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Data supplement

Table DS1 Baseline demographics, clinical characteristics and baseline scores for randomised participants

	OROS-MPH ($n = 15$)	Placebo ($n = 15$)
Age, years		
Mean (95% CI)	33.5 (26.7–40.2)	35.3 (30.2–40.3)
Median (range)	28 (21–61)	34 (22–49)
Gender, male: *n* (%)	15 (100)	15 (100)
Time to serve in prison, months		
Mean (95% CI)	68.3 (37.4–99.1)	68.5 (40.7–96.4)
Median (range)	58 (16–240)	54 (27–240)
Educational level, 9-year compulsory school, or less, *n* (%)	12 (80)	13 (87)
Full scale IQ		
Mean (95% CI)	88.9 (83.2–94.5)	85.4 (78.2–92.7)
Median (range)	89 (72–112)	84 (68–105)
ADHD subtype,[a] *n* (%)		
Combined type	13 (87)	15 (100)
Predominantly inattentive	2 (13)	0
Lifetime psychiatric comorbidity,[a] *n* (%)		
Autism-spectrum disorder	4 (27)	3 (20)
Mood and anxiety disorders	10 (67)	12 (80)
Conduct disorder	15 (100)	15 (100)
Antisocial personality disorder	15 (100)	14 (93)
Psychopathy[b]	2 (13)	1 (7)
Lifetime substance use disorder,[a] *n* (%)	15 (100)	15 (100)
Primary substance use disorder, *n* (%)		
Alcohol	2 (13)	2 (13)
Amphetamine	10 (67)	8 (53)
Cocaine	1 (7)	3 (20)
Cannabis	0	1 (7)
Opioids	1 (7)	0
Anabolic steroids	1 (7)	0
Other	0	1 (7)
Concurrent treatment for psychiatric disorders, *n* (%)	8 (53)	5 (33)
Wender Utah Rating Scale-25,[c] mean (95% CI)	72.0 (64.3–79.7)	62.9 (56.3–69.4)
Conners' Adult ADHD Rating Scale – Observer: Screening Version,[d] total score: mean (95% CI)	40.0 (37.5–42.5)	39.9 (36.9–43.0)
Adult ADHD Self-Report Scale, total score:[e] mean (95% CI)	53.9 (49.0–58.7)	56.7 (51.7–61.8)
Global Assessment of Functioning Scale, total score[f]		
Mean (95% CI)	33.9 (31.2–36.6)	36.5 (33.6–39.3)
Median (range)	34 (25–42)	38 (25–43)
Clinical Global Impression – Severity Scale[g]		
Mean (95% CI)	6.1 (5.8–6.3)	5.7 (5.4–6.1)
Median	6	6
Marked, *n* (%)	1 (7)	5 (33)
Severe, *n* (%)	12 (80)	9 (60)
Extremely severe, *n* (%)	2 (13)	1 (7)

OROS-MPH, osmotic-release oral system methylphenidate; ADHD, attention-deficit hyperactivity disorder.
a. Attention-deficit hyperactivity disorder, psychiatric comorbidity and substance use disorder in accordance to DSM-IV.
b. Psychopathy (total sum $\geqslant 30$) in accordance to Hare by Psychopathy Checklist-Revised (PCL-R).
c. Wender Utah Rating Scale, (range 0–100), total sum >36 indicates childhood ADHD.
d. Conners' Adult ADHD Rating Scale – Observer: Screening Version, 18 symptom frequencies, rated 0 = not at all, to 3 = very much/very frequently, (0–54).
e. Adult ADHD Self-Report Scale, 18 symptom frequencies, rated 0 = never, to 4 = very often, (0–72).
f. Global Assessment of Functioning Scale, total score, a visual analogue scale 0–100, higher values reflect increased level of functioning.
g. Clinical Global Impression – Severity Scale, from 1 = not ill to 7 = extremely ill.

Table DS2 Mean changes in outcome measures from baseline until end of open-label extension at week 52[a]

Efficacy measures	OROS-MPH ($n = 15$)	Placebo ($n = 15$)	*P*	Effect size Cohen's *d*
Observer-rated ADHD-symptoms, CAARS-O:SV, total score: mean (95% CI)				
Baseline	40.0 (37.5 to 42.5)	39.9 (36.9 to 43.0)		
Final double-blind visit, week 5	20.4 (14.8 to 26.0)	38.1 (35.0 to 41.1)		
Decrease from baseline to week 5 (RCT)	19.6 (14.7 to 24.5)	1.9 (–0.4 to 4.2)	<0.001	2.17
Final open-label visit, week 52	10.7 (7.7 to 13.7)	17.5 (12.8 to 22.3)		
Decrease from week 5 to week 52 (OLE)	9.7 (4.3 to 15.1)	20.5 (14.5 to 26.5)		
Decrease from baseline to week 52 (RCT + OLE)	29.3 (25.6 to 33.0)	22.4 (16.6 to 28.2)		
Self-reported ADHD symptoms, total score: mean (95% CI)				
Baseline	53.9 (49.0 to 58.7)	56.7 (51.7 to 61.8)		
Final double-blind visit, week 5	36.8 (30.1 to 43.5)	54.7 (49.7 to 59.6)		
Decrease from baseline to week 5 (RCT)	17.1 (9.5 to 24.4)	2.1 (0.02 to 4.1)	0.003	1.67
Final open-label visit, week 52	23.2 (18.3 to 28.1)	32.7 (25.2 to 40.1)		
Decrease from week 5 to week 52 (OLE)	13.6 (6.8 to 20.4)	22.0 (15.2 to 28.8)		
Decrease from baseline to week 52 (RCT + OLE)	30.7 (22.0 to 39.3)	24.1 (16.5 to 31.6)		
Global Assessment of Functioning, mean (95% CI)				
Baseline	33.9 (31.2 to 36.6)	36.5 (33.6 to 39.3)		
Final double-blind visit, week 5	55.2 (48.4 to 62.0)	39.4 (35.9 to 42.9)		
Increase from baseline to week 5 (RCT)	21.3 (14.8 to 27.9)	2.9 (0.3 to 5.5)	0.004	1.62
Final open-label visit, week 52	70.3 (65.8 to 74.9)	64.3 (56.1 to 72.5)		
Increase from week 5 to week 52 (OLE)	15.1 (8.2 to 22.1)	24.9 (16.6 to 33.1)		
Increase from baseline to week 52 (RCT + OLE)	36.5 (31.2 to 41.8)	27.8 (20.0 to 35.6)		
Global ADHD severity, CGI-S ADHD: mean (95% CI)				
Baseline	6.1 (5.8 to 6.3)	5.7 (5.4 to 6.1)		
Final double-blind visit, week 5	4.1 (3.6 to 4.5)	5.7 (5.4 to 6.1)		
Decrease from baseline to week 5 (RCT)	2.0 (1.4 to 2.6)	0.0 (–0.2 to 0.2)	<0.001	2.36
Final open-label visit, week 52	3.1 (2.7 to 3.5)	3.5 (2.8 to 4.2)		
Decrease from week 5 to week 52 (OLE)	0.9 (0.5 to 1.4)	2.2 (1.4 to 3.0)		
Decrease from baseline to week 52 (RCT + OLE)	2.9 (2.4 to 3.4)	2.2 (1.5 to 2.9)		
CGI-Severity ADHD, baseline: *n* (%)				
Not impaired	0	0		
Very mild	0	0		
Mild	0	0		
Moderate	0	0		
Marked	1 (7)	5 (33)		
Severe	12 (80)	9 (60)		
Extremely severe	2 (13)	1 (7)		
CGI-Severity ADHD, final double-blind visit, week 5: *n* (%)				
Not impaired	0	0		
Very mild	0	0		
Mild	3 (20)	0		
Moderate	9 (60)	0		
Marked	2 (13)	5 (33)		
Severe	1 (7)	9 (60)		
Extremely severe	0	1 (7)		
CGI-Severity ADHD, final open-label visit, week 52: *n* (%)				
Not impaired	0	1 (7)		
Very mild	3 (20)	2 (13)		
Mild	7 (47)	4 (27)		
Moderate	5 (33)	5 (33)		
Marked	0	2 (13)		
Severe	0	1 (7)		
Extremely severe	0	0		

ADHD, attention-deficit hyperactivity disorder; CAARS-O:SV, Conners' Adult ADHD Rating Scale – Observer: Screening Version; RCT, randomised controlled trial; OLE, open-label extension; CGI-S, Clinical Global Impression – Severity Scale; OROS-MPH, osmotic-release oral system methylphenidate.
a. *P*-values were calculated using the mixed between–within participants analysis of variance, intention-to-treat (ITT) population, using last observation carried forward (LOCF) for missing values. Changes within participants across different time points were calculated by paired *t*-tests with 95% confidence intervals, divided by group. The CAARS-O:SV was *a priori* defined as the primary outcome measure; therefore no corrections were employed for multiple analyses. Effect size, Cohen's *d* was defined as the difference between the means at end-point week 5, divided by the pool standard deviation. Cohen defined effect sizes as 'small, $d = 0.2$', 'medium, $d = 0.5$' and 'large $d = 0.8$'.

Table DS3 Changes in blood pressure, heart rate and body weight as a function of treatment group and time

Safety parameters	OROS methylphenidate ($n = 15$)	Placebo ($n = 15$)	*P*
Systolic blood pressure, mmHg: mean (95% CI)			
Baseline	122.5 (113.8 to 131.2)	128.9 (118.6 to 139.2)	
Final double-blind visit, week 5	135.6 (129.2 to 142.0)	135.9 (130.4 to 141.3)	0.79
Increase from baseline to week 5 (RCT)	13.1 (2.7 to 23.6)	7.0 (−4.4 to 18.4)	
Final open-label visit, week 52	143.9 (132.3 to 155.6)	135.1 (126.9 to 143.4)	
Increase from week 5 to week 52 (OLE)	8.3 (−1.6 to 18.3)	−0.7 (−9.8 to 8.4)	
Increase from baseline to week 52 (RCT + OLE)	21.5 (8.9 to 34.0)	6.3 (−6.7 to 19.2)	
Diastolic blood pressure, mmHg: mean (95% CI)			
Baseline	69.2 (64.2 to 74.2)	73.0 (69.0 to 77.0)	
Final double-blind visit, week 5	74.4 (68.3 to 80.5)	72.8 (66.3 to 79.3)	0.86
Increase from baseline to week 5 (RCT)	5.2 (1.0 to 9.4)	−0.2 (−7.4 to 7.0)	
Final open-label visit, week 52	80.2 (74.4 to 86.0)	73.5 (68.3 to 78.6)	
Increase from week 5 to week 52 (OLE)	5.8 (−1.4 to 13.0)	0.7 (−3.7 to 5.0)	
Increase from baseline to week 52 (RCT + OLE)	11.0 (4.9 to 17.1)	0.5 (−4.9 to 5.9)	
Heart rate, bpm: mean (95% CI)			
Baseline	66.9 (60.9 to 73.0)	64.5 (61.5 to 67.6)	
Final double-blind visit, week 5	70.9 (63.8 to 78.1)	65.5 (57.3 to 73.6)	0.15
Increase from baseline to week 5 (RCT)	4.0 (–2.1 to 10.1)	0.93 (−6.1 to 8.0)	
Final open-label visit, week 52	71.5 (65.4 to 77.7)	77.7 (70.8 to 84.7)	
Increase from week 5 to week 52 (OLE)	0.6 (–9.1 to 10.3)	12.3 (5.4 to 19.2)	
Increase from baseline to week 52 (RCT + OLE)	4.6 (–1.9 to 11.1)	13.2 (7.0 to 19.4)	
Body weight, kg			
Baseline			
Mean (95% CI)	88.0 (81.1 to 94.9)	91.0 (82.5 to 99.5)	
Median (range)	88.2 (70.2 to 118.0)	88.8 (70.4 to 129.8)	
Final double-blind visit, week 5			
Mean (95% CI)	85.9 (78.9 to 92.9)	90.8 (82.5 to 99.1)	0.44
Median (range)	87.7 (69.3 to 116.0)	85.7 (69.8 to 127.0)	
Decrease from baseline to week 5 (RCT), mean (95% CI)	2.1 (0.9 to 3.3)	0.2 (−1.0 to 1.5)	
Final open-label visit, week 52			
Mean (95% CI)	86.4 (78.5 to 94.3)	87.9 (79.0 to 96.7)	
Median (range)	85.5 (62.4 to 116.0)	86.5 (68.9 to 130.0)	
Decrease from week 5 to week 52 (OLE), mean (95% CI)	−0.5 (−3.0 to 1.9)	2.9 (0.1 to 5.8)	
Decrease from baseline to week 52 (RCT + OLE), mean (95% CI)	1.6 (−1.2 to 4.4)	3.2 (−0.03 to 6.4)	

OROS, osmotic-release oral system; RCT, randomised controlled trial; OLE, open-label extension; bpm, beats per minute.