Supplementary Appendix

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This appendix has been provided by the authors to give readers additional information about the work.

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Trial of Training to Reduce Driver Inattention in Teens with ADHD

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1. Representativeness of Study Participants

Table S1. Representativeness of Study Participants	
Category	Example
Disease, problem, or condition under investigation	Attention-Deficit/Hyperactivity Disorder (ADHD)
Special considerations related to:	
Age	As children age, hyperactivity/impulsivity symptoms of ADHD become less prominent, while symptoms of inattention persist (APA, 2013).
Sex and gender	ADHD affects males more than females, typically at a 2:1 ratio (APA, 2013), with females more likely than males to present primarily with inattentive features.
Race/Ethnicity	Incidence rates for ADHD are highest in White children, slightly lower in Black and Hispanic children, and lowest for Asian children (Shi et al, 2021). Black and Hispanic drivers are less likely than non-Hispanic White drivers to get their driver's license before age 18 (Shults, Banerjee, & Perry, 2016; Tefft, Williams, & Grabowski, 2014; Vaca et al., 2021).
Other considerations	ADHD is typically treated with stimulant medication, particularly in adolescents and young adults, for whom there are fewer behavioral/psychosocial treatments (Pelham & Fabiano, 2008; Smith, Waschbusch, Willoughby, & Evans, 2000).

Overall Representativeness of this Trial	The participants in the current trial demonstrated the expected ratio of males to females. There was a higher percentage of White participants than other racial categories in the study, and the percentage of Black and Hispanic participants was somewhat lower than expected given national and local prevalence rates. Data from the 2020 US Census indicates that the ethnic composition of the greater Cincinnati metropolitan area is 79% Caucasian, 12% African American, 3% Hispanic, 3% Asian, and 3% biracial/multiracial (US Census Bureau, 2019). However, White drivers are more likely to receive their driver's license prior to age 18 (Shults, Tanerjee, & Perry, 2016; Tefft, Williams, & Grabowski, 2014). As expected (Halbrook et al., 2016), given the age of our sample (*M* = 17.38 years, *SD* = .93), inattentive symptom ratings were higher than hyperactivity/impulsivity symptom ratings. At baseline, 68.4% of participants reported taking stimulant medication to manage their ADHD. Information on age, sex, and race/ethnicity was obtained on a questionnaire completed by participants or their caregivers. Date of birth and current age were provided; sex was coded as male (0) or female (1). Race was reported as White, Black or African American, Asian, American Indian or Alaskan Native, Native Hawaiian or Other Pacific Islander, or Other (if other was selected, the participant or caregiver were asked to specify race). Ethnicity was reported as Hispanic or Latino/a or Not Hispanic or Latino/a. Each of the ADHD inattentive and hyperactive/impulsive symptoms were rated on a 4-point scale (0=never, 1=occasionally, 2=often, 3=very often) on the Vanderbilt Parent Assessment Scale (Wolraich et al., 2003). Stimulant medication use was captured in a series of questions rated by the participant (i.e., Do you take any medications for attention, learning, emotional or behavioral difficulties? Yes/No; What is the name of the medication? List of 39 medications provided to select from and an "Other" category.)

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2. Sample sociodemographics and rates of psychiatric comorbidity

Table S2: Sociodemographics and rates of psychiatric diagnoses across all participants and within the FOCAL+ and Control groups

	All participants (*n*=152)	**FOCAL+ (*n*=76)**	**Control (*n*=76)**
Sociodemographics			
Maternal/paternal education (highest)			
High school graduate [N (%)]	18 (11.9)	5 (6.6)	13 (17.1)
Bachelor's degree [N (%)]	64 (42.1)	38 (50.0)	26 (34.2)
Graduate degree [N (%)]	66 (43.4)	32 (42.1)	34 (44.7)
Unknown [N (%)]	4 (2.6)	1 (1.3)	3 (3.9)
Family income (dollars)			
0 - $40,000 [N (%)]	8 (5.3)	3 (3.9)	5 (6.6)
$40,001 - $80,000 [N (%)]	28 (18.4)	15 (19.7)	13 (17.1)
$80,000+ [N (%)]	116 (76.3)	58 (76.3)	58 (76.3)
Unknown	1 (0.7)	1 (1.3)	0 (0.0)
Psychiatric Comorbidities*			
Oppositional Defiant Disorder [N (%)]	11 (7.2)	5 (6.6)	6 (7.9)
Anxiety Disorder (includes GAD and PTSD) [N (%)]	32 (21.1)	11 (14.5)	21 (27.6)
Mood Disorder (includes Depression, Dysthymia, & Mania) [N (%)]	15 (9.9)	4 (5.3)	11 (14.5)

Notes: FOCAL+: Enhanced FOcused Concentration and Attention Learning; KSADS: Schedule for Affective Disorders and Schizophrenia for School-Aged Children; GAD: Generalized Anxiety Disorder; PTSD: Post-Traumatic Stress Disorder; *based on KSADS interview

3. Randomization method

Participants were randomized to the two training groups according to a 1:1 ratio. The randomization scheme was done using blocks of 10 so that for every 10 participants, 5 were randomized to each group. A data manager (JS) generated the allocation sequence using the Microsoft Excel random number function. At study outset, each assignment for the full sample was placed in sequentially numbered sealed envelopes. When participants attended the initial training visit, the randomization envelope for that participant was opened at which time the participant's randomized group was revealed to the individual conducting the participant's training.

4. Driving Simulation Figure

Figure S1: Driving evaluation consisted of two simulated 15-minute drives. Approximately once per minute, the driver was alerted with an auditory and visual cue (i.e., a letter on the dashboard). Within 20 secs, they were asked to identify how many roads started with the target letter on a GPS map displayed on the simulated center console (map search task).

5. Power Analyses

Effect size estimates from our preliminary data suggested a single FOCAL+ training session improves extended eye glances among teens with ADHD with an effect size (Cohen's *d*) of 1.19. Since this effect size will surely diminish over the course of the 1-year of assessments, we used a conservative effect size estimate of .6 to power our research hypotheses. Monte Carlo simulation power analyses were performed under the following assumptions: (a) $\alpha<.05$ (two-tailed); (b) FOCAL+ effect size of .6, (c) effect size of .10 for our sham training, and (d) inclusion of months of driving experience as a covariate. Power analysis with these assumptions indicated that sample sizes of N = 43 per group with complete data at 1-month and 6-month time points will result in power $\geq$ .80 to detect an adjusted mean difference $\left(\bar{X}_{Adj.}\right)$ ≤ -0.36 in standard deviation of lane position between FOCAL+ and control groups and an incidence rate ratio ≤ 0.88 between FOCAL+ and control groups for count of long glances.

However, the original grant application (see Aim #4 in original protocol) included additional aims to examine potential moderators of training effects. These moderators included baseline cognitive performance, ADHD symptom severity, and psychiatric comorbidities. Power analyses for detecting moderation effects suggested that we would require a sample size of 136 with complete data at 1-month and 6-month timepoints to provide 80% power.

Note that we powered based on complete data at 1-month and 6-month timepoints because we were unsure about rates of sample retention given the nature of the patient population (i.e., teens with ADHD). Hence, when we reached our original goal of randomizing 136 participants, we examined rates of retention at that point and estimated how many additional participants would be required to achieve 136 participants with completed data at the 1- and 6- month timepoints. The calculation suggested that we needed to recruit a randomized sample size of 152 to achieve 136 participants with 1- and 6-month simulator outcomes (primary endpoints). Note that this strategy largely worked as we had 135 participants with complete data at the 1-month timepoint and 135 participants with complete data at the 6-month timepoint.

To avoid listwise deletion and to be able to conduct an intent-to-treat analyses, we used imputation for any missing data (see section 6). For our intent-to-treat analyses for our primary outcomes with the full complement of randomized participants, N=152 (n=76 per group) participants provided 96% power to detect an incidence rate ratio of ≤ 0.88 between FOCAL+ and controls for count of long-glances and an adjusted mean difference of ≤ -0.36 for standard-deviation of lateral-position between FOCAL+ and controls.

6. Missing Data Handling

Primary Analyses (see manuscript)

Two different types of multiple imputation models, data analysis model-based imputation, and fully-conditional specification imputation (Enders, 2010; Graham, 2012; Muthén & Muthén, 1998-2017, p. 576), were used to handle primary analysis missing data because the two primary outcomes were measured on two different scales. Missing data for standard-deviation of lane-position, a continuous response variable, was handled using model based imputation assuming a normal distribution. Specifically, a model in which specific driving simulator “runs” (level 1) nested within drive types over time (level 2) across participants (level 3) formed the foundation of the missing data imputation model. A binary indicator of the specific driving simulator “run” was the sole level 1 predictor of standard-deviation of lane-position (“DV”), and that effect was allowed to vary across driving types at level 2 (i.e., slope variance; “RUN1VAR”). Binary indicators of 1-month (“DriveType_1”) and 6-month (“DriveType_2”) predicted both standard-deviation of lane-position (“DV”) and the variation in the effect of specific “run” as a predictor of standard-deviation of lane-position (“RUN1VAR”) at level 2, and all four of those predictive effects (shown as “Dr1_DV”, “Dr2_DV”, “Dr1_Run1”, “Dr2_Run1”) were allowed to vary across participants at level 3. Randomization (“TxGroup”) was entered as a level 3 predictor of all 5 sources of variance (“Run1Var”, “Dr1_DV”, “Dr2_DV”, “Dr1_Run1”, “Dr2_Run1”). Driving experience, a level 3 covariate, was included in the model as a predictor of standard-deviation of lane-position (“DV”) variance across participants. The standard-deviation of lane-position multiple imputation model is represented graphically in the figure below.

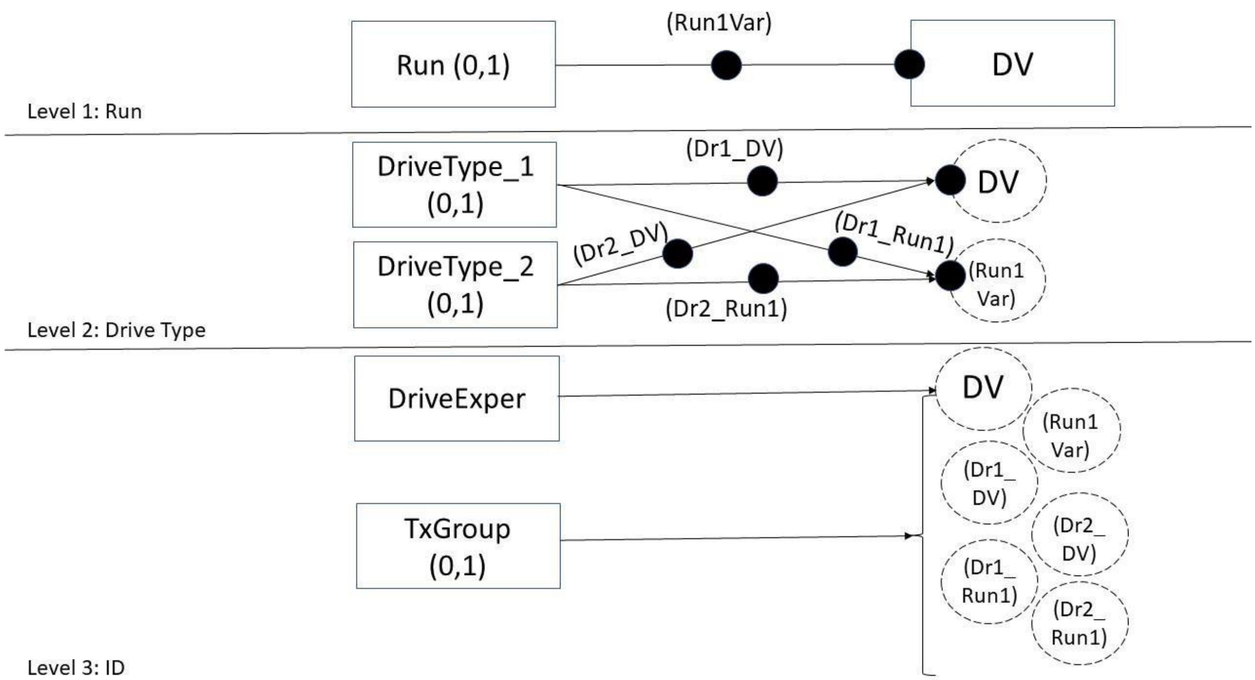

Figure S2: Missing data modeling for standard deviation of lane position.

Missing data for long-glances, a Poisson-distributed count response variable, could not be imputed with the same 3-level model used to impute missing standard-deviation of lane-position data. Currently, there is no statistical analysis software package capable of imputing missing 3-level count response variable data. In fact, only Mplus (version 8.8) is capable imputing missing multilevel count data, but only under two conditions: 1.) the imputation model can have no more than two levels, and 2.) missing count of long-glances data can only be imputed with a fully conditional specification (or H_A:) model. As such, the multiple imputation model used to handle missing long - glance data is different from the imputation model used to handle missing standard-deviation of lane-position data in two ways: 1.) a 2-level imputation model, where long-glances variation in driving "runs" nested within post-baseline "drive types" constituted the level 1 model, and long-glances variation across participants constituted the level 2 model, and 2.) all available analysis variable information (i.e., means, variances [where applicable], and covariances [where applicable]) at both levels was used to impute missing long-glances data.

M = 100 imputed datasets were generated for all multiple imputation models. Imputed standard-deviation of lane-position and long-glances primary outcomes data were analyzed using generalized estimating equations (GEE) allowing response variable data non-independence from "runs" nested within "drive types" across participants to be modeled. Specifically, the standard-deviation of lane-position GEE model was specified using a normal distribution assumption with an identity link function. The GEE for long-glances, a count variable, was modeled specifying a Poisson distribution and a natural logarithmic link function. All primary and secondary GEE analyses of imputed data pooled the estimates based on Rubin's rules, and all standard errors were computed based on the average standard errors across imputations and the parameter estimate variation across imputations (Rubin, 1987; Schafer, 1997).

Secondary Analyses (see manuscript)

The two outcomes for the secondary analyses, off-road glances and crash/near crash were both measured on a binary scale. Some participants did not have any events either due to the DriveCam not being installed in their car or they did not have any events. Such missing data was not imputed, and we conducted non intent-to-treat analysis using those participants with event data. There was no missing data for the ‘crash/near crash’ secondary outcome across events for those with a DriveCam installed. The GEE analysis for the ‘crash/near crash’ outcome was performed using all participants with DriveCam event data available. However, long glance data was missing for some events due to unforeseen circumstances (e.g., DriveCam view obstruction or participant driver was wearing sunglasses). Missing data for the ‘long-glance’ outcome was imputed using GEE model-based imputation. Specifically, a logistic link function was used within a missing data imputation model that allowed the effect of random assignment to predict the presence (=1) or absence (=0) of long-glances nested within participants while controlling for months of driving experience and days DriveCam was operational in vehicle.

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Muthén, L.K. and Muthén, B.O. (1998-2017). Mplus User’s Guide. (8th ed.). Los Angeles, CA: Muthén & Muthén

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8. <u>Adverse Events Table</u>

Table S3. Adverse events across all participants and within the FOCAL+ and Control groups				
	All Participants (n=152)	**FOCAL+ (*n*=76)**	**Control (*n*=76)**	**p-value***
	# (%) of Subjects	# (%) of Subjects	# (%) of Subjects	
Simulator Sickness including nausea and headache during assessment±	2 (1%)	0 (0%)	2 (3%)	0.50
Simulator Sickness including nausea and headache during training±	10 (7%)	6 (8%)	4 (5%)	0.75
Frustration with simulator training	2 (1%)	2 (3%)	0 (0%)	0.50

*p-value from Fisher's Exact Test comparing FOCAL+ to Control; ± Of these participants who reported simulator sickness during a training or assessment, all but two (one in each group) went on to complete their 1-month and 6-month drives. FOCAL+: Enhanced FOcused Concentration and Attention Learning

9. Graph of FOCAL+ vs. Control Training Effects on Number of Long Eye Glances Away from Roadway

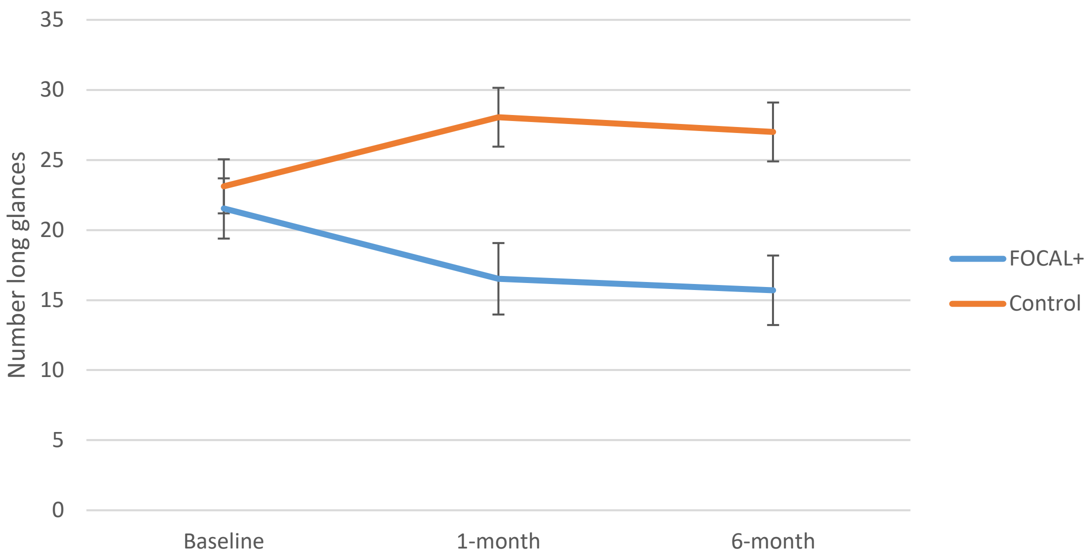

Figure S3: Mean number (with 95% confidence intervals) of long-glances per 15 minute run (adjusted for months of driving experience) during driving simulation among teens with ADHD across FOCAL+ and Control groups after controlling for driver's experience. FOCAL+: Enhanced FOcused Concentration and Attention Learning

10. Graph of FOCAL+ vs. Control Training Effects on Standard Deviation of Lane Position

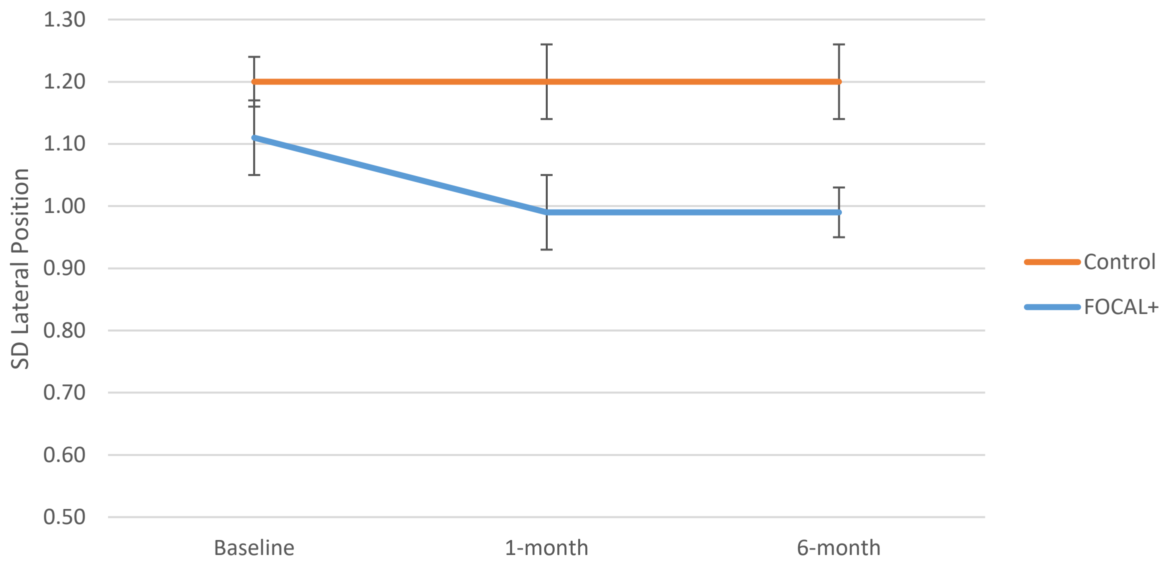

Figure S4: Mean (with 95% confidence intervals) standard-deviation of lane-position (adjusted for months of driving experience) during driving simulation among teens with across FOCAL+ and Control groups after controlling for driver's experience. FOCAL+: Enhanced FOcused Concentration and Attention Learning

11. Moderation Analyses – Medication

While an overall beneficial effect of FOCAL+ compared to Control is reported in the primary analyses, it is possible that FOCAL+ effectiveness was moderated by ADHD medication given the known impact of stimulant medication on improving driving in teens with ADHD (Chang et al., 2017). Of the 140 teens who completed a medication use questionnaire during the 1-year of naturalistic driving, 46 (68.7%) teens in the FOCAL+ group took stimulant medication and 53 (72.6%) teens in the Control group took stimulant medication. It is possible that FOCAL+ training was moderated by teen's medication status.

For the driving simulation outcomes, we examined whether the improvements from baseline to 1-month post-training and baseline to 6-months post-training were moderated by medication status. These analyses were not intent-to-treat since only the 140 teens for whom we had information about medication status during the 1 year of follow-up were included in these analyses. Adjusted mean differences for standard-deviation of lane-position and incident rate ratios for count of long glances were computed using multiple group analysis methods. Specifically, conditional on months of driving experience, training group difference statistics were computed separately across binary medication status.

For DriveCam outcomes, relative risk statistics for binary indicators of long glances and crash/near crash were computed conditional on both months of driving experience and days of DriveCam installation. Specifically, relative risk statistics were computed separately across binary medication status.

Table S4 reports on the results of these analyses.

Table S4. FOCAL+ and Control Training Effects Across Teens Taking and Not Taking Stimulant Medication

Medication Status	Driving Simulation Outcomes*	FOCAL+ (N=76)	Control (N=76)	Incidence Rate Ratio [95% CI])*
Medicated	Count of long-glances/15 min – 1-month post-training	16.57 (13.81, 19.33)	27.03 (24.72, 29.34)	0.61 (0.46, 0.76)
Non-medicated	Count of long-glances/15 min – 1-month post-training	19.45 (15.77, 23.13)	27.86 (24.24, 31.48)	0.70 (0.49, 0.91)
Medicated	Count of long-glances/15 min – 6-months post-training	15.63 (12.98, 18.28)	26.66 (24.42, 28.90)	0.58 (0.44, 0.72)
Non-medicated	Count of long-glances/15 min – 6-months post-training	20.00 (16.91, 23.08)	25.86 (21.69, 30.04)	0.78 (0.55, 1.01)
				Adjusted Mean Difference* (95% CI)
Medicated	Standard-deviation of lane-position – 1-month post-training	0.90 (0.85, 0.96)	1.20 (1.09, 1.31)	-0.30 (-0.42, -0.17)
Non-medicated	Standard-deviation of lane-position – 1-months post-training	0.96 (0.85, 1.07)	1.06 (0.97, 1.16)	-0.11 (-0.26, 0.04)
Medicated	Standard-deviation of lane-position – 6-month post-training	0.92 (0.87, 0.98)	1.25 (1.13, 1.36)	-0.32 (-0.45, -0.20)
Non-medicated	Standard-deviation of lane-position – 6-months post-training	0.96 (0.79, 1.12)	1.02 (0.92, 1.12)	-0.06 (-0.26, 0.13)
	DriveCam outcomes**	**FOCAL+ (N=72)** no./total events (%)	**Control (N=72)** no./total events (%)	**Adjusted Relative Risk** (95% CI)**
Medicated	Long-glance	248/1297 (19%)	423/1450 (29%)	0.71 (0.56, 0.87)
Non-medicated	Long-glance	208/894 (23%)	165/411 (40%)	0.62 (0.43, 0.81)
Medicated	Crash/Near crash	60/1621 (4%)	123/1919 (6%)	0.59 (0.35, 0.99)
Non-medicated	Crash/Near crash	39/1139 (3%)	33/656 (5%)	0.69 (0.33, 1.45)

FOCAL+: Enhanced FOcused Concentration and Attention Learning; *Mean values and difference values are adjusted for teen's driving experience. Numbers in parentheses are ± 95% confidence interval. **Relative risks are adjusted for teen's driving experience (months) and number of days DriveCam operational in car. The widths of confidence intervals are not adjusted for multiple comparisons and no definite conclusions can be drawn from these results.

Chang Z, Quinn PD, Hur K, et al. Association between medication use for attention-deficit/hyperactivity disorder and risk of motor vehicle crashes. JAMA Psychiatry 2017;74:597-603.

13. COVID-19 Sensitivity Analysis

Recruitment for this study was performed between December 21, 2016 and March 4, 2020. The final participant's conclusion of their 1-year of naturalistic driving occurred on November 25, 2021. COVID-19 related restrictions began on March 15, 2020. With the institution of COVID-19 restrictions, teen driving patterns may have been affected due to remote schooling, closed businesses, etc. (Stavrinos et al., 2020). Hence, it is important to assess whether the observed benefits of FOCAL+ were impacted by COVID-19 related driving patterns.

For 56 (FOCAL+: n=29 teens; Control: n=27 teens) of the 152 participants, their 1-year of naturalistic driving included days beyond March 15, 2020 when COVID restrictions were put into place. We conducted a sensitivity analyses of our naturalistic driving results by re-running our primary and secondary analyses but including only the 96 teens (FOCAL+ n=47; Control n=49) whose 1-year of naturalistic driving ended prior to COVID restrictions. Below are results of those analyses. Note that the widths of confidence intervals are not adjusted for multiple comparisons and no definite conclusions can be drawn from these results.

Table S5. Driving Simulation Outcomes Across Control and FOCAL+ Training Groups at 1-Month and 6-Months Post-Training – Limited to Teens whose 1-year of Naturalistic Driving Ended Prior to COVID-19 restrictions

	Control (N=49)	FOCAL+ (N=47)	**Incidence Rate Ratio (95% CI)**
Primary outcomes*			
Count of long-glances/15 min – 1-month post-training	29.89 (27.31, 32.47)	17.82 (14.83, 20.78)	0.63 (0.49, 0.76)
Count of long-glances/15 min – 6-months post-training	29.40 (26.95, 31.84)	17.10 (14.20, 20.01)	0.61 (0.48, 0.74)
			Adjusted Mean Difference* (95% CI)
Standard-deviation of lane-position – 1-month post-training	1.18 (1.11, 1.26)	0.97 (0.89, 1.05)	-0.22 (-0.30, -0.13)
Standard-deviation of lane-position – 6-months post-training	1.20 (1.11, 1.29)	1.01 (0.93, 1.08)	-0.19 (-0.29, -0.10)

FOCAL+: Enhanced FOcused Concentration and Attention Learning; *All mean values and difference values are adjusted for teen's driving experience. Numbers in parentheses are ± 95% confidence interval. The widths of confidence intervals are not adjusted for multiple comparisons and no definite conclusions can be drawn from these results.

With the sample constrained to include only teens whose 1 year of naturalistic post-training driving did not encompass COVID-19 restrictions, FOCAL+ teens had a relative risk of 0.73 (95% confidence interval [CI], 0.55 to 0.91) of having a long-glances and a relative risk of 0.60 (95% CI, 0.38 to 0.96) of having a crash/near crash event compared to control teens.

Stavrinos, D., McManus, B., Mrug, S., He, H., Gresham, B., Albright, M. G., ... & White, D. M. (2020). Adolescent driving behavior before and during restrictions related to COVID-19. *Accident Analysis & Prevention*, *144*, 105686.