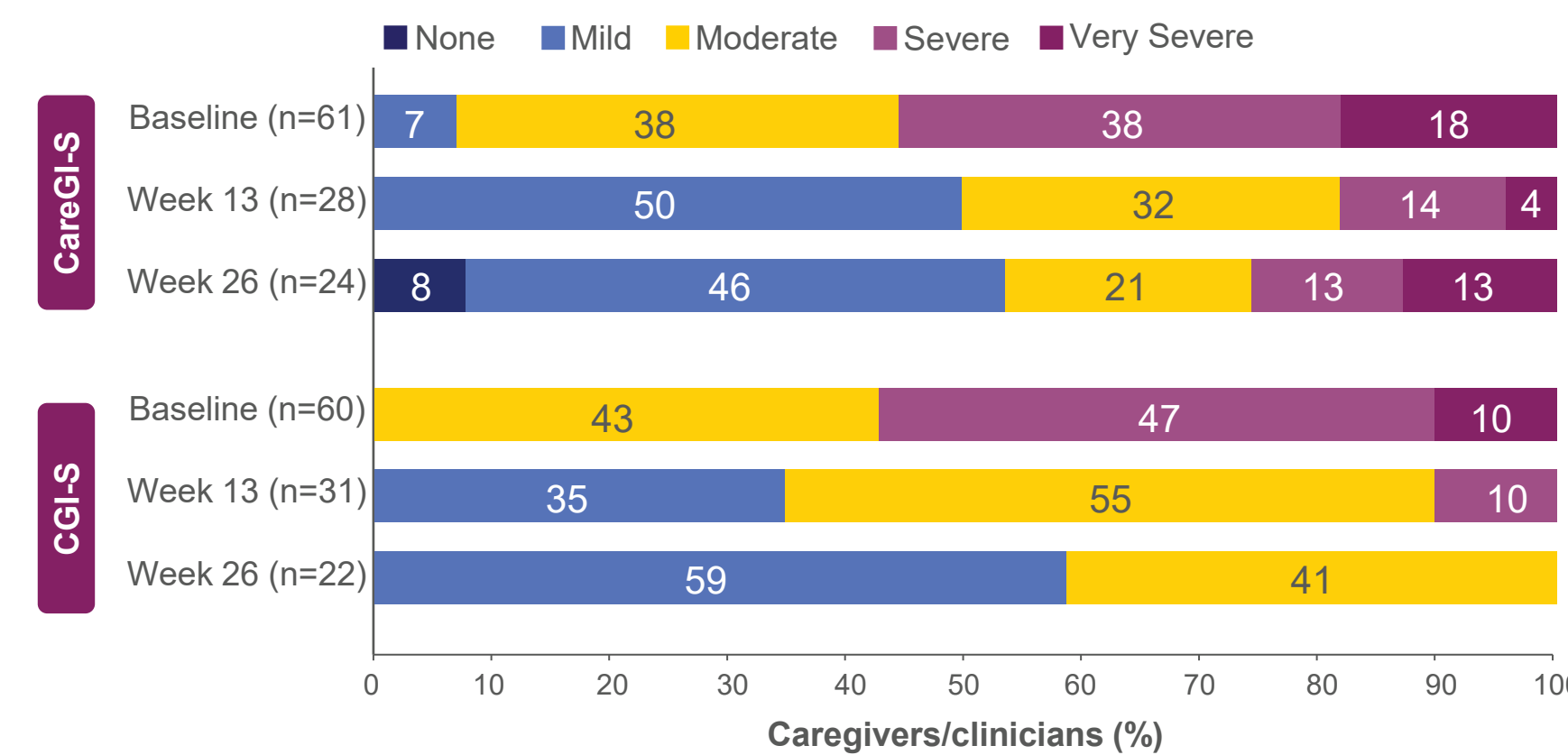
- Among the ABC subscales, the greatest reduction from baseline to Week 26 was seen in irritability (–8.0 [–10.0, –2.0]) and hyperactive noncompliance (–7.0 [–13.0, –2.0]) scores (**Figure 4**; **Table 3**)

Table 3. Change from baseline in Aberrant Behaviour Checklist (ABC) subscale scores

	Baseline (n=60), median	Change from baseline at Week 13 (n=30), median (95% CI) ^a	Change from baseline at Week 26 (n=23), median (95% CI) ^a
Hyperactive noncompliance	24.0	–9.0 (–16.0, –2.0)	–7.0 (–13.0, –2.0)
Irritability	21.0	–8.5 (–12.0, –4.0)	–8.0 (–10.0, –2.0)
Social withdrawal	11.0	–4.0 (–6.0, –1.0)	–3.0 (–8.0, –1.0)
Stereotypic behaviour	9.0	–3.0 (–5.0, –2.0)	–3.0 (–5.0, 0.0)
Inappropriate speech	5.0	–1.0 (–3.0, 0.0)	–2.0 (–3.0, 0.0)

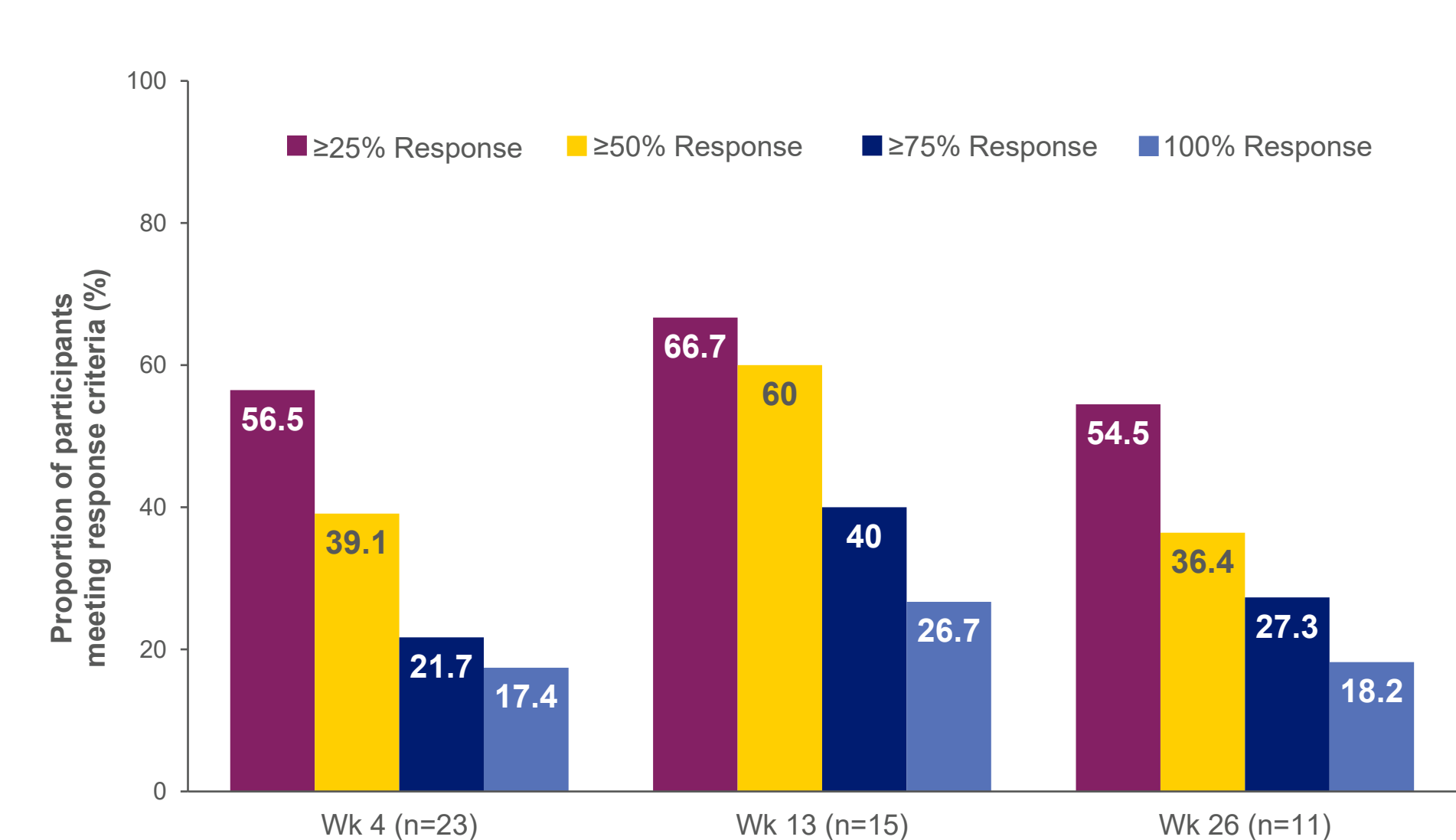
*95% CI for the median change from baseline was calculated using the distribution-free method. N numbers differ between the graph and table due to the potential for missing data at baseline and/or visits. CI, confidence interval.

Figure 5. Caregiver (CareGI-S) and Clinician (CGI-S) Global Impression of Severity in problems with behaviour



- Compared with baseline, smaller proportions of caregivers and clinicians rated behavioural problems as severe/very severe at Weeks 13 and 26, respectively (**Figure 5**)

Figure 6. Seizure response from baseline to Week 26



A participant was considered a responder if they had reached a ≥25%, ≥50%, ≥75%, or 100% reduction in total seizure count from baseline during the treatment period. Full analysis set, n=62. Participants who were not experiencing seizures at baseline were removed; 38/61 at Wk 4, 24/39 at Wk 13, and 14/25 at Wk 26. Wk, week.

- Over half of the participants experiencing seizures at baseline (60%) achieved a ≥50% reduction in total seizure count at Week 13, and more than one third (36%) achieved this threshold at Week 26
- 67% of the participants experiencing seizures at baseline achieved ≥25% reduction in total seizure count from baseline at Week 13, as did 55% at Week 26 (**Figure 6**)

Table 4. Safety outcomes

	CBD (N=79)
Participants with ≥1:	n (%)
TEAEs	49 (62.0)
Related TEAEs	34 (43.0)
TEAEs leading to CBD discontinuation ^a	11 (13.9)
Serious TEAEs ^b	6 (7.6)
TEAEs occurring in >15% of participants	n (%)
Diarrhoea	19 (24.1)
Infections	18 (22.8)
Psychiatric disorders	13 (16.5)

*Some patients may have had ≥1 TEAEs leading to CBD discontinuation. *Serious TEAEs that were considered treatment-related included hypernatraemia and seizures (in the same patient), and suicidal ideation and hypokalaemia in 1 patient each. 2 out of 3 patients discontinued – 1 due to suicidal ideation and 1 due to hypokalaemia (n=1). 1 patient had their CBD dose reduced due to hypernatraemia. All events were resolved. CBD, cannabidiol; TEAEs, treatment-emergent adverse events.

- TEAEs occurred in 49 (62.0%) participants, most commonly diarrhoea, infections, and psychiatric disorders (**Table 4**)
- Serious TEAEs were reported in 6 (7.6%) participants; 4 AEs in 3 participants were considered treatment-related (resolved)

Change from baseline in Child Behaviour Checklist (CBCL)^a at Week 26

- At Week 26, improvements in scores from baseline were seen across several problem scales of the CBCL (**Table S3**)
- Among children attending school, the greatest improvement in score was seen in Aggressive Behaviour syndrome scale (median [95% CI] –6.0 [–8.0, 3.0])

*CBCL is used for participants aged between ≥6 and ≤17 years. Higher score is indicative of a greater problem.

Change from baseline in Adult Behaviour Checklist (ABCL)^b at Week 26

- At Week 26, improvements in scores from baseline were observed across most problem scales of the ABCL (**Table S4**)
- Among adults, the greatest improvement in scores were seen in Rule-breaking Behaviour (median [95% CI] –3.0 [–6.0, 1.0]) and Other Problems^c syndrome scale (median [95% CI] –3.0 [–7.0, 2.0])

*ABCL is used for participants aged between ≥18 and ≤59 years. Higher score is indicative of a greater problem. *Includes clinically relevant items that do not fit into the other defined syndrome scales, such as (but not limited to) sleep disturbances, unusual thought patterns, repetitive behaviours, and emotional dysregulation.

Retention

- At the time of this intermediate data analysis, the probability of participants remaining on CBD treatment at Week 26 was 86%; only 1 participant transitioned to SOC after 26 weeks of CBD treatment

Limitations

- This is an intermediate analysis of an open-label study that did not include a control group. Observed improvements may be confounded by potential regression to the mean, particularly given the smaller Week 26 sample size

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Supplementary Material

Figure S1. TSC-Associated Neuropsychiatric Disorders (TAND) clusters¹

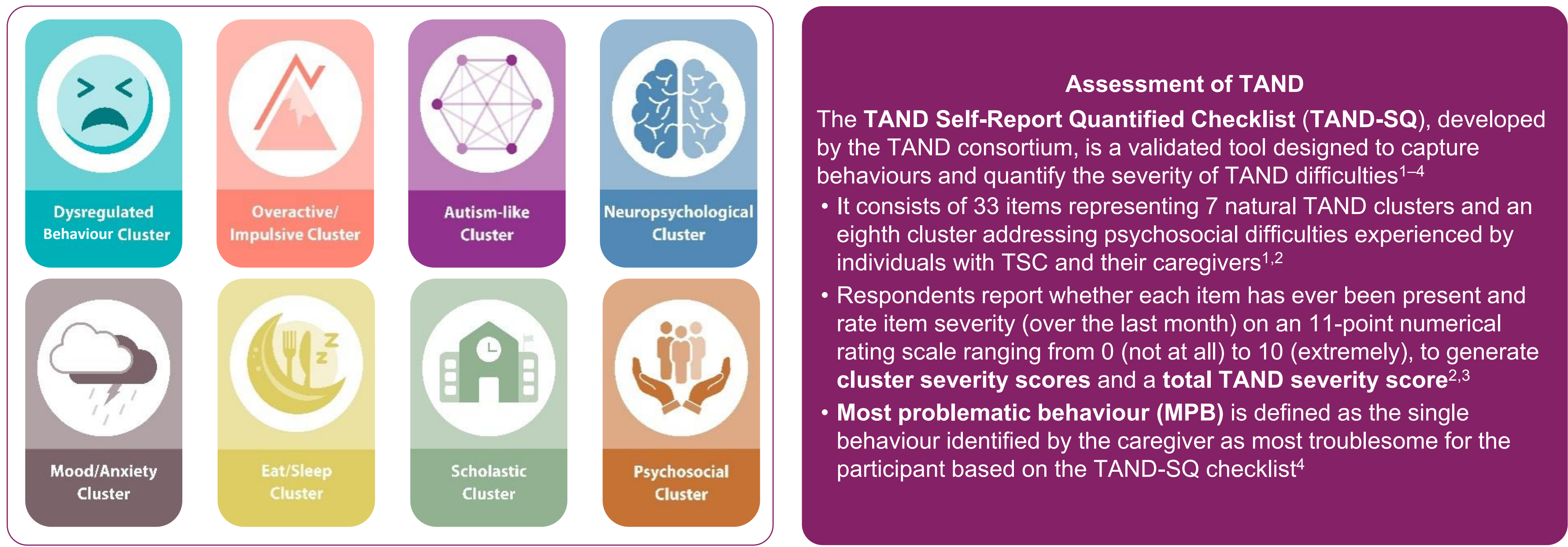


Table S1. Key inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Confirmed diagnosis of TSC with a history of seizures • Moderate/severe behavioural challenges (eg, aggression, impulsivity, temper tantrums, self-injury, and hyperactivity), with a most problematic behaviour score of ≥6 on the TAND-SQ at baseline^a • On ≥1 antiseizure medication • Naive to CBD or has been off CBD for ≥3 months before screening	• Any medical condition that could affect study outcomes • Felbamate initiation within the year before screening • Use of cannabis or cannabinoid-based products within the 3 months before screening • Significant hepatic impairment and any history of suicidal behaviour or ideation of type 4 or 5 as evaluated by the Columbia-Suicide Severity Rating Scale

^aBased on the Likert scale: 1 = Very unimportant; 5 = Neither important nor unimportant; and 10 = Extremely important.
CBD, cannabidiol; TAND, TSC-associated neuropsychiatric disorder; TAND-SQ, TAND Self-Report, Quantified Checklist; TSC, tuberous sclerosis complex.

Table S2. Patient demographics and baseline characteristics

	CBD (N=79)		CBD (N=79)
Age, years		Number of ASMs at baseline, median (min–max)	2 (1–6)
Mean (SD) ^a	18.5 (10.32)	Most common baseline ASMs, n (%)	
Median (min–max)	16.0 (3–42)	Lamotrigine	24 (30.4)
Sex, n (%)		Midazolam ^c	18 (22.8)
Male	46 (58.2)	Clobazam	13 (16.5)
Female	33 (41.8)	Valproate	13 (16.5)
Race, n (%)		Caregiver’s view of intellectual disability, n (%) ^d	
White	70 (88.6)	Above average-normal intellect	7 (11.3)
Asian	3 (3.8)	Mild-moderate disability	21 (33.9)
Black or African American	3 (3.8)	Severe-profound disability	31 (50.0)
Declined to state	3 (3.8)	Did not state	3 (4.8)
American Indian or Alaska Native	0	Neuropsychiatric comorbidities, n (%)	
Native Hawaiian or other Pacific Islander	0	Autism spectrum disorder	47 (59.5)
Multiple	0	Anxiety disorder	27 (34.2)
Ethnicity, n (%)		ADHD	21 (26.6)
Hispanic or Latino	10 (12.7)	Other psychiatric disorder(s)	11 (13.9)
Not Hispanic or Latino	69 (87.3)	OCD	8 (10.1)
Number of participants reporting seizures within 12 months prior to screening, n (%) ^b	56 (70.9)	Depression	4 (5.1)
Average number of seizures per 28 days at baseline, mean (SD) ^b	20.4 (47.7)	Psychotic disorders, including schizophrenia	1 (1.3)

^an=37 were adults (≥18 years). ^bConsiders participants with any seizure type recorded within 12 months of screening. All participants had a history of seizure(s) but were not necessarily experiencing seizure(s) at the start of the study. The average number of seizures per 28 days at baseline is calculated from seizure diary records. ^cRescue medication. ^dn=62.
ADHD, attention-deficit/hyperactivity disorder; ASMs, antiseizure medications; CBD, cannabidiol; OCD, obsessive-compulsive disorder.

- Median (min–max) age was 16.0 (3–42) years, and 2.0 (1–6) antiseizure medications were being used at baseline (**Table S2**)
 - The most common concomitant antiseizure medications being used were lamotrigine (n=24 [30%]), midazolam (n=18 [23%]), clobazam (n=13 [17%]), and valproate (n=13 [17%])
- Half of the caregivers (50%) characterised their participants as having severe to profound intellectual disability, while a third of them (34%) reported mild to moderate disability
- The majority of participants reported ≥1 neuropsychiatric comorbidity at baseline, most commonly autism spectrum disorder (60%), anxiety disorder (34%), and ADHD (27%)

Table S3. Change from baseline in Child Behaviour Checklist (CBCL) at Week 26

Problem scale	Syndrome scale	Baseline (n=28), median	Week 26 (n=7), median	Change from baseline at Week 26 (n=7), median (95% CI) ^a
Internalising	Anxious/Depressed	5.0	2.0	–2.0 (–4.0, 5.0)
	Withdrawn/Depressed	3.0	1.0	–1.0 (–4.0, 4.0)
	Somatic Complaints	2.0	2.0	0.0 (–4.0, 3.0)
	Total	9.5	10.0	–4.0 (–10.0, 6.0)
Externalising	Aggressive Behaviour	14.5	10.0	–6.0 (–8.0, 3.0)
	Rule-breaking Behaviour	3.0	1.0	–1.0 (–3.0, 2.0)
	Total	18.0	11.0	–8.0 (–9.0, 5.0)
Other	Social Problems	8.0	4.0	–2.0 (–3.0, 4.0)
	Thought Problems	7.0	4.0	1.0 (–4.0, 7.0)
	Attention Problems	11.5	7.0	–2.0 (–6.0, 9.0)
	Other Problems	7.0	7.0	–1.0 (–5.0, 5.0)
	Other Total	36.0	21.0	–10.0 (–13.0, 25.0)
Total	Total	64.5	41.0	–12.0 (–31.0, 35.0)

CBCL is used for participants aged between ≥6 and ≤17 years. Higher score is indicative of a greater problem.
^a95% CI for the median change from baseline is calculated using the distribution-free method.
CI, confidence interval.

Table S4. Change from baseline in Adult Behaviour Checklist (ABCL) at Week 26

Problem scale	Syndrome scale	Baseline (n=28), median	Week 26 (n=15), median	Change from baseline at Week 26 (n=14), median (95% CI) ^a
Internalising	Anxious/Depressed	4.5	2.0	–2.0 (–3.0, 2.0)
	Withdrawn	4.5	2.0	–1.0 (–4.0, 0.0)
	Somatic Complaints	2.5	2.0	0.0 (–4.0, 1.0)
	Total	11.0	6.0	–4.0 (–5.0, –2.0)
Externalising	Aggressive Behaviour	11.0	5.0	–2.0 (–5.0, 1.0)
	Rule-breaking Behaviour	7.0	2.0	–3.0 (–6.0, 1.0)
	Intrusive	3.0	2.0	–1.0 (–2.0, 0.0)
	Total	22.0	8.0	–8.0 (–13.0, 3.0)
Other	Thought Problems	5.5	3.0	–1.5 (–4.0, 1.0)
	Attention Problems	10.0	10.0	–1.5 (–3.0, 1.0)
	Other Problems ^b	13.0	10.0	–3.0 (–7.0, 2.0)
	Other Total	29.0	21.0	–7.0 (–13.0, 3.0)
Total	Total	68.5	37.0	–15.0 (–28.0, 1.0)

ABCL is used for participants aged between ≥18 and ≤59 years. Higher score is indicative of a greater problem.
^a95% CI for the median change from baseline is calculated using the distribution-free method. ^bIncludes clinically relevant items that do not fit into the other defined syndrome scales such as (but not limited to) sleep disturbances, unusual thought patterns, repetitive behaviours, and emotional dysregulation.
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Epidyolex® is approved in the EU for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, in patients ≥2 years of age; it is additionally approved in the EU for the adjunctive treatment of seizures associated with tuberous sclerosis complex in patients ≥2 years of age.

Clinical trial ID: NCT05864846.

Tuberous Sclerosis Complex–Associated Neuropsychiatric Disorders (TAND) Outcomes Following Adjunctive Cannabidiol Treatment: 6-Month Intermediate Analysis of the EpiCom Trial

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*Epidyol[®] is approved in the EU for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, in patients ≥2 years of age; it is additionally approved in the EU for the adjunctive treatment of seizures associated with tuberous sclerosis complex in patients ≥2 years of age.
*Epidiolex[®] is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients ≥1 year of age.

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What is tuberous sclerosis complex (TSC)?

- TSC is a rare disease that occurs when a person has a mutation in genes called **TSC1** or **TSC2**. The mutations cause noncancerous tumours to grow in multiple organs throughout the body, including the brain^{1,2}
- About 85% of people with TSC experience **epilepsy**²
- About 90% of people with TSC experience TSC-associated neuropsychiatric disorders, or **TAND**³
- TAND include different types of **behavioural, psychiatric, academic, and/or social problems** that can affect quality of life for people with TSC and their caregivers. TAND clusters are shown in the figure⁴
- Treatment options for TAND are limited^{3,5}



What is cannabidiol (CBD)?

- A plant-derived, highly purified pharmaceutical formulation of **CBD (Epidyol[®] [EU]/Epidiolex[®] [US])*** approved for the treatment of **seizures associated with TSC**^{6–8}
- People in the **TSC community**, including patients, caregivers, and clinicians, have shared their observations that **treatment with approved CBD may help improve behavioural challenges** related to aggression and lack of attention in people with TSC. These effects have not been investigated in a clinical trial²

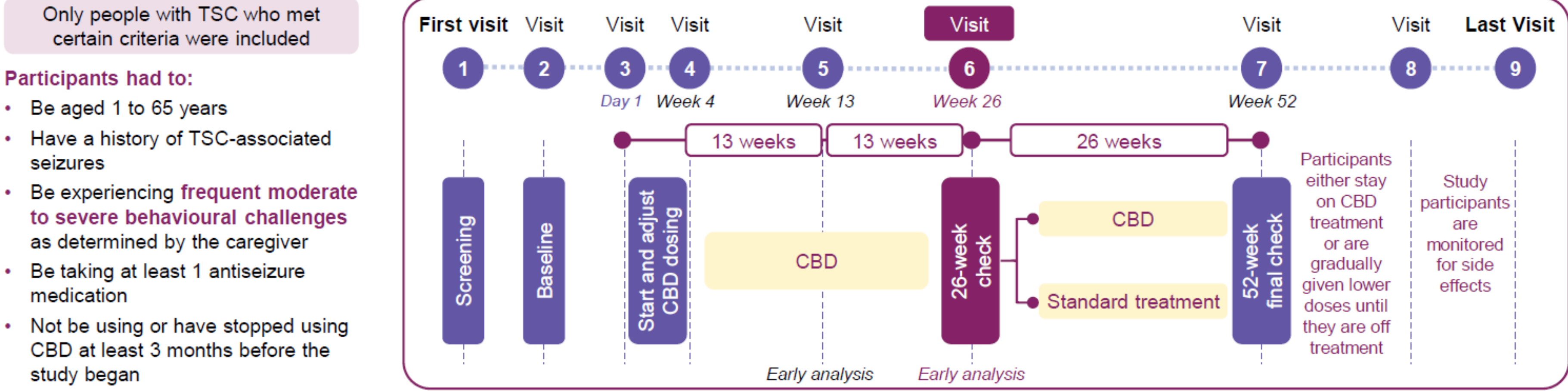


What is EpiCom?

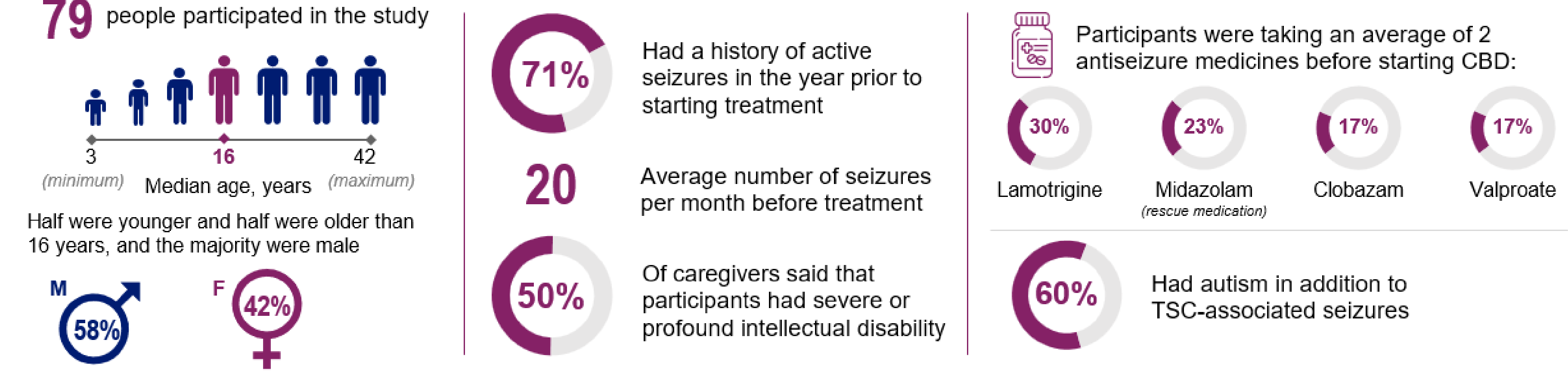
- EpiCom (Epilepsy Comorbidities)** is an **ongoing** clinical study that explores whether behaviour problems and other challenges in people with TSC improve after starting CBD treatment⁵
- EpiCom used Epidyol[®]/Epidiolex[®], and results do not apply to other CBD-containing products



How was the EpiCom study designed?



What were the key features of people who had participated in the study at the time of this analysis?



What are the key findings from this early analysis in participants who had reached Week 26?

