

CHDR
Centre for Human Drug Research

**Statistical appendix: Analysis of
pharmacodynamic parameters
CHDR1939-B**

**Randomized, double-blind, placebo-
controlled, two way crossover, single
centre study evaluating the acute and
chronic effect of clonazepam on
cognitive tests and patientreported
outcome measures in patients with
ARID1B-related intellectual disability**

PROTOCOL MANAGEMENT

CHDR protocol ID	CHDR1939-B
Short title	Clonazepam in ARID1B Evaluation (CARE study)
Sponsor protocol ID	
File name	CHDR1939-B_FPD_2023-01-18_ABC
Date	2023-01-18

Investigator site

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Sponsor

Company name	Centre for Human Drug Research
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Description of the analysis

Changes in data

This report focuses on the ABC Questionnaire data.

Calculations

Using 58 ABC scales for every corresponding parent/teacher, 5 ABC subscales are calculated as follows:

- Irritability = sum(ABC_Quest_02, ABC_Quest_04, ABC_Quest_08, ABC_Quest_10, ABC_Quest_14, ABC_Quest_19, ABC_Quest_25, ABC_Quest_29, ABC_Quest_34, ABC_Quest_36, ABC_Quest_47, ABC_Quest_50, ABC_Quest_52, ABC_Quest_57)
- Lethargy = sum(ABC_Quest_03, ABC_Quest_05, ABC_Quest_12, ABC_Quest_16, ABC_Quest_20, ABC_Quest_23, ABC_Quest_26, ABC_Quest_30, ABC_Quest_32, ABC_Quest_37, ABC_Quest_40, ABC_Quest_42, ABC_Quest_43, ABC_Quest_53, ABC_Quest_55, ABC_Quest_58)
- Stereotypic = sum(ABC_Quest_06, ABC_Quest_11, ABC_Quest_17, ABC_Quest_27, ABC_Quest_35, ABC_Quest_45, ABC_Quest_49)
- Hyperactivity = sum(ABC_Quest_07, ABC_Quest_13, ABC_Quest_15, ABC_Quest_18, ABC_Quest_21, ABC_Quest_24, ABC_Quest_28, ABC_Quest_31, ABC_Quest_38, ABC_Quest_39, ABC_Quest_44, ABC_Quest_48, ABC_Quest_51, ABC_Quest_54, ABC_Quest_56)
- Inappropriate = sum(ABC_Quest_09, ABC_Quest_22, ABC_Quest_33, ABC_Quest_46)

Analysis

All ABC variables are listed by subject, treatment, visit and time, and individual plots per treatment by time are generated.

ABC variables are summarized by treatment and time. CGI variables are summarized by frequency tables and graphs.

Every ABC subscale test is analysed using mixed model analysis of variance with fixed factors treatment and period, with random factor subject and score on day 1 as covariate. Only ABC subscales scored by parents are analysed. ABC subscales scored by teachers are not analysed as more than half of the data is missing.

The following contrast is calculated within the models:

- Clonazepam versus Placebo on day 22

A summary table of the analysis results per variable is generated with estimates of the difference of the different contrasts and a back transformed estimate of the difference in percentage for log transformed parameters, 95% confidence intervals (in percentage for log-transformed parameters) and Least Square Means (geometric means for log transformed parameters), and the p-value of the contrasts. Least Square Means graphs are generated, with the Least Square Means of the analysis.

Finally the full ANOVA SAS output is added, as is the used SAS program.

All calculations were performed using SAS for windows V9.4 (SAS Institute, Inc., Cary, NC, USA).

Individual pharmacodynamic response data

DRAFT

Listing 1 Parents: ABC Hyperactive/Noncompliance subscale score

**Listing 1 Parents: ABC Hyperactive/Noncompliance subscale score
Safety population**

Subject	Visit	Treatment	Date	Time from dosing			Parents: ABC Hyperactive/Noncompliance subscale score
				Time (hh:mm)	Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	11SEP2021	9:30	-0:18	-1:28	13
			02OCT2021	11:52	503:42	504:54	13
	2	Clonazepam	23OCT2021	11:14	-0:18	0:43	9
			13NOV2021	14:34	503:42	508:03	11
202	1	Clonazepam	11SEP2021	11:27	-0:18	-0:58	22
			02OCT2021	12:15	503:42	503:50	16
	2	Placebo	23OCT2021	11:16	-0:18	0:17	21
			13NOV2021	14:35	503:42	507:36	13
203	1	Placebo	11SEP2021	11:29	-0:18	-1:07	7
			02OCT2021	12:23	503:42	503:47	3
	2	Clonazepam	23OCT2021	12:27	-0:18	0:19	3
			13NOV2021	14:36	503:42	506:28	6
204	1	Clonazepam	25SEP2021	M	-0:18		4
			16OCT2021	16:00	503:42	507:45	2
	2	Placebo	06NOV2021	10:22	-0:18	-0:08	4
			27NOV2021	11:02	503:42	504:32	1
205	1	Placebo	25SEP2021	M	-0:18		31
			16OCT2021	17:00	503:42	509:07	32
	2	Clonazepam	06NOV2021	14:32	-0:18	3:25	15
			27NOV2021	11:07	503:42	504:00	21
206	1	Clonazepam	25SEP2021	M	-0:18		21
			16OCT2021	17:02	503:42	508:17	M
	2	Placebo	21NOV2021	10:52	-0:18	0:47	M
			12DEC2021	10:42	503:42	504:37	9
207	1	Clonazepam	09OCT2021	11:12	-0:18	0:10	20
			M	M	503:42	M	M
208	1	Placebo	10OCT2021	14:49	-0:18	3:18	7
			31OCT2021	11:13	503:42	503:42	8
	2	Clonazepam	21NOV2021	9:39	-0:18	-1:09	8
			12DEC2021	M	503:42		7
209	1	Clonazepam	10OCT2021	14:49	-0:18	4:23	7
			31OCT2021	11:14	503:42	504:48	4
	2	Placebo	21NOV2021	10:54	-0:18	-0:14	1
			M	M	503:42	M	M
210	1	Placebo	10OCT2021	11:47	-0:18	0:35	19

M=Missing

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Listing 1 Parents: ABC Hyperactive/Noncompliance subscale score
Safety population

Subject	Visit	Treatment	Date	Time from dosing			Parents: ABC Hyperactive/Noncompliance subscale score
				Time (hh:mm)	Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	31OCT2021	11:05	503:42	503:53	19
	2	Clonazepam	21NOV2021	10:56	-0:18	0:19	23
			12DEC2021	10:55	503:42	504:18	40
211	1	Placebo	12MAR2022	12:40	-0:18	0:00	8
			02APR2022	15:57	503:42	507:17	4
	2	Clonazepam	14MAY2022	10:55	-0:18	0:24	5
			03JUN2022	11:05	503:42	480:34	10
212	1	Clonazepam	29JAN2022	13:58	-0:18	3:23	3
			19FEB2022	13:00	503:42	506:25	3
	2	Placebo	12MAR2022	10:21	-0:18	0:26	0
			02APR2022	10:43	503:42	504:48	M
213	1	Clonazepam	29JAN2022	11:34	-0:18	0:45	19
			19FEB2022	13:30	503:42	506:41	30
	2	Placebo	12MAR2022	10:27	-0:18	0:22	26
			02APR2022	10:48	503:42	504:43	7
214	1	Placebo	29JAN2022	13:58	-0:18	2:37	10
			19FEB2022	15:22	503:42	508:01	7
	2	Clonazepam	12MAR2022	11:45	-0:18	0:28	7
			02APR2022	11:04	503:42	503:47	11
215	1	Clonazepam	12MAR2022	13:17	-0:18	0:12	2
			02APR2022	13:07	503:42	504:02	3
	2	Placebo	23APR2022	11:03	-0:18	0:44	0
			14MAY2022	10:54	503:42	504:35	0
216	1	Placebo	12MAR2022	M	-0:18		M
			02APR2022	13:08	503:42	504:56	M
	2	Clonazepam	23APR2022	10:06	-0:18	0:23	M
			12MAY2022	10:32	503:42	456:49	M

M=Missing

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Listing 2 Parents: ABC Inappropriate Speech subscale score

**Listing 2 Parents: ABC Inappropriate Speech subscale score
Safety population**

Subject	Visit	Treatment	Date	Time from dosing			Parents: ABC Inappropriate Speech subscale score
				Time (hh:mm)	Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	11SEP2021	9:30	-0:18	-1:28	4
			02OCT2021	11:52	503:42	504:54	8
	2	Clonazepam	23OCT2021	11:14	-0:18	0:43	3
			13NOV2021	14:34	503:42	508:03	4
202	1	Clonazepam	11SEP2021	11:27	-0:18	-0:58	3
			02OCT2021	12:15	503:42	503:50	2
	2	Placebo	23OCT2021	11:16	-0:18	0:17	2
			13NOV2021	14:35	503:42	507:36	1
203	1	Placebo	11SEP2021	11:29	-0:18	-1:07	1
			02OCT2021	12:23	503:42	503:47	2
	2	Clonazepam	23OCT2021	12:27	-0:18	0:19	1
			13NOV2021	14:36	503:42	506:28	0
204	1	Clonazepam	25SEP2021	M	-0:18		0
			16OCT2021	16:00	503:42	507:45	0
	2	Placebo	06NOV2021	10:22	-0:18	-0:08	0
			27NOV2021	11:02	503:42	504:32	0
205	1	Placebo	25SEP2021	M	-0:18		1
			16OCT2021	17:00	503:42	509:07	3
	2	Clonazepam	06NOV2021	14:32	-0:18	3:25	1
			27NOV2021	11:07	503:42	504:00	2
206	1	Clonazepam	25SEP2021	M	-0:18		0
			16OCT2021	17:02	503:42	508:17	1
	2	Placebo	21NOV2021	10:52	-0:18	0:47	0
			12DEC2021	10:42	503:42	504:37	0
207	1	Clonazepam	09OCT2021	11:12	-0:18	0:10	9
			M	M	503:42	M	M
208	1	Placebo	10OCT2021	14:49	-0:18	3:18	1
			31OCT2021	11:13	503:42	503:42	1
	2	Clonazepam	21NOV2021	9:39	-0:18	-1:09	1
			12DEC2021	M	503:42		1
209	1	Clonazepam	10OCT2021	14:49	-0:18	4:23	1
			31OCT2021	11:14	503:42	504:48	1
	2	Placebo	21NOV2021	10:54	-0:18	-0:14	1
			M	M	503:42	M	M

M=Missing

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Listing 2 Parents: ABC Inappropriate Speech subscale score
Safety population

Subject	Visit	Treatment	Date	Time from dosing		Parents: ABC Inappropriate Speech subscale score	
				Time (hh:mm)	Actual (hh:mm)		
210	1	Placebo	10OCT2021	11:47	-0:18	0:35	0
			31OCT2021	11:05	503:42	503:53	1
	2	Clonazepam	21NOV2021	10:56	-0:18	0:19	0
			12DEC2021	10:55	503:42	504:18	2
211	1	Placebo	12MAR2022	12:40	-0:18	0:00	0
			02APR2022	15:57	503:42	507:17	0
	2	Clonazepam	14MAY2022	10:55	-0:18	0:24	0
			03JUN2022	11:05	503:42	480:34	0
212	1	Clonazepam	29JAN2022	13:58	-0:18	3:23	2
			19FEB2022	13:00	503:42	506:25	M
	2	Placebo	12MAR2022	10:21	-0:18	0:26	0
			02APR2022	10:43	503:42	504:48	1
213	1	Clonazepam	29JAN2022	11:34	-0:18	0:45	6
			19FEB2022	13:30	503:42	506:41	6
	2	Placebo	12MAR2022	10:27	-0:18	0:22	7
			02APR2022	10:48	503:42	504:43	2
214	1	Placebo	29JAN2022	13:58	-0:18	2:37	1
			19FEB2022	15:22	503:42	508:01	0
	2	Clonazepam	12MAR2022	11:45	-0:18	0:28	1
			02APR2022	11:04	503:42	503:47	0
215	1	Clonazepam	12MAR2022	13:17	-0:18	0:12	0
			02APR2022	13:07	503:42	504:02	0
	2	Placebo	23APR2022	11:03	-0:18	0:44	0
			14MAY2022	10:54	503:42	504:35	0
216	1	Placebo	12MAR2022	M	-0:18		0
			02APR2022	13:08	503:42	504:56	0
	2	Clonazepam	23APR2022	10:06	-0:18	0:23	0
			12MAY2022	10:32	503:42	456:49	0

M=Missing

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Listing 3 Parents: ABC Irritability subscale score

**Listing 3 Parents: ABC Irritability subscale score
Safety population**

Subject	Visit	Treatment	Date	Time (hh:mm)	Time from dosing		Parents: ABC Irritability subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	11SEP2021	9:30	-0:18	-1:28	M
			02OCT2021	11:52	503:42	504:54	14
	2	Clonazepam	23OCT2021	11:14	-0:18	0:43	11
			13NOV2021	14:34	503:42	508:03	11
202	1	Clonazepam	11SEP2021	11:27	-0:18	-0:58	20
			02OCT2021	12:15	503:42	503:50	9
	2	Placebo	23OCT2021	11:16	-0:18	0:17	17
			13NOV2021	14:35	503:42	507:36	15
203	1	Placebo	11SEP2021	11:29	-0:18	-1:07	2
			02OCT2021	12:23	503:42	503:47	3
	2	Clonazepam	23OCT2021	12:27	-0:18	0:19	1
			13NOV2021	14:36	503:42	506:28	2
204	1	Clonazepam	25SEP2021	M	-0:18		7
			16OCT2021	16:00	503:42	507:45	2
	2	Placebo	06NOV2021	10:22	-0:18	-0:08	4
			27NOV2021	11:02	503:42	504:32	5
205	1	Placebo	25SEP2021	M	-0:18		18
			16OCT2021	17:00	503:42	509:07	17
	2	Clonazepam	06NOV2021	14:32	-0:18	3:25	6
			27NOV2021	11:07	503:42	504:00	13
206	1	Clonazepam	25SEP2021	M	-0:18		15
			16OCT2021	17:02	503:42	508:17	16
	2	Placebo	21NOV2021	10:52	-0:18	0:47	M
			12DEC2021	10:42	503:42	504:37	6
207	1	Clonazepam	09OCT2021	11:12	-0:18	0:10	26
			M	M	503:42	M	M
208	1	Placebo	10OCT2021	14:49	-0:18	3:18	0
			31OCT2021	11:13	503:42	503:42	0
	2	Clonazepam	21NOV2021	9:39	-0:18	-1:09	0
			12DEC2021	M	503:42		0
209	1	Clonazepam	10OCT2021	14:49	-0:18	4:23	4
			31OCT2021	11:14	503:42	504:48	1
	2	Placebo	21NOV2021	10:54	-0:18	-0:14	3
			M	M	503:42	M	M
210	1	Placebo	10OCT2021	11:47	-0:18	0:35	5

M=Missing

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Listing 3 Parents: ABC Irritability subscale score
Safety population

Subject	Visit	Treatment	Date	Time (hh:mm)	Time from dosing		Parents: ABC Irritability subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	31OCT2021	11:05	503:42	503:53	8
	2	Clonazepam	21NOV2021	10:56	-0:18	0:19	4
	12DEC2021		10:55	503:42	504:18	19	
211	1	Placebo	12MAR2022	12:40	-0:18	0:00	2
			02APR2022	15:57	503:42	507:17	0
211	2	Clonazepam	14MAY2022	10:55	-0:18	0:24	1
			03JUN2022	11:05	503:42	480:34	0
212	1	Clonazepam	29JAN2022	13:58	-0:18	3:23	11
			19FEB2022	13:00	503:42	506:25	7
212	2	Placebo	12MAR2022	10:21	-0:18	0:26	7
			02APR2022	10:43	503:42	504:48	9
213	1	Clonazepam	29JAN2022	11:34	-0:18	0:45	11
			19FEB2022	13:30	503:42	506:41	M
213	2	Placebo	12MAR2022	10:27	-0:18	0:22	15
			02APR2022	10:48	503:42	504:43	2
214	1	Placebo	29JAN2022	13:58	-0:18	2:37	17
			19FEB2022	15:22	503:42	508:01	11
214	2	Clonazepam	12MAR2022	11:45	-0:18	0:28	9
			02APR2022	11:04	503:42	503:47	11
215	1	Clonazepam	12MAR2022	13:17	-0:18	0:12	4
			02APR2022	13:07	503:42	504:02	2
215	2	Placebo	23APR2022	11:03	-0:18	0:44	0
			14MAY2022	10:54	503:42	504:35	0
216	1	Placebo	12MAR2022	M	-0:18		3
			02APR2022	13:08	503:42	504:56	M
216	2	Clonazepam	23APR2022	10:06	-0:18	0:23	3
			12MAY2022	10:32	503:42	456:49	1

M=Missing

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Listing 4 Parents: ABC Social Withdrawal subscale score

**Listing 4 Parents: ABC Social Withdrawal subscale score
Safety population**

Subject	Visit	Treatment	Date Time (hh:mm)		Time from dosing		Parents: ABC Social Withdrawal subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	11SEP2021	9:30	-0:18	-1:28	9
			02OCT2021	11:52	503:42	504:54	15
	2	Clonazepam	23OCT2021	11:14	-0:18	0:43	8
			13NOV2021	14:34	503:42	508:03	10
202	1	Clonazepam	11SEP2021	11:27	-0:18	-0:58	31
			02OCT2021	12:15	503:42	503:50	15
	2	Placebo	23OCT2021	11:16	-0:18	0:17	18
			13NOV2021	14:35	503:42	507:36	22
203	1	Placebo	11SEP2021	11:29	-0:18	-1:07	21
			02OCT2021	12:23	503:42	503:47	M
	2	Clonazepam	23OCT2021	12:27	-0:18	0:19	M
			13NOV2021	14:36	503:42	506:28	15
204	1	Clonazepam	25SEP2021	M	-0:18		18
			16OCT2021	16:00	503:42	507:45	8
	2	Placebo	06NOV2021	10:22	-0:18	-0:08	10
			27NOV2021	11:02	503:42	504:32	5
205	1	Placebo	25SEP2021	M	-0:18		10
			16OCT2021	17:00	503:42	509:07	12
	2	Clonazepam	06NOV2021	14:32	-0:18	3:25	5
			27NOV2021	11:07	503:42	504:00	2
206	1	Clonazepam	25SEP2021	M	-0:18		34
			16OCT2021	17:02	503:42	508:17	29
	2	Placebo	21NOV2021	10:52	-0:18	0:47	M
			12DEC2021	10:42	503:42	504:37	M
207	1	Clonazepam	09OCT2021	11:12	-0:18	0:10	M
			M	M	503:42	M	M
208	1	Placebo	10OCT2021	14:49	-0:18	3:18	16
			31OCT2021	11:13	503:42	503:42	M
	2	Clonazepam	21NOV2021	9:39	-0:18	-1:09	21
			12DEC2021	M	503:42		14
209	1	Clonazepam	10OCT2021	14:49	-0:18	4:23	4
			31OCT2021	11:14	503:42	504:48	2
	2	Placebo	21NOV2021	10:54	-0:18	-0:14	3
			M	M	503:42	M	M
210	1	Placebo	10OCT2021	11:47	-0:18	0:35	13

M=Missing

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**Listing 4 Parents: ABC Social Withdrawal subscale score
Safety population**

Subject	Visit	Treatment	Date	Time (hh:mm)	Time from dosing		Parents: ABC Social Withdrawal subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	31OCT2021	11:05	503:42	503:53	13
	2	Clonazepam	21NOV2021 12DEC2021	10:56 10:55	-0:18 503:42	0:19 504:18	12 17
211	1	Placebo	12MAR2022 02APR2022	12:40 15:57	-0:18 503:42	0:00 507:17	2 1
	2	Clonazepam	14MAY2022 03JUN2022	10:55 11:05	-0:18 503:42	0:24 480:34	1 6
212	1	Clonazepam	29JAN2022 19FEB2022	13:58 13:00	-0:18 503:42	3:23 506:25	8 M
	2	Placebo	12MAR2022 02APR2022	10:21 10:43	-0:18 503:42	0:26 504:48	0 M
213	1	Clonazepam	29JAN2022 19FEB2022	11:34 13:30	-0:18 503:42	0:45 506:41	16 21
	2	Placebo	12MAR2022 02APR2022	10:27 10:48	-0:18 503:42	0:22 504:43	24 M
214	1	Placebo	29JAN2022 19FEB2022	13:58 15:22	-0:18 503:42	2:37 508:01	12 6
	2	Clonazepam	12MAR2022 02APR2022	11:45 11:04	-0:18 503:42	0:28 503:47	6 9
215	1	Clonazepam	12MAR2022 02APR2022	13:17 13:07	-0:18 503:42	0:12 504:02	11 21
	2	Placebo	23APR2022 14MAY2022	11:03 10:54	-0:18 503:42	0:44 504:35	8 M
216	1	Placebo	12MAR2022 02APR2022	M 13:08	-0:18 503:42		M M
	2	Clonazepam	23APR2022 12MAY2022	10:06 10:32	-0:18 503:42	0:23 456:49	22 M

M=Missing

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Listing 5 Parents: ABC Stereotypic Behavior subscale score

**Listing 5 Parents: ABC Stereotypic Behavior subscale score
Safety population**

Subject	Visit	Treatment	Date Time (hh:mm)		Time from dosing		Parents: ABC Stereotypic Behavior subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	11SEP2021	9:30	-0:18	-1:28	0
			02OCT2021	11:52	503:42	504:54	0
	2	Clonazepam	23OCT2021	11:14	-0:18	0:43	0
			13NOV2021	14:34	503:42	508:03	0
202	1	Clonazepam	11SEP2021	11:27	-0:18	-0:58	5
			02OCT2021	12:15	503:42	503:50	2
	2	Placebo	23OCT2021	11:16	-0:18	0:17	4
			13NOV2021	14:35	503:42	507:36	4
203	1	Placebo	11SEP2021	11:29	-0:18	-1:07	5
			02OCT2021	12:23	503:42	503:47	4
	2	Clonazepam	23OCT2021	12:27	-0:18	0:19	5
			13NOV2021	14:36	503:42	506:28	2
204	1	Clonazepam	25SEP2021	M	-0:18		3
			16OCT2021	16:00	503:42	507:45	2
	2	Placebo	06NOV2021	10:22	-0:18	-0:08	2
			27NOV2021	11:02	503:42	504:32	1
205	1	Placebo	25SEP2021	M	-0:18		1
			16OCT2021	17:00	503:42	509:07	0
	2	Clonazepam	06NOV2021	14:32	-0:18	3:25	0
			27NOV2021	11:07	503:42	504:00	1
206	1	Clonazepam	25SEP2021	M	-0:18		2
			16OCT2021	17:02	503:42	508:17	0
	2	Placebo	21NOV2021	10:52	-0:18	0:47	0
			12DEC2021	10:42	503:42	504:37	0
207	1	Clonazepam	09OCT2021 M	11:12 M	-0:18 503:42	0:10 M	8 M
208	1	Placebo	10OCT2021	14:49	-0:18	3:18	0
			31OCT2021	11:13	503:42	503:42	0
	2	Clonazepam	21NOV2021	9:39	-0:18	-1:09	0
			12DEC2021	M	503:42		0
209	1	Clonazepam	10OCT2021	14:49	-0:18	4:23	1
			31OCT2021	11:14	503:42	504:48	2
	2	Placebo	21NOV2021	10:54	-0:18	-0:14	1
			M	M	503:42	M	M

M=Missing

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Listing 5 Parents: ABC Stereotypic Behavior subscale score
Safety population

Subject	Visit	Treatment	Date Time (hh:mm)		Time from dosing		Parents: ABC Stereotypic Behavior subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	10OCT2021	11:47	-0:18	0:35	5
			31OCT2021	11:05	503:42	503:53	7
	2	Clonazepam	21NOV2021	10:56	-0:18	0:19	5
			12DEC2021	10:55	503:42	504:18	16
211	1	Placebo	12MAR2022	12:40	-0:18	0:00	1
			02APR2022	15:57	503:42	507:17	0
	2	Clonazepam	14MAY2022	10:55	-0:18	0:24	0
			03JUN2022	11:05	503:42	480:34	0
212	1	Clonazepam	29JAN2022	13:58	-0:18	3:23	0
			19FEB2022	13:00	503:42	506:25	0
	2	Placebo	12MAR2022	10:21	-0:18	0:26	0
			02APR2022	10:43	503:42	504:48	0
213	1	Clonazepam	29JAN2022	11:34	-0:18	0:45	5
			19FEB2022	13:30	503:42	506:41	8
	2	Placebo	12MAR2022	10:27	-0:18	0:22	9
			02APR2022	10:48	503:42	504:43	1
214	1	Placebo	29JAN2022	13:58	-0:18	2:37	3
			19FEB2022	15:22	503:42	508:01	3
	2	Clonazepam	12MAR2022	11:45	-0:18	0:28	0
			02APR2022	11:04	503:42	503:47	0
215	1	Clonazepam	12MAR2022	13:17	-0:18	0:12	4
			02APR2022	13:07	503:42	504:02	1
	2	Placebo	23APR2022	11:03	-0:18	0:44	0
			14MAY2022	10:54	503:42	504:35	1
216	1	Placebo	12MAR2022	M	-0:18		5
			02APR2022	13:08	503:42	504:56	M
	2	Clonazepam	23APR2022	10:06	-0:18	0:23	8
			12MAY2022	10:32	503:42	456:49	M

M=Missing

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Listing 6 Teacher: ABC Hyperactive/Noncompliance subscale score

**Listing 6 Teacher: ABC Hyperactive/Noncompliance subscale score
Safety population**

Subject	Visit	Treatment	Date	Time from dosing		Actual Hyperactive/Noncompliance subscale score	Teacher: ABC score
				Time (hh:mm)	Protocol (hh:mm)		
201	1	Placebo	M	M	24:07	M	M
			M	M	528:06		
	2	Clonazepam	11NOV2021	M	24:07		10
			25NOV2021	M	528:06		6
202	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06		
	2	Placebo	27OCT2021	M	24:07		19
			M	M	528:06		M
203	1	Placebo	M	M	24:07	M	M
			M	M	528:06		
	2	Clonazepam	26OCT2021	M	24:07		1
			15NOV2021	M	528:06		1
204	1	Clonazepam	M	M	24:07	M	M
			16OCT2021	M	528:06		
	2	Placebo	03DEC2021	M	24:07		M
			03DEC2021	M	528:06		M
205	1	Placebo	M	M	24:07	M	M
			25OCT2021	M	528:06		
	2	Clonazepam	M	M	24:07	M	M
			24NOV2021	M	528:06		
206	1	Clonazepam	M	M	24:07	M	M
			27OCT2021	M	528:06		
	2	Placebo	M	M	24:07	M	M
			12DEC2021	M	528:06		
207	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06		
208	1	Placebo	13OCT2021	M	24:07		5
			01NOV2021	M	528:06		2
	2	Clonazepam	M	M	24:07	M	M
			13DEC2021	M	528:06		
209	1	Clonazepam	11OCT2021	M	24:07		2
			31OCT2021	M	528:06		4
	2	Placebo	M	M	24:07	M	5
			M	M	528:06		
210	1	Placebo	11OCT2021	M	24:07		34

M=Missing

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Listing 6 Teacher: ABC Hyperactive/Noncompliance subscale score
Safety population

Subject	Visit	Treatment	Date	Time from dosing			Teacher: ABC Hyperactive/Noncompliance subscale score
				Time (hh:mm)	Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	02NOV2021	M	528:06		20
	2	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
	211	1	Placebo	14MAR2022	M	24:07	18
			04APR2022	M	528:06		15
	2	Clonazepam	16MAY2022	M	24:07		18
			07JUN2022	M	528:06		32
	212	1	Clonazepam	01FEB2022	M	24:07	M
			23FEB2022	M	528:06		M
	2	Placebo	22MAR2022	M	24:07		9
			05APR2022	M	528:06		2
	213	1	Clonazepam	M	M	24:07	M
			11MAR2022	M	528:06		18
	2	Placebo	M	M	24:07	M	21
			05APR2022	M	528:06		M
	214	1	Placebo	M	M	24:07	M
			20FEB2022	M	528:06		10
	2	Clonazepam	M	M	24:07		13
			M	M	528:06	M	17
	215	1	Clonazepam	M	M	24:07	M
			02APR2022	M	528:06		6
	2	Placebo	M	M	24:07	M	7
			M	M	528:06	M	M
	216	1	Placebo	M	M	24:07	M
			06APR2022	M	528:06		M
	2	Clonazepam	26APR2022	M	24:07		7
			M	M	528:06	M	M

M=Missing

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Listing 7 Teacher: ABC Inappropriate Speech subscale score

**Listing 7 Teacher: ABC Inappropriate Speech subscale score
Safety population**

Subject	Visit	Treatment	Date	Time from dosing		Actual Inappropriate Speech (hh:mm)	Teacher: ABC Inappropriate Speech subscale score
				Time (hh:mm)	Protocol (hh:mm)		
201	1	Placebo	M	M	24:07	M	M
			M	M	528:06		0
	2	Clonazepam	11NOV2021	M	24:07		8
			25NOV2021	M	528:06		6
202	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Placebo	27OCT2021	M	24:07		M
			M	M	528:06		M
203	1	Placebo	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Clonazepam	26OCT2021	M	24:07		0
			15NOV2021	M	528:06		0
204	1	Clonazepam	M	M	24:07	M	M
			16OCT2021	M	528:06		0
	2	Placebo	03DEC2021	M	24:07		0
			03DEC2021	M	528:06		0
205	1	Placebo	M	M	24:07	M	M
			25OCT2021	M	528:06		0
	2	Clonazepam	M	M	24:07	M	M
			24NOV2021	M	528:06		0
206	1	Clonazepam	M	M	24:07	M	M
			27OCT2021	M	528:06		0
	2	Placebo	M	M	24:07	M	0
			12DEC2021	M	528:06		0
207	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
208	1	Placebo	13OCT2021	M	24:07		1
			01NOV2021	M	528:06		0
	2	Clonazepam	M	M	24:07	M	0
			13DEC2021	M	528:06		0
209	1	Clonazepam	11OCT2021	M	24:07		0
			31OCT2021	M	528:06		0
	2	Placebo	M	M	24:07	M	0
			M	M	528:06	M	M

M=Missing

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**Listing 7 Teacher: ABC Inappropriate Speech subscale score
Safety population**

Subject	Visit	Treatment	Date	Time from dosing		Actual Inappropriate Speech subscale score
				Time (hh:mm)	Protocol (hh:mm)	
210	1	Placebo	11OCT2021	M	24:07	2
			02NOV2021	M	528:06	0
	2	Clonazepam	M	M	24:07	M
			M	M	528:06	M
211	1	Placebo	14MAR2022	M	24:07	3
			04APR2022	M	528:06	2
	2	Clonazepam	16MAY2022	M	24:07	3
			07JUN2022	M	528:06	3
212	1	Clonazepam	01FEB2022	M	24:07	2
			23FEB2022	M	528:06	5
	2	Placebo	22MAR2022	M	24:07	3
			05APR2022	M	528:06	1
213	1	Clonazepam	M	M	24:07	M
			11MAR2022	M	528:06	1
	2	Placebo	M	M	24:07	M
			05APR2022	M	528:06	1
214	1	Placebo	M	M	24:07	M
			20FEB2022	M	528:06	1
	2	Clonazepam	M	M	24:07	1
			M	M	528:06	1
215	1	Clonazepam	M	M	24:07	M
			02APR2022	M	528:06	0
	2	Placebo	M	M	24:07	M
			M	M	528:06	M
216	1	Placebo	M	M	24:07	M
			06APR2022	M	528:06	0
	2	Clonazepam	26APR2022	M	24:07	0
			M	M	528:06	M

M=Missing

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Listing 8 Teacher: ABC Irritability subscale score

**Listing 8 Teacher: ABC Irritability subscale score
Safety population**

Subject	Visit	Treatment	Date	Time (hh:mm)	Time from dosing		Teacher: ABC Irritability subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	M	M	24:07	M	M
			M	M	528:06		9
	2	Clonazepam	11NOV2021	M	24:07		10
			25NOV2021	M	528:06		6
202	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Placebo	27OCT2021	M	24:07		M
			M	M	528:06		M
203	1	Placebo	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Clonazepam	26OCT2021	M	24:07		1
			15NOV2021	M	528:06		0
204	1	Clonazepam	M	M	24:07	M	M
			16OCT2021	M	528:06		6
	2	Placebo	03DEC2021	M	24:07		M
			03DEC2021	M	528:06		2
205	1	Placebo	M	M	24:07	M	M
			25OCT2021	M	528:06		5
	2	Clonazepam	M	M	24:07	M	M
			24NOV2021	M	528:06		10
206	1	Clonazepam	M	M	24:07	M	M
			27OCT2021	M	528:06		0
	2	Placebo	M	M	24:07	M	0
			12DEC2021	M	528:06		0
207	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
208	1	Placebo	13OCT2021	M	24:07		4
			01NOV2021	M	528:06		2
	2	Clonazepam	M	M	24:07	M	3
			13DEC2021	M	528:06		0
209	1	Clonazepam	11OCT2021	M	24:07		0
			31OCT2021	M	528:06		1
	2	Placebo	M	M	24:07	M	2
			M	M	528:06	M	M
210	1	Placebo	11OCT2021	M	24:07		9

M=Missing

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Listing 8 Teacher: ABC Irritability subscale score
Safety population

Subject	Visit	Treatment	Date	Time (hh:mm)	Time from dosing		Teacher: ABC Irritability subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	02NOV2021	M	528:06		7
	2	Clonazepam		M	24:07	M	M
				M	528:06	M	M
	211	1	Placebo	14MAR2022	M	24:07	8
			04APR2022	M	528:06		13
	2	Clonazepam	16MAY2022	M	24:07		8
			07JUN2022	M	528:06		15
	212	1	Clonazepam	01FEB2022	M	24:07	M
			23FEB2022	M	528:06		M
	2	Placebo	22MAR2022	M	24:07		M
			05APR2022	M	528:06		5
	213	1	Clonazepam	M	24:07	M	4
			11MAR2022	M	528:06		4
	2	Placebo	M	24:07	M		4
			05APR2022	M	528:06	M	0
	214	1	Placebo	M	24:07	M	13
			20FEB2022	M	528:06		18
	2	Clonazepam	M	24:07			17
			M	528:06	M		18
	215	1	Clonazepam	M	24:07	M	M
			02APR2022	M	528:06		6
	2	Placebo	M	24:07	M		7
			M	528:06	M		M
	216	1	Placebo	M	24:07	M	2
			06APR2022	M	528:06		5
	2	Clonazepam	26APR2022	M	24:07		1
			M	528:06	M		M

M=Missing

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Listing 9 Teacher: ABC Social Withdrawal subscale score

**Listing 9 Teacher: ABC Social Withdrawal subscale score
Safety population**

Subject	Visit	Treatment	Date Time (hh:mm)		Time from dosing		Teacher: ABC Social Withdrawal subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	M	M	24:07	M	M
			M	M	528:06		1
	2	Clonazepam	11NOV2021	M	24:07		3
			25NOV2021	M	528:06		0
202	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Placebo	27OCT2021	M	24:07		12
			M	M	528:06		12
203	1	Placebo	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Clonazepam	26OCT2021	M	24:07		5
			15NOV2021	M	528:06		7
204	1	Clonazepam	M	M	24:07	M	M
			16OCT2021	M	528:06		8
	2	Placebo	03DEC2021	M	24:07		M
			03DEC2021	M	528:06		1
205	1	Placebo	M	M	24:07	M	M
			25OCT2021	M	528:06		0
	2	Clonazepam	M	M	24:07	M	M
			24NOV2021	M	528:06		1
206	1	Clonazepam	M	M	24:07	M	M
			27OCT2021	M	528:06		M
	2	Placebo	M	M	24:07	M	M
			12DEC2021	M	528:06		1
207	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
208	1	Placebo	13OCT2021	M	24:07		13
			01NOV2021	M	528:06		14
	2	Clonazepam	M	M	24:07	M	M
			13DEC2021	M	528:06		M
209	1	Clonazepam	11OCT2021	M	24:07		0
			31OCT2021	M	528:06		1
	2	Placebo	M	M	24:07	M	0
			M	M	528:06	M	M
210	1	Placebo	11OCT2021	M	24:07		6

M=Missing

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18JAN2023 12:43 - produced by Maria Joanna Juachon

Listing 9 Teacher: ABC Social Withdrawal subscale score
Safety population

Subject	Visit	Treatment	Date Time (hh:mm)		Time from dosing		Teacher: ABC Social Withdrawal subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	02NOV2021	M	528:06		8
	2	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
	211	1	Placebo	14MAR2022	M	24:07	
			04APR2022	M	528:06		13
	2	Clonazepam	16MAY2022	M	24:07		13
			07JUN2022	M	528:06		17
	212	1	Clonazepam	01FEB2022	M	24:07	
			23FEB2022	M	528:06		11
	2	Placebo	22MAR2022	M	24:07		M
			05APR2022	M	528:06		M
	213	1	Clonazepam	M	M	24:07	M
			11MAR2022	M	528:06		7
	2	Placebo	M	M	24:07	M	5
			05APR2022	M	528:06		1
	214	1	Placebo	M	M	24:07	M
			20FEB2022	M	528:06		0
	2	Clonazepam	M	M	24:07		2
			M	M	528:06	M	1
	215	1	Clonazepam	M	M	24:07	M
			02APR2022	M	528:06		8
	2	Placebo	M	M	24:07	M	8
			M	M	528:06	M	M
	216	1	Placebo	M	M	24:07	M
			06APR2022	M	528:06		18
	2	Clonazepam	26APR2022	M	24:07		5
			M	M	528:06	M	M

M=Missing

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
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Listing 10 Teacher: ABC Stereotypic Behavior subscale score

**Listing 10 Teacher: ABC Stereotypic Behavior subscale score
Safety population**

Subject	Visit	Treatment	Date Time (hh:mm)		Time from dosing		Teacher: ABC Stereotypic Behavior subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
201	1	Placebo	M	M	24:07	M	M
			M	M	528:06		1
	2	Clonazepam	11NOV2021	M	24:07		0
			25NOV2021	M	528:06		0
202	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Placebo	27OCT2021	M	24:07		0
			M	M	528:06		0
203	1	Placebo	M	M	24:07	M	M
			M	M	528:06	M	M
	2	Clonazepam	26OCT2021	M	24:07		0
			15NOV2021	M	528:06		0
204	1	Clonazepam	M	M	24:07	M	M
			16OCT2021	M	528:06		0
	2	Placebo	03DEC2021	M	24:07		M
			03DEC2021	M	528:06		0
205	1	Placebo	M	M	24:07	M	M
			25OCT2021	M	528:06		0
	2	Clonazepam	M	M	24:07	M	M
			24NOV2021	M	528:06		0
206	1	Clonazepam	M	M	24:07	M	M
			27OCT2021	M	528:06		0
	2	Placebo	M	M	24:07	M	0
			12DEC2021	M	528:06		0
207	1	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
208	1	Placebo	13OCT2021	M	24:07		7
			01NOV2021	M	528:06		7
	2	Clonazepam	M	M	24:07	M	4
			13DEC2021	M	528:06		3
209	1	Clonazepam	11OCT2021	M	24:07		0
			31OCT2021	M	528:06		0
	2	Placebo	M	M	24:07	M	0
			M	M	528:06	M	M

M=Missing

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

**Listing 10 Teacher: ABC Stereotypic Behavior subscale score
Safety population**

Subject	Visit	Treatment	Date Time (hh:mm)		Time from dosing		Teacher: ABC Stereotypic Behavior subscale score
					Protocol (hh:mm)	Actual (hh:mm)	
210	1	Placebo	11OCT2021	M	24:07		13
			02NOV2021	M	528:06		18
	2	Clonazepam	M	M	24:07	M	M
			M	M	528:06	M	M
211	1	Placebo	14MAR2022	M	24:07		5
			04APR2022	M	528:06		0
	2	Clonazepam	16MAY2022	M	24:07		5
			07JUN2022	M	528:06		3
212	1	Clonazepam	01FEB2022	M	24:07		0
			23FEB2022	M	528:06		1
	2	Placebo	22MAR2022	M	24:07		2
			05APR2022	M	528:06		0
213	1	Clonazepam	M	M	24:07	M	0
			11MAR2022	M	528:06		0
	2	Placebo	M	M	24:07	M	1
			05APR2022	M	528:06		0
214	1	Placebo	M	M	24:07	M	0
			20FEB2022	M	528:06		0
	2	Clonazepam	M	M	24:07		0
			M	M	528:06	M	0
215	1	Clonazepam	M	M	24:07	M	0
			02APR2022	M	528:06		0
	2	Placebo	M	M	24:07	M	0
			M	M	528:06	M	M
216	1	Placebo	M	M	24:07	M	10
			06APR2022	M	528:06		10
	2	Clonazepam	26APR2022	M	24:07		4
			M	M	528:06	M	M

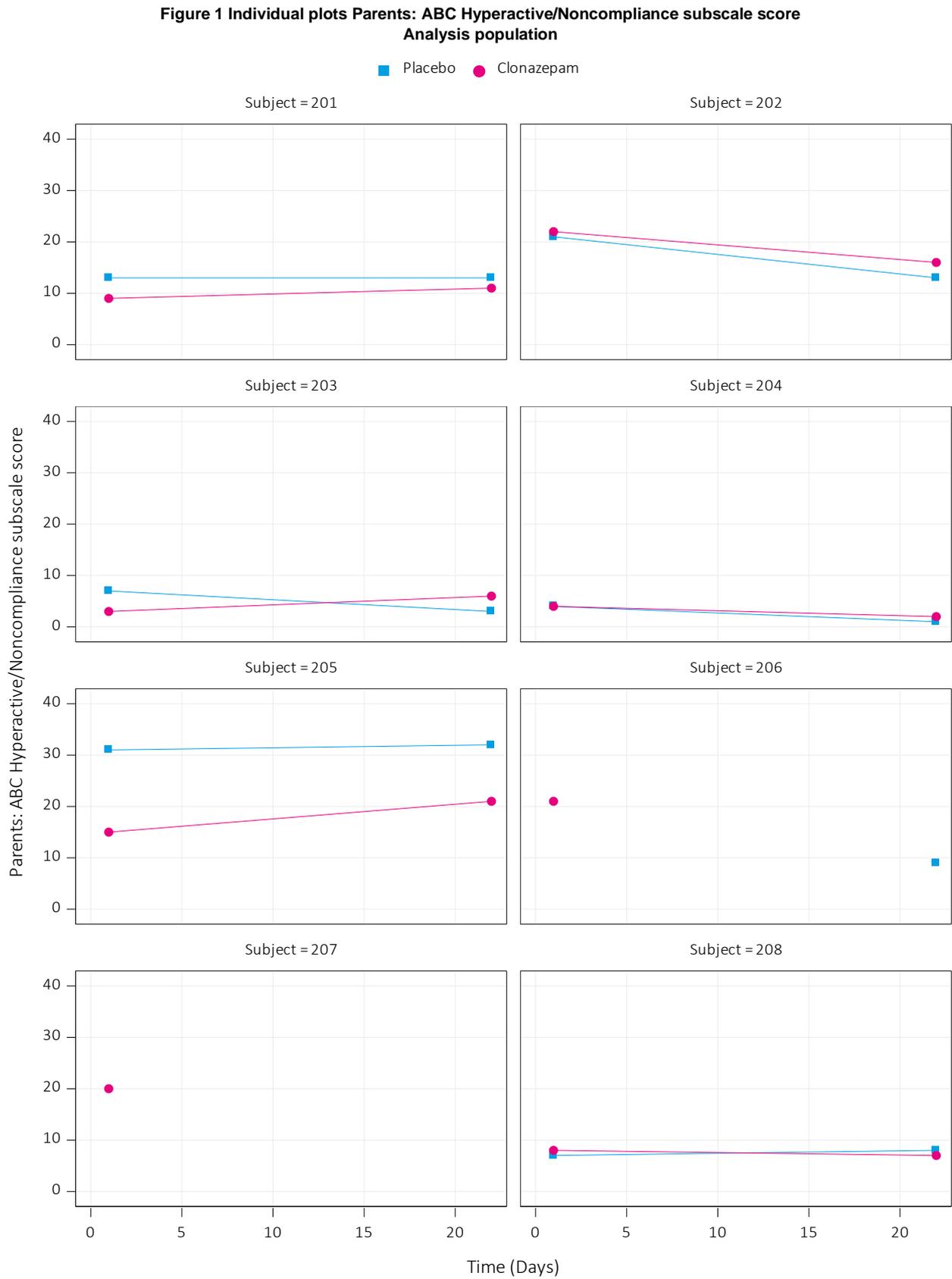
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Individual pharmacodynamic response plots

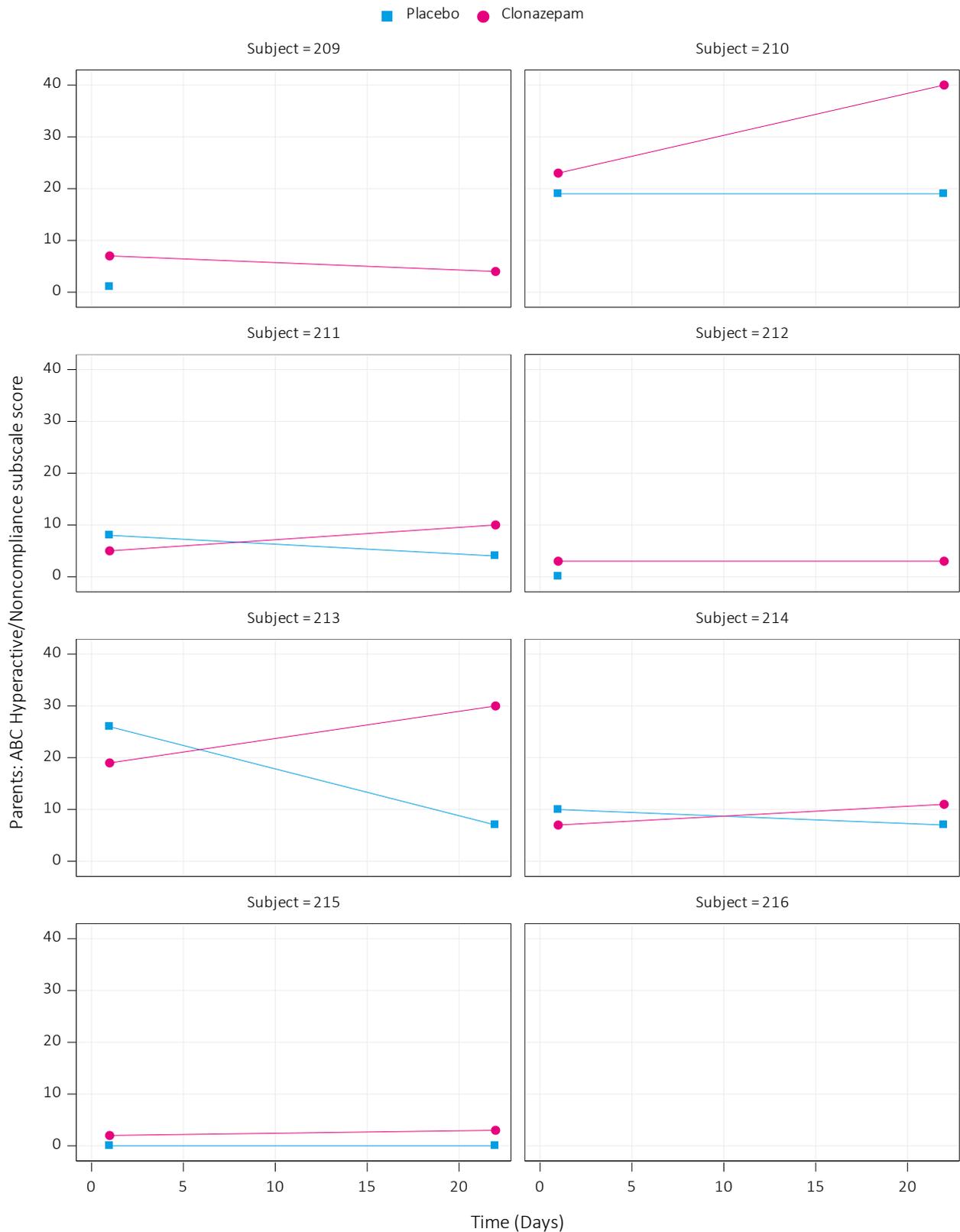
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Figure 1 Individual plots Parents: ABC Hyperactive/Noncompliance subscale score



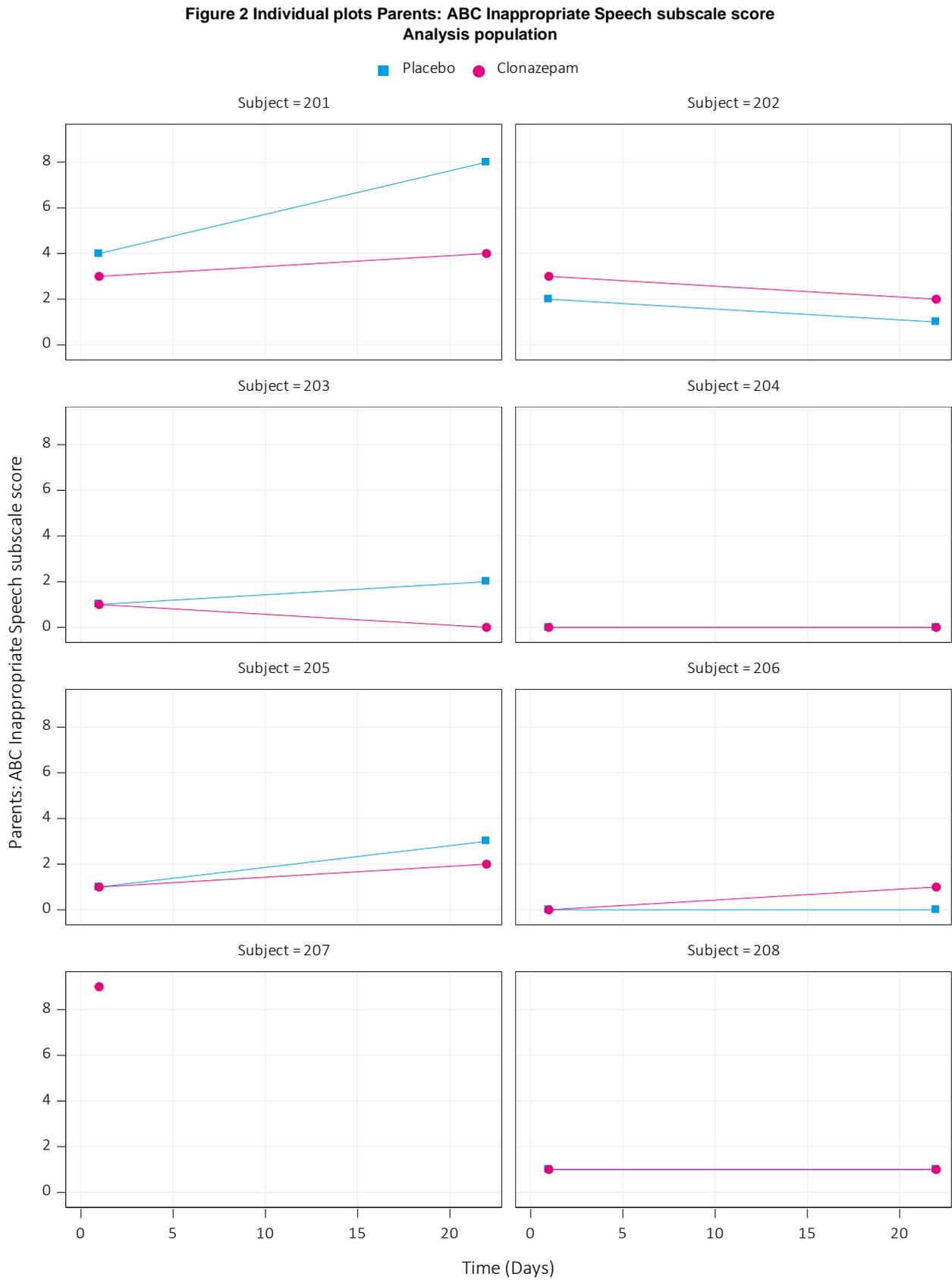
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18JAN2023 12:43 - produced by Maria Joanna Juachon

**Figure 1 Individual plots Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population**



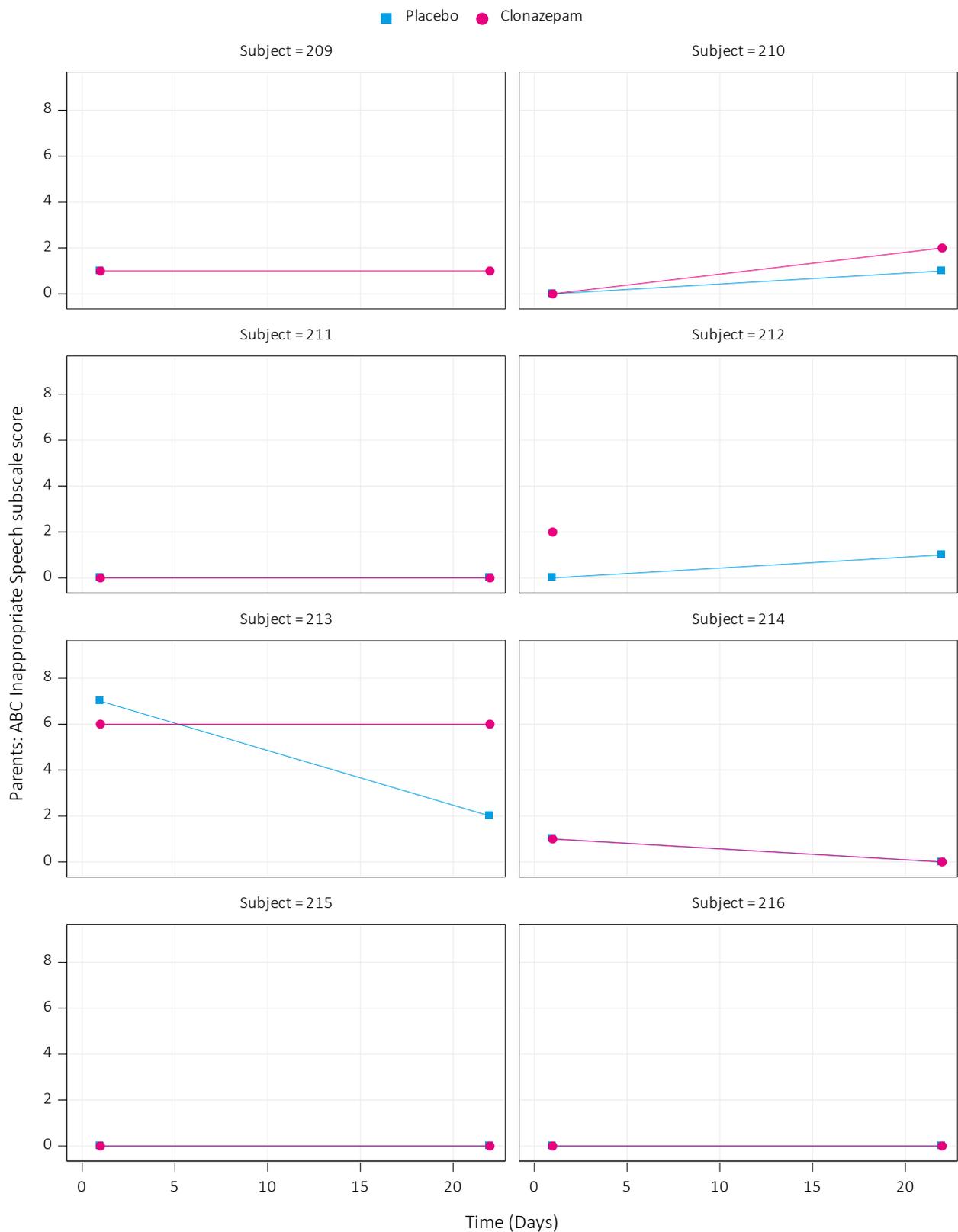
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18JAN2023 12:43 - produced by Maria Joanna Juachon

Figure 2 Individual plots Parents: ABC Inappropriate Speech subscale score



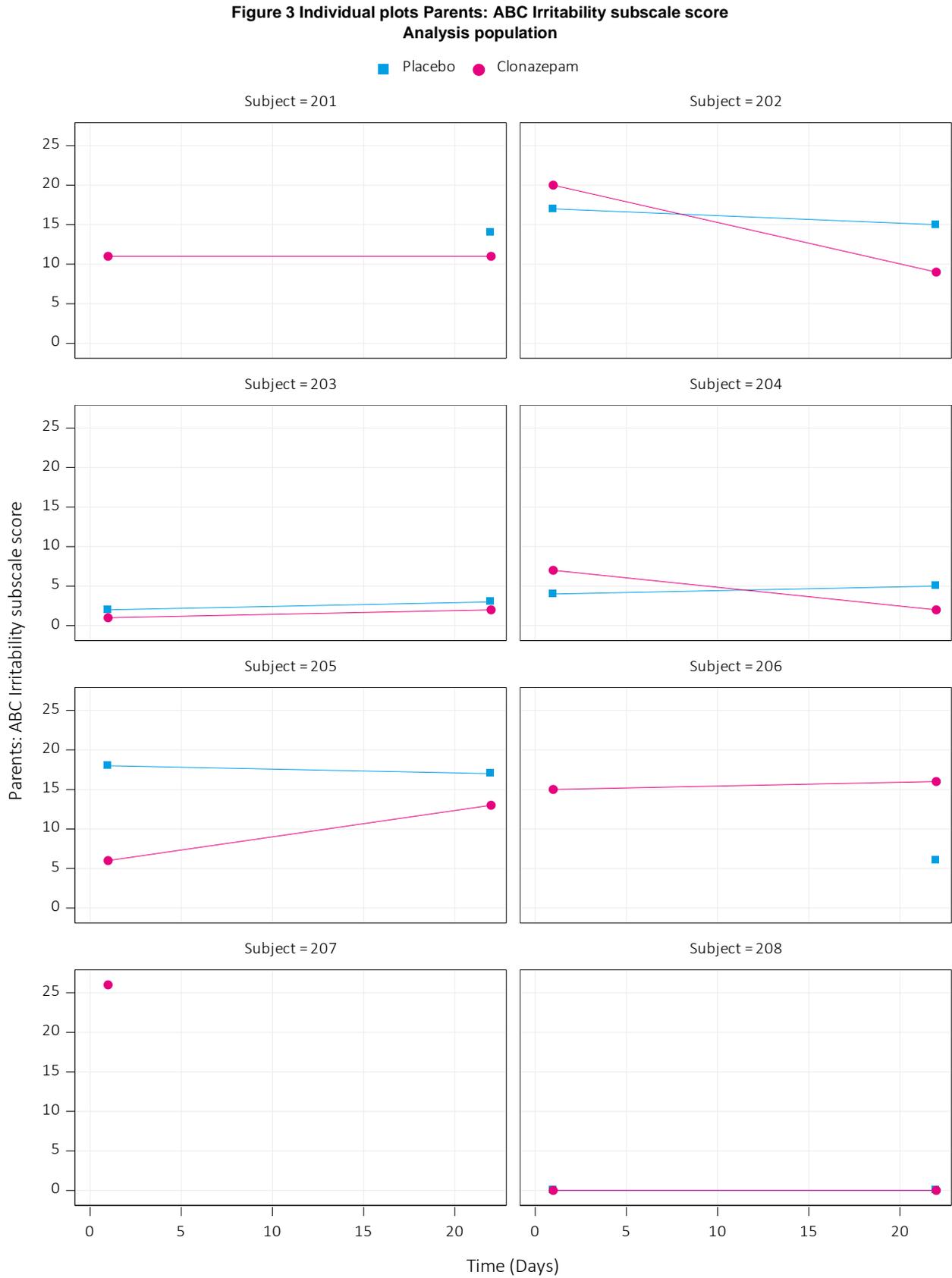
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18JAN2023 12:43 - produced by Maria Joanna Juachon

**Figure 2 Individual plots Parents: ABC Inappropriate Speech subscale score
Analysis population**



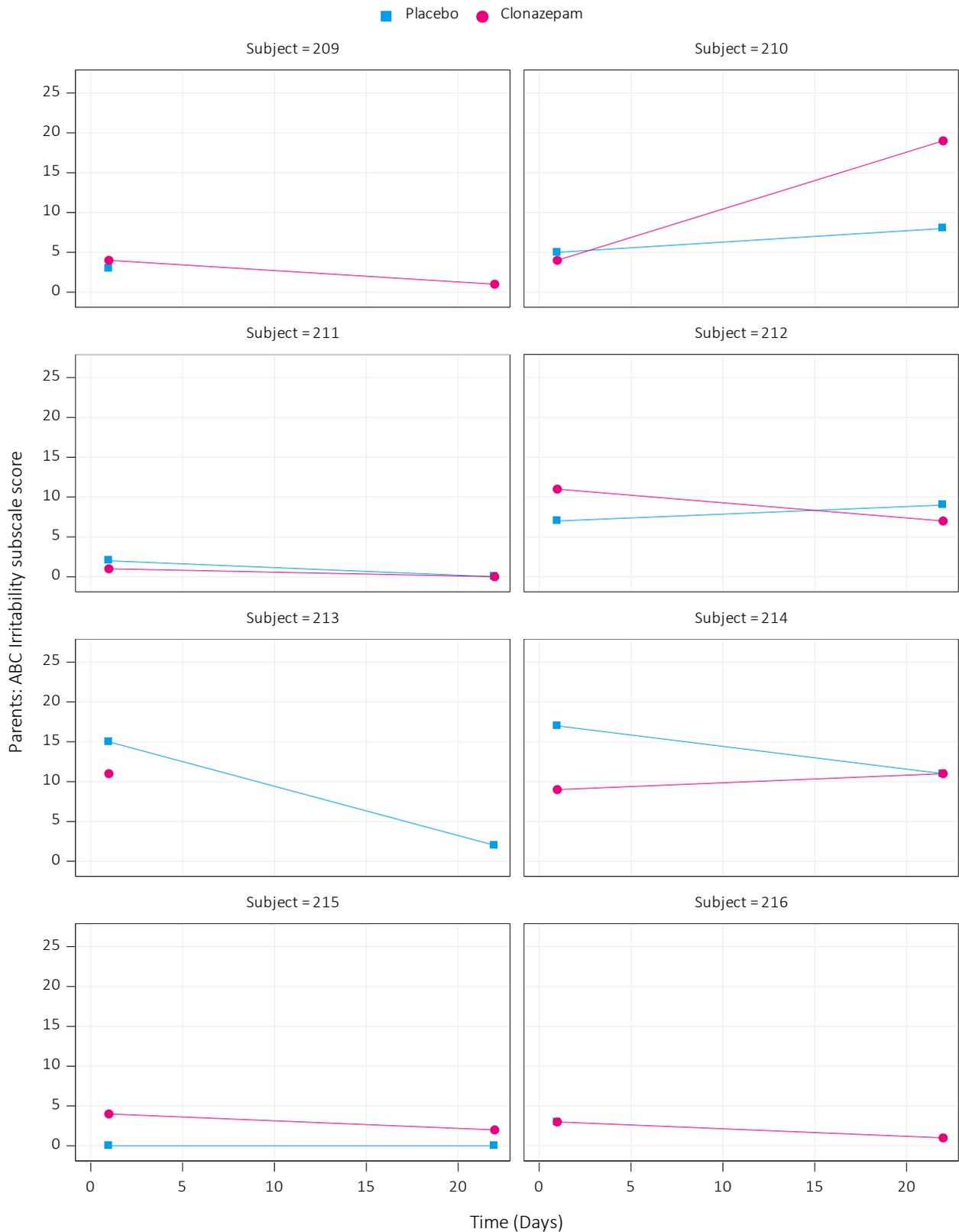
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Figure 3 Individual plots Parents: ABC Irritability subscale score



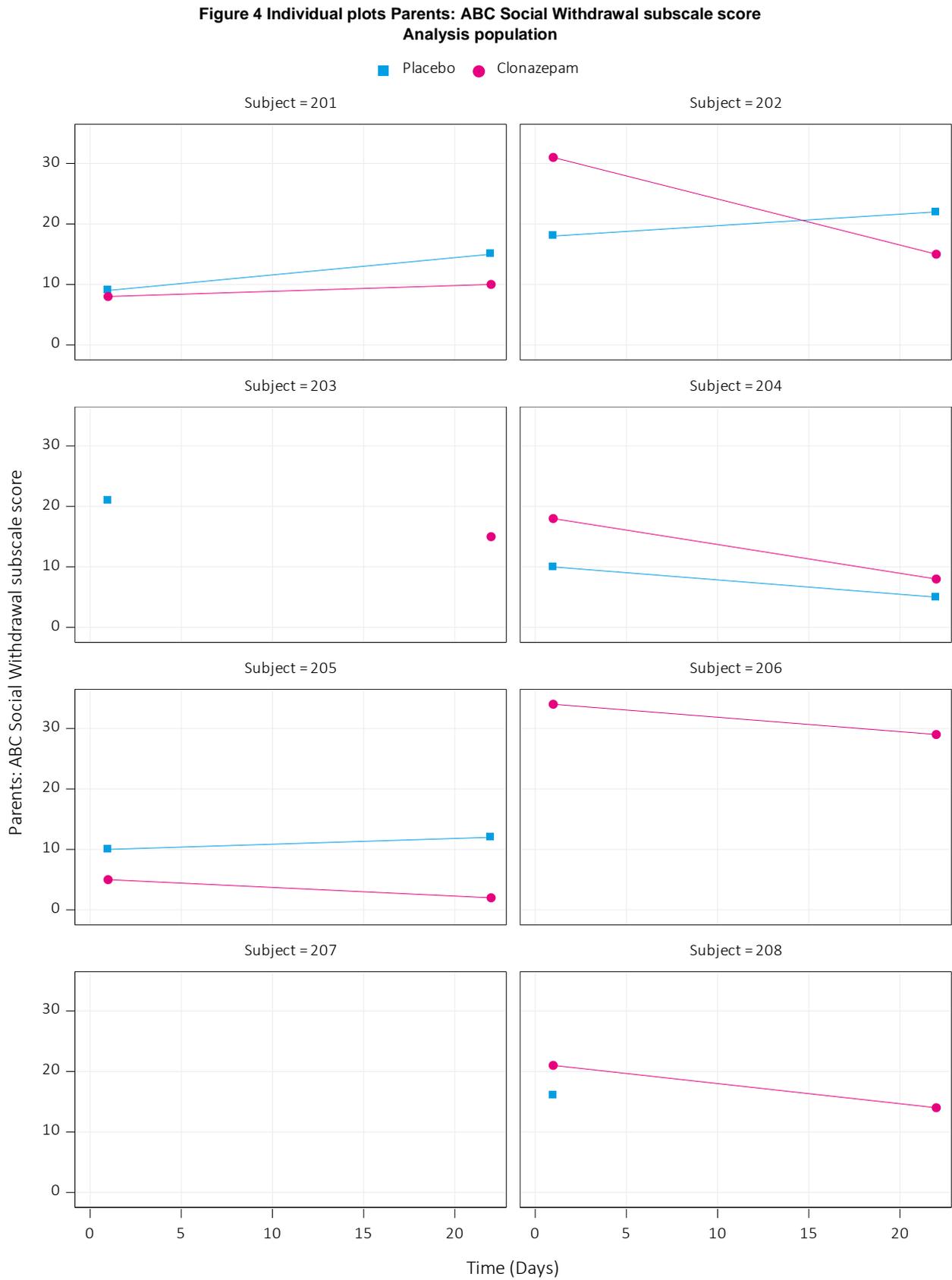
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18JAN2023 12:43 - produced by Maria Joanna Juachon

**Figure 3 Individual plots Parents: ABC Irritability subscale score
Analysis population**



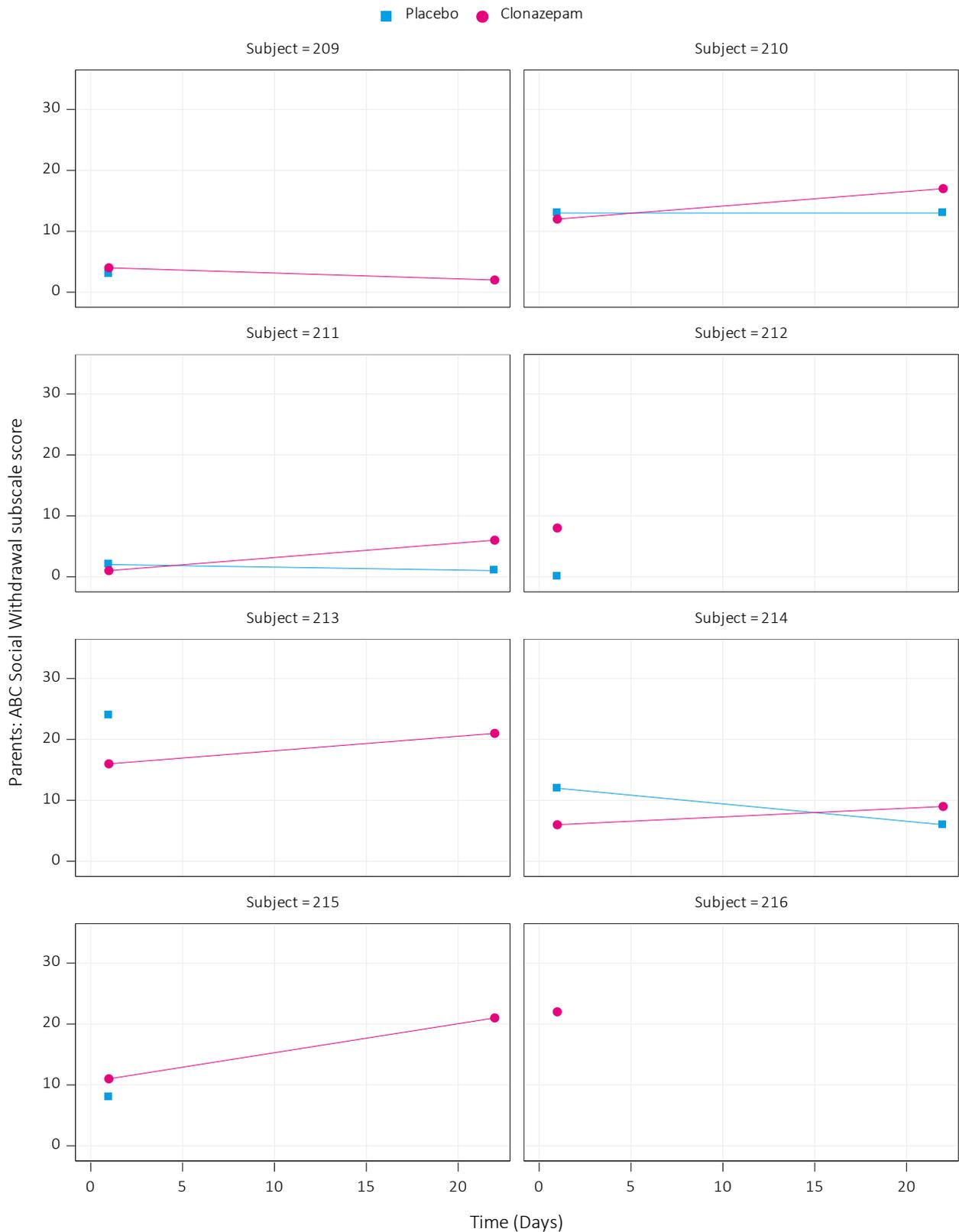
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Figure 4 Individual plots Parents: ABC Social Withdrawal subscale score



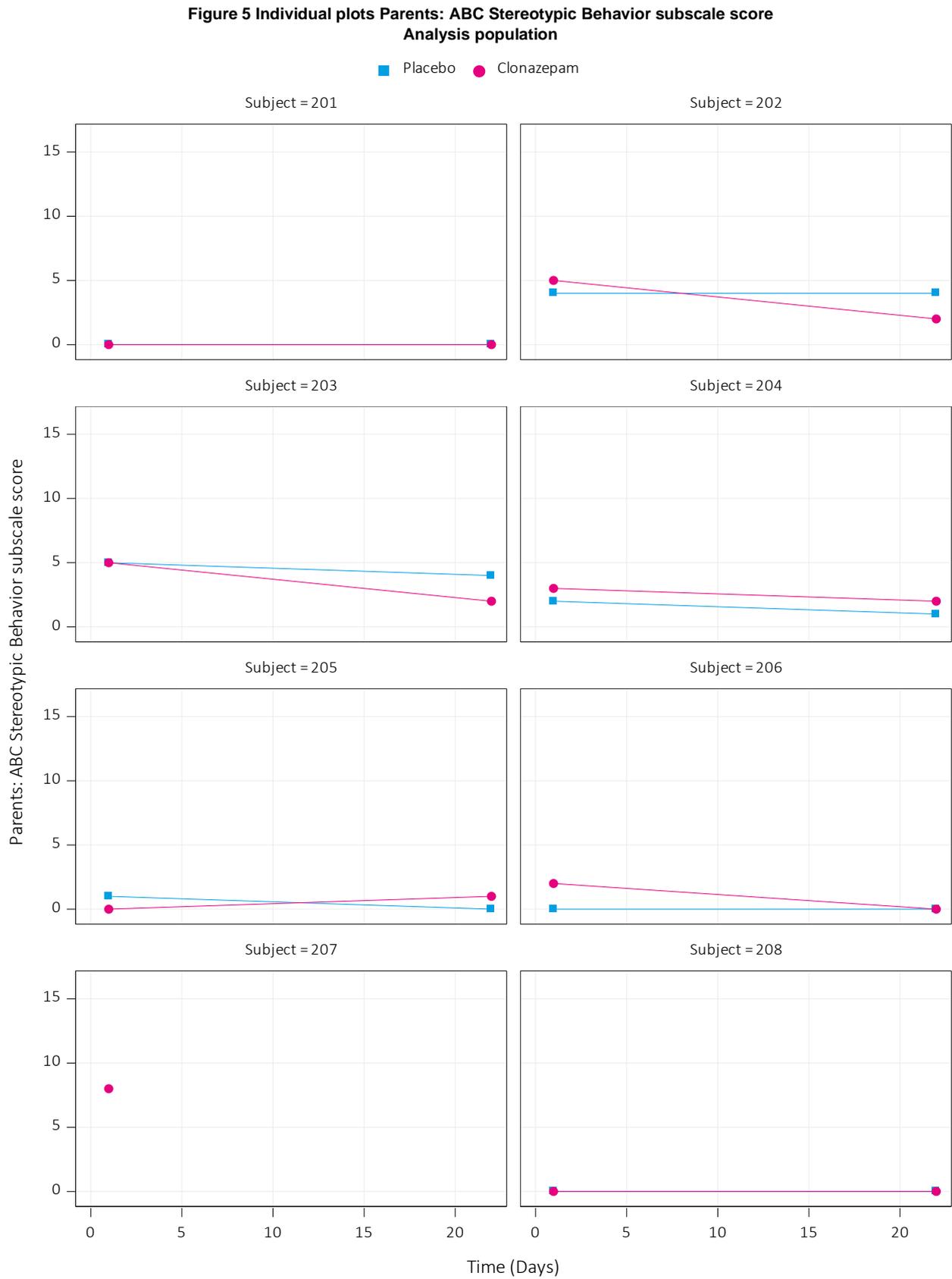
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**Figure 4 Individual plots Parents: ABC Social Withdrawal subscale score
Analysis population**



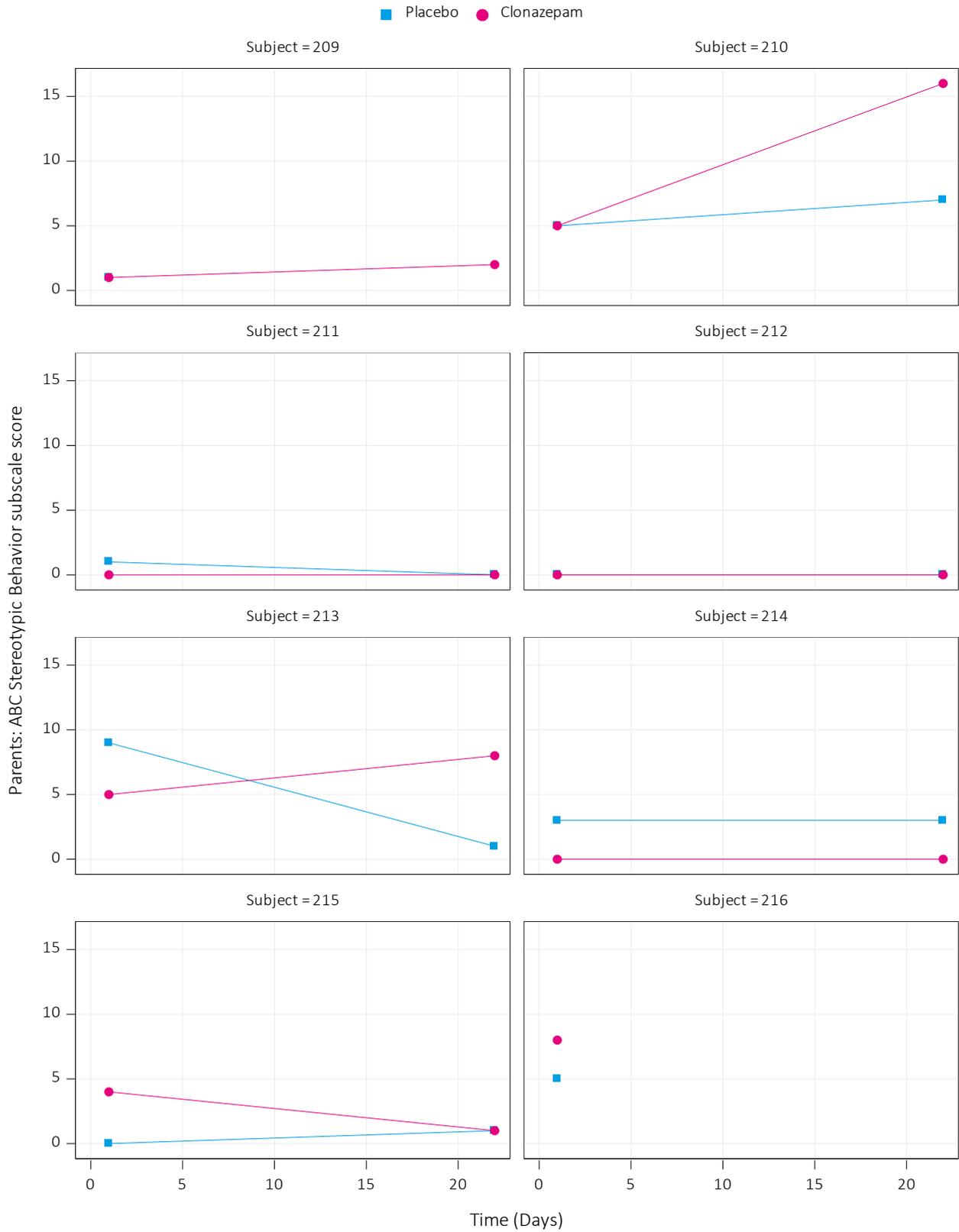
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18JAN2023 12:43 - produced by Maria Joanna Juachon

Figure 5 Individual plots Parents: ABC Stereotypic Behavior subscale score



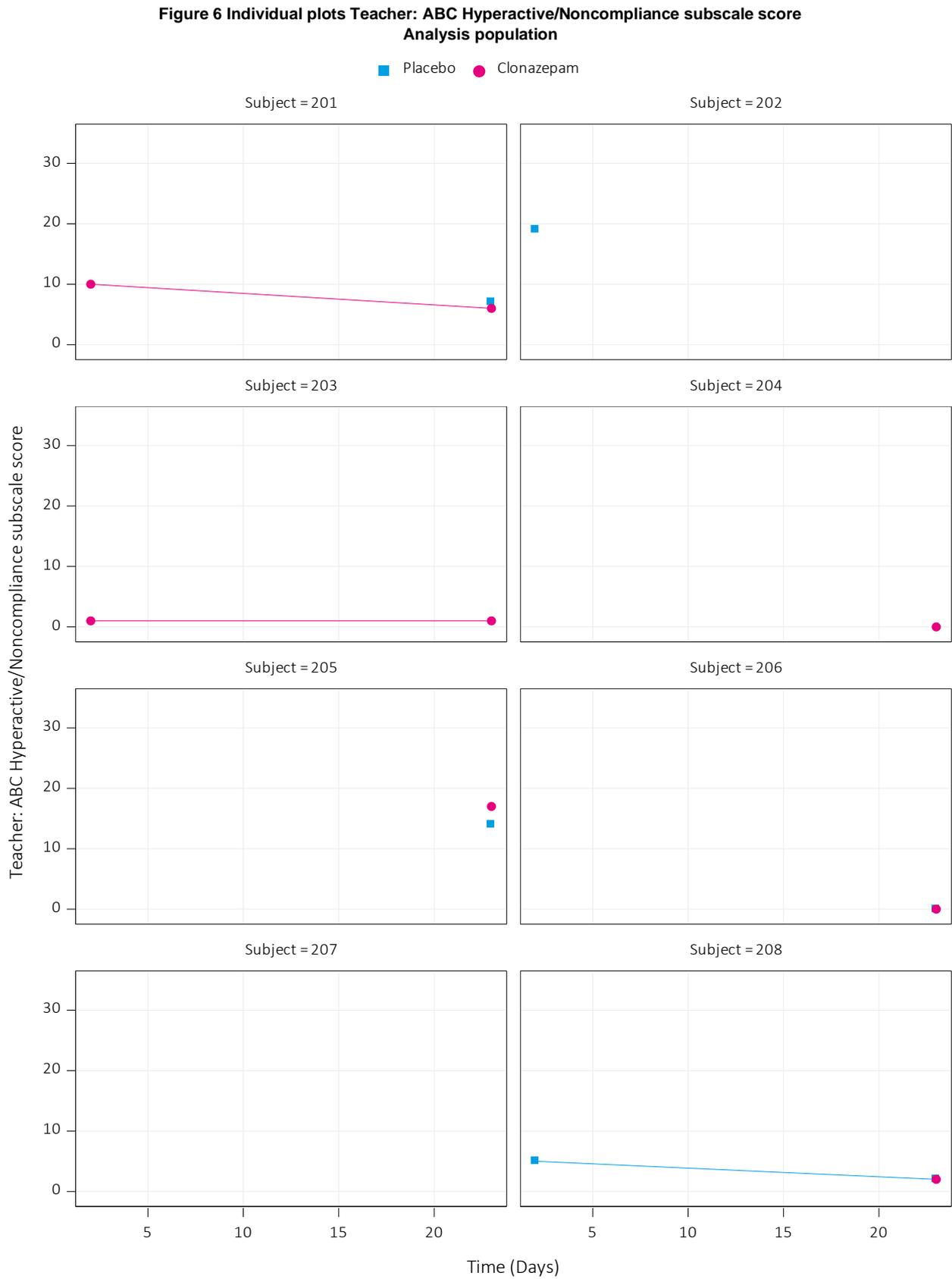
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**Figure 5 Individual plots Parents: ABC Stereotypic Behavior subscale score
Analysis population**



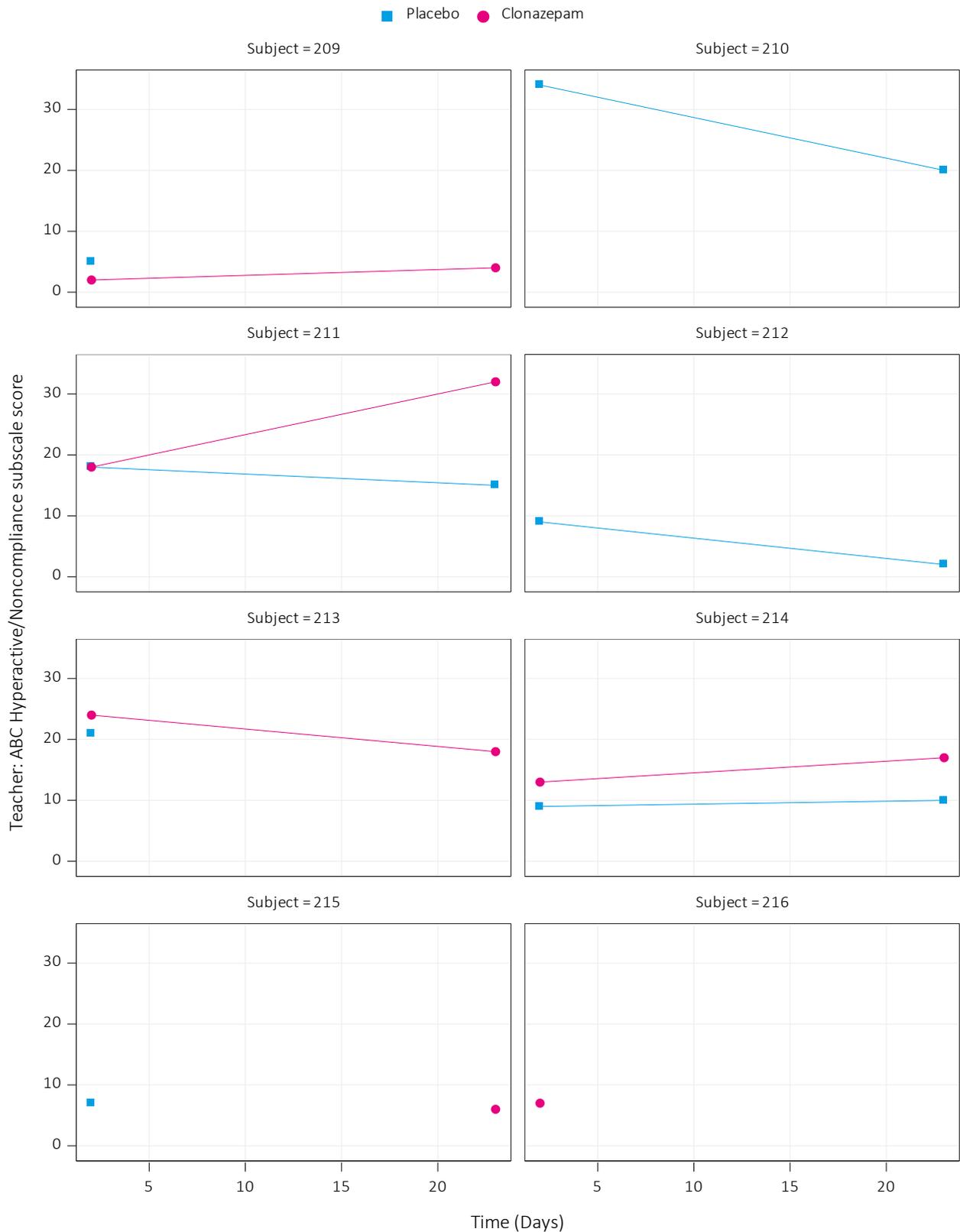
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18JAN2023 12:43 - produced by Maria Joanna Juachon

Figure 6 Individual plots Teacher: ABC Hyperactive/Noncompliance subscale score



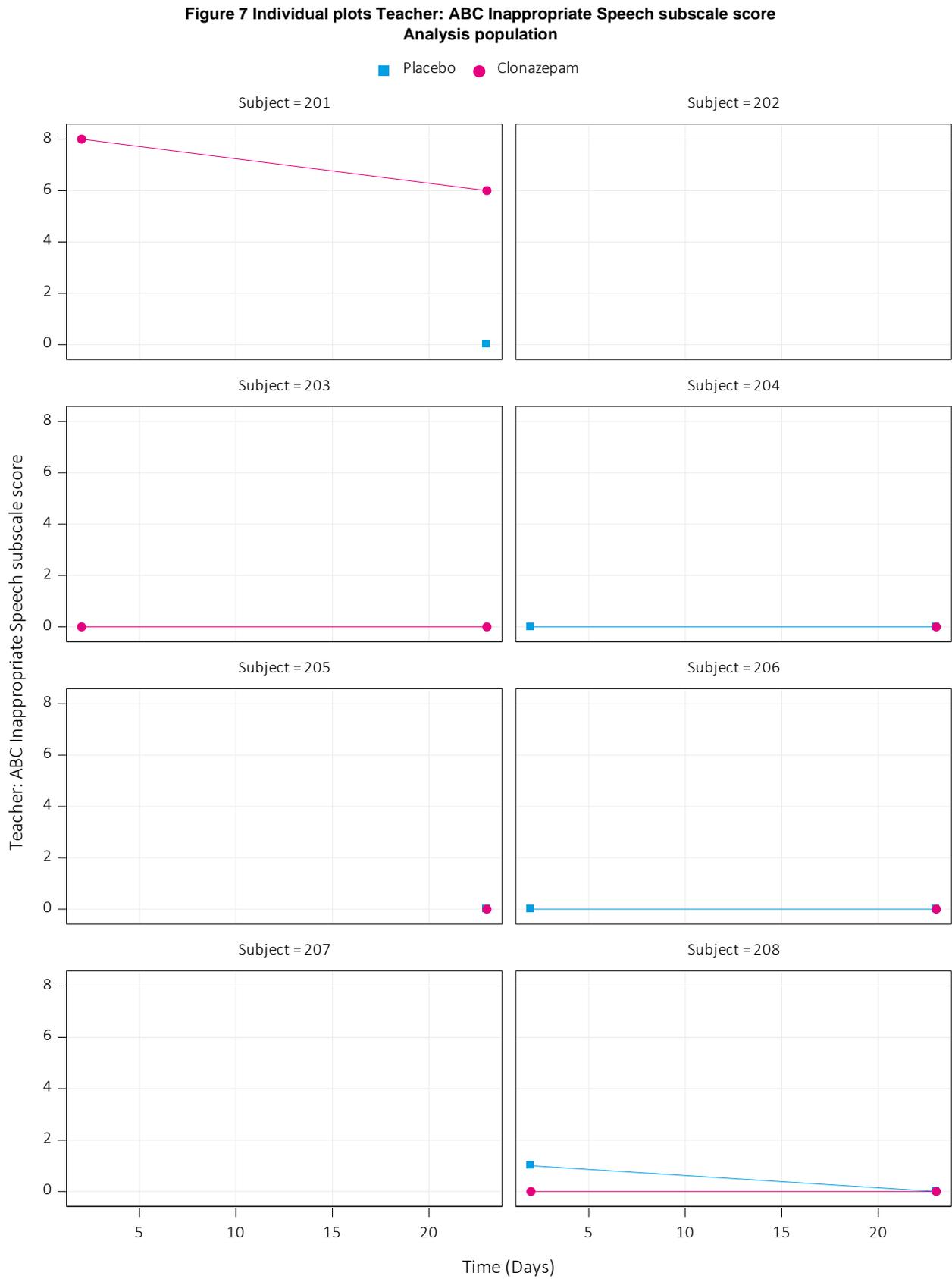
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**Figure 6 Individual plots Teacher: ABC Hyperactive/Noncompliance subscale score
Analysis population**



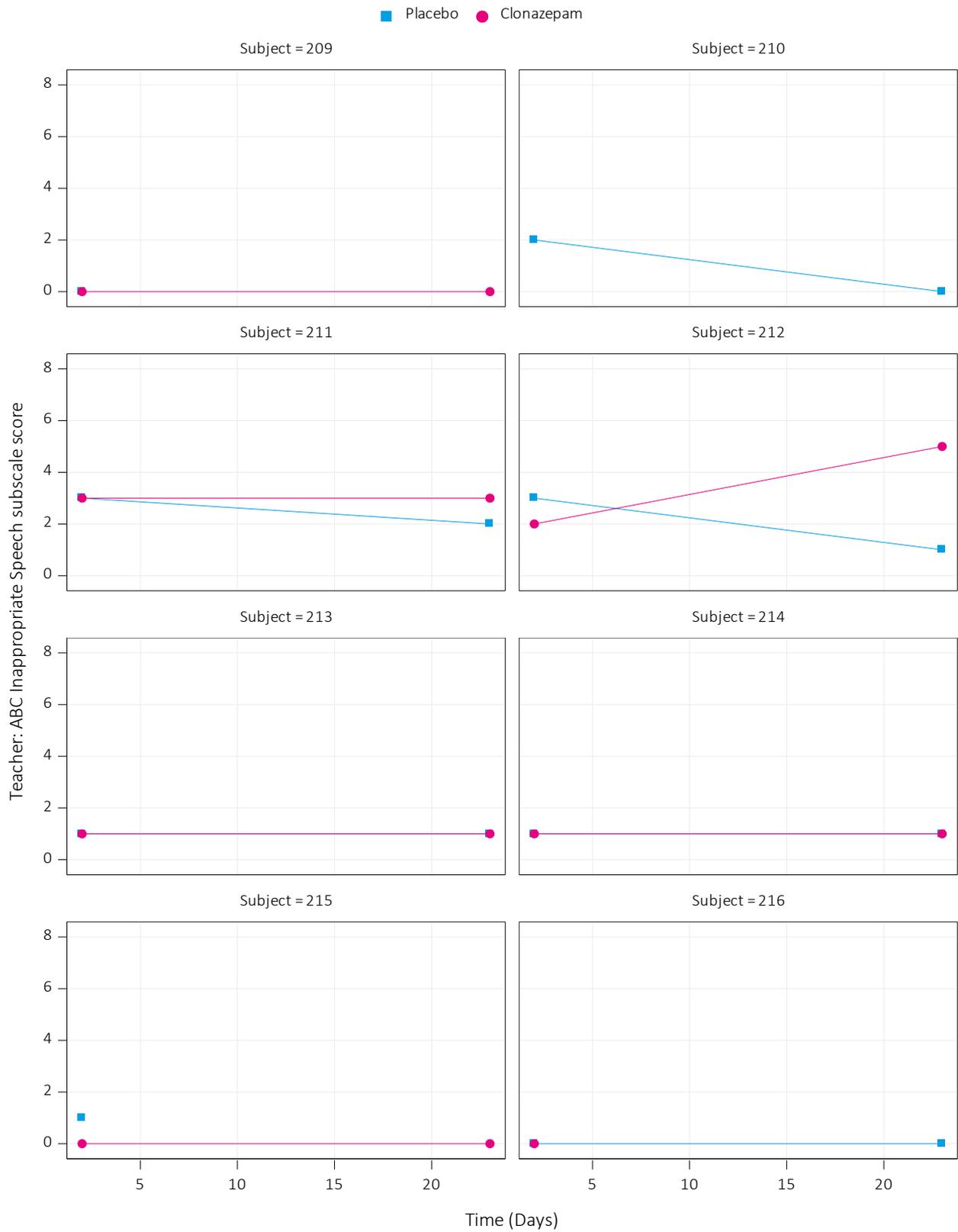
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Figure 7 Individual plots Teacher: ABC Inappropriate Speech subscale score



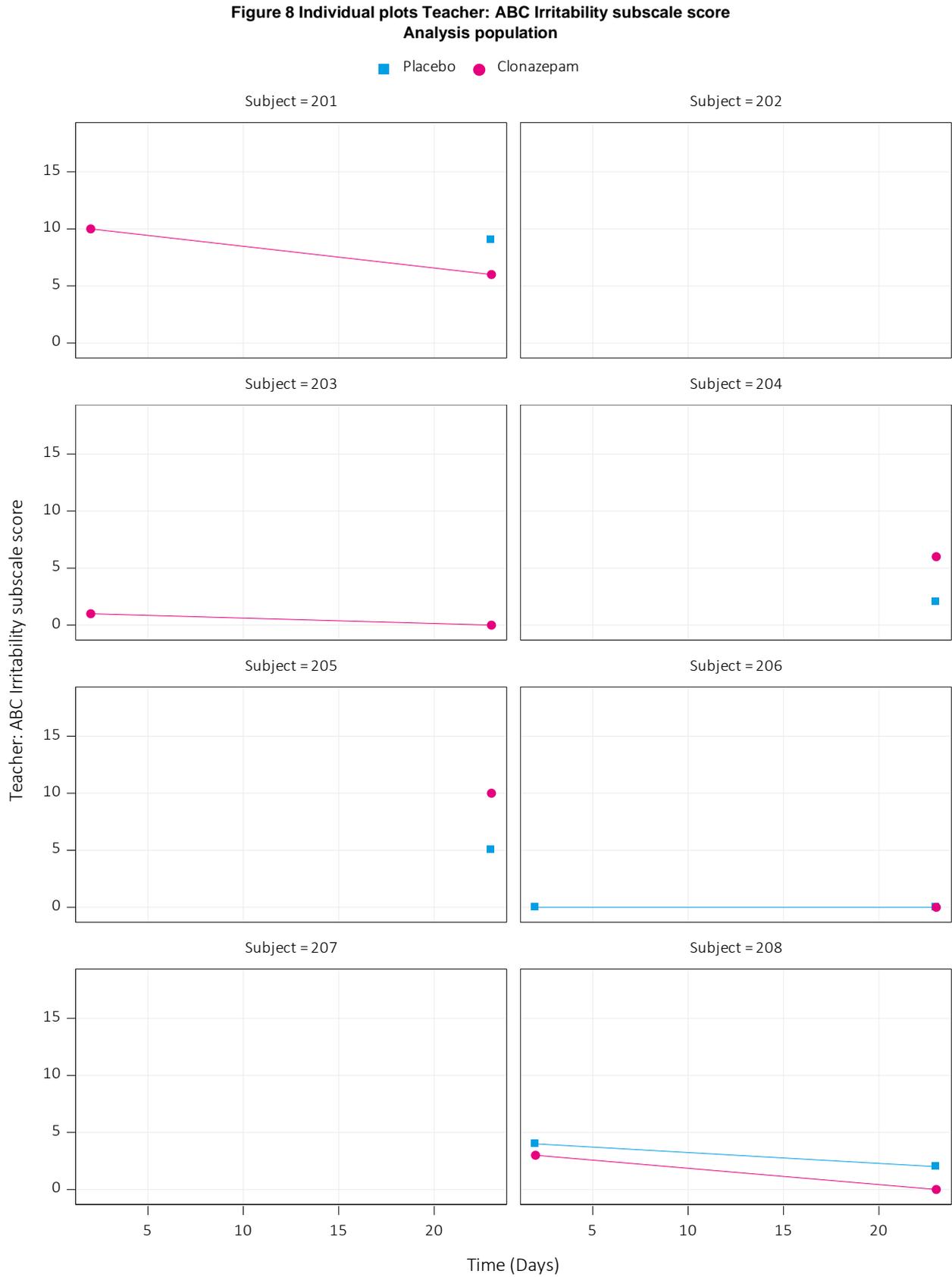
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18JAN2023 12:43 - produced by Maria Joanna Juachon

**Figure 7 Individual plots Teacher: ABC Inappropriate Speech subscale score
Analysis population**



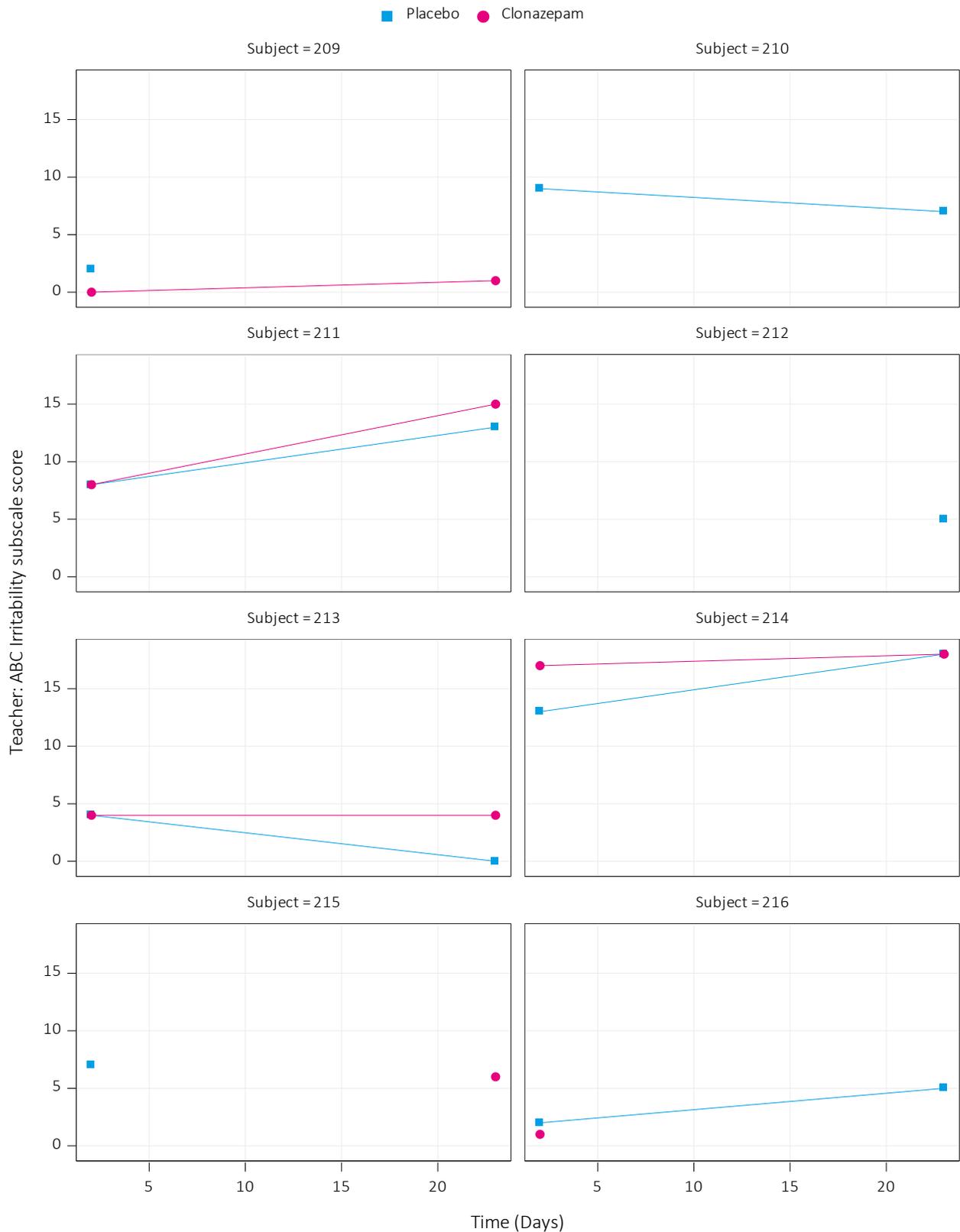
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18JAN2023 12:43 - produced by Maria Joanna Juachon

Figure 8 Individual plots Teacher: ABC Irritability subscale score



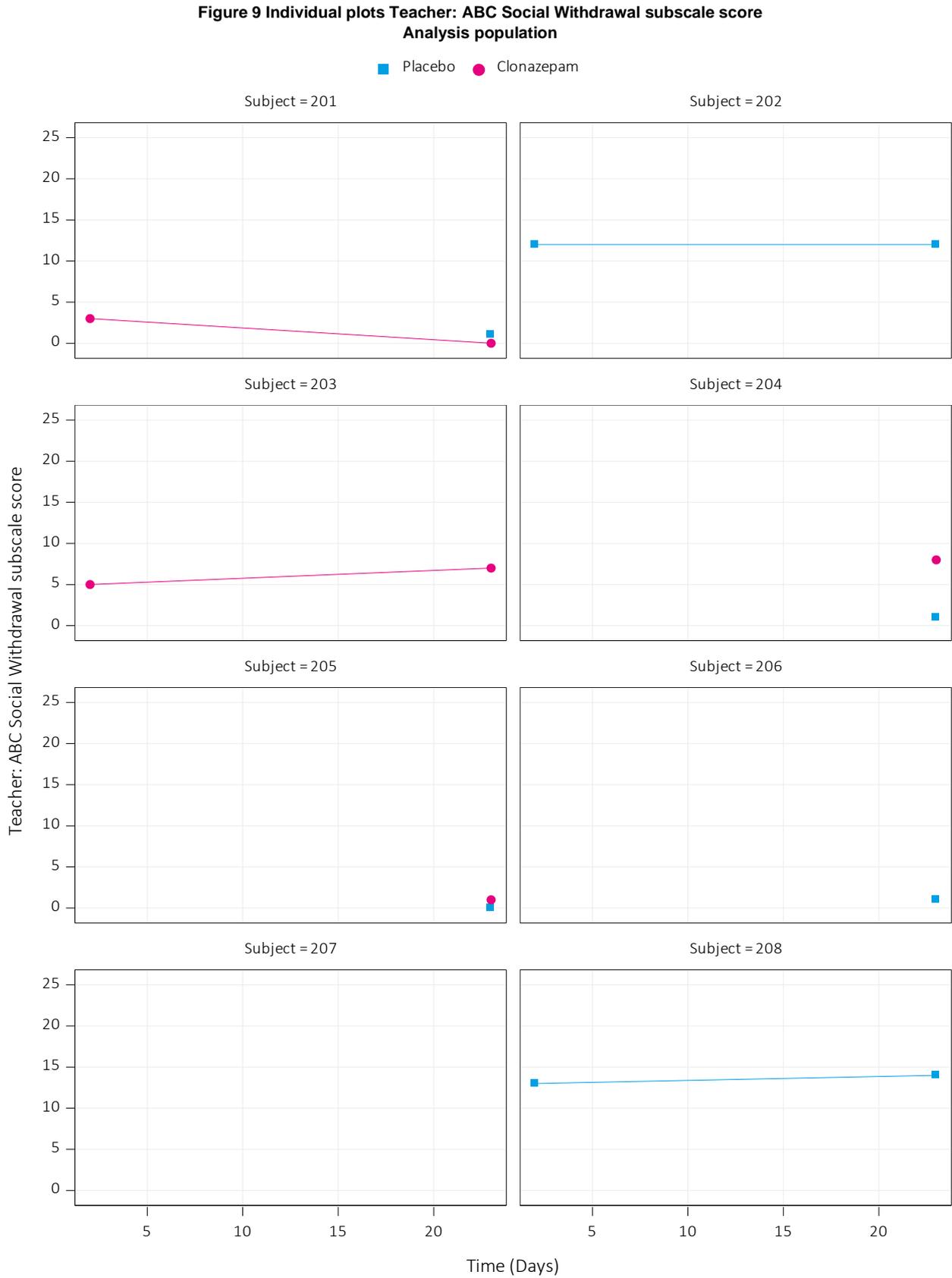
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18JAN2023 12:43 - produced by Maria Joanna Juachon

**Figure 8 Individual plots Teacher: ABC Irritability subscale score
Analysis population**



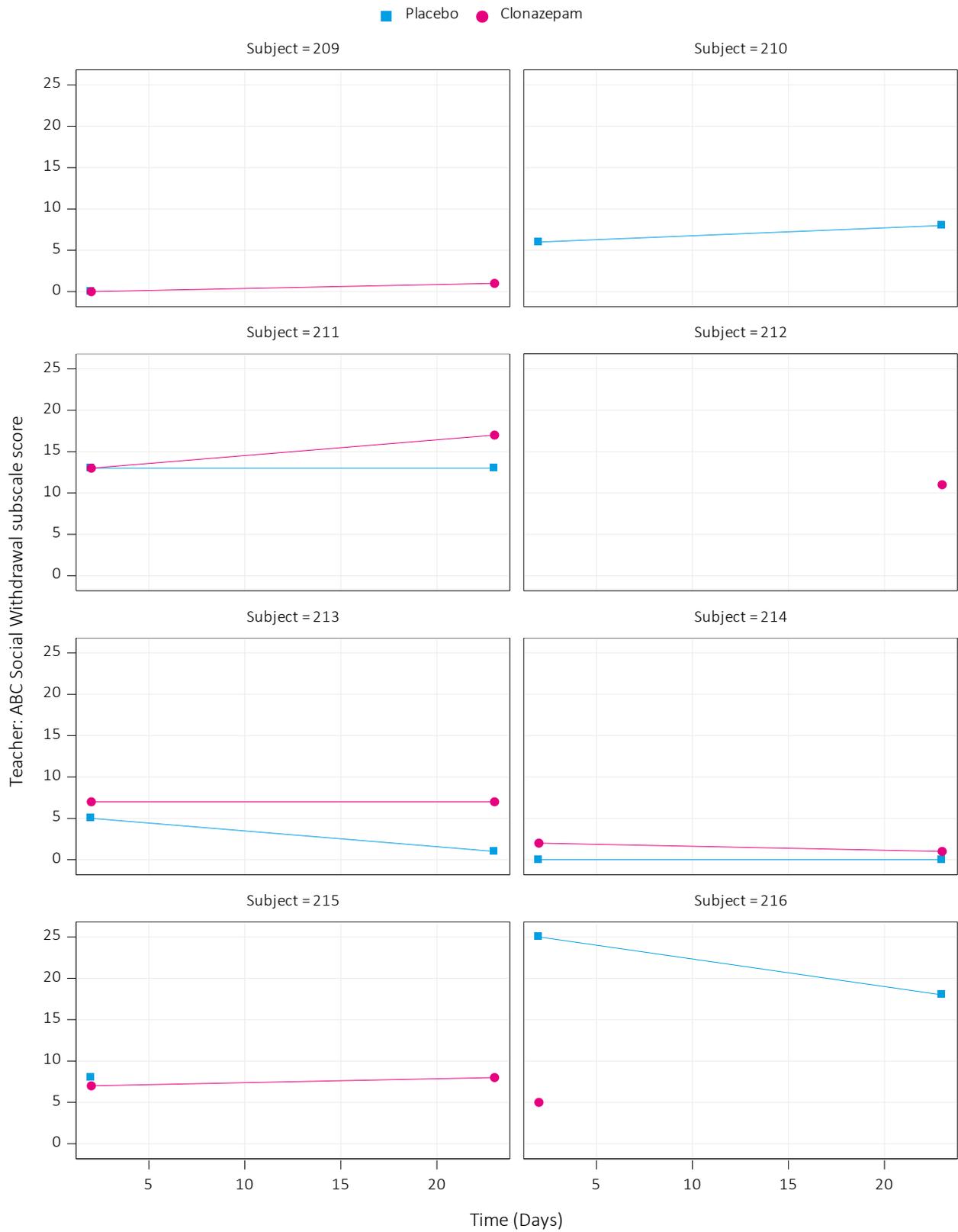
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18JAN2023 12:43 - produced by Maria Joanna Juachon

Figure 9 Individual plots Teacher: ABC Social Withdrawal subscale score



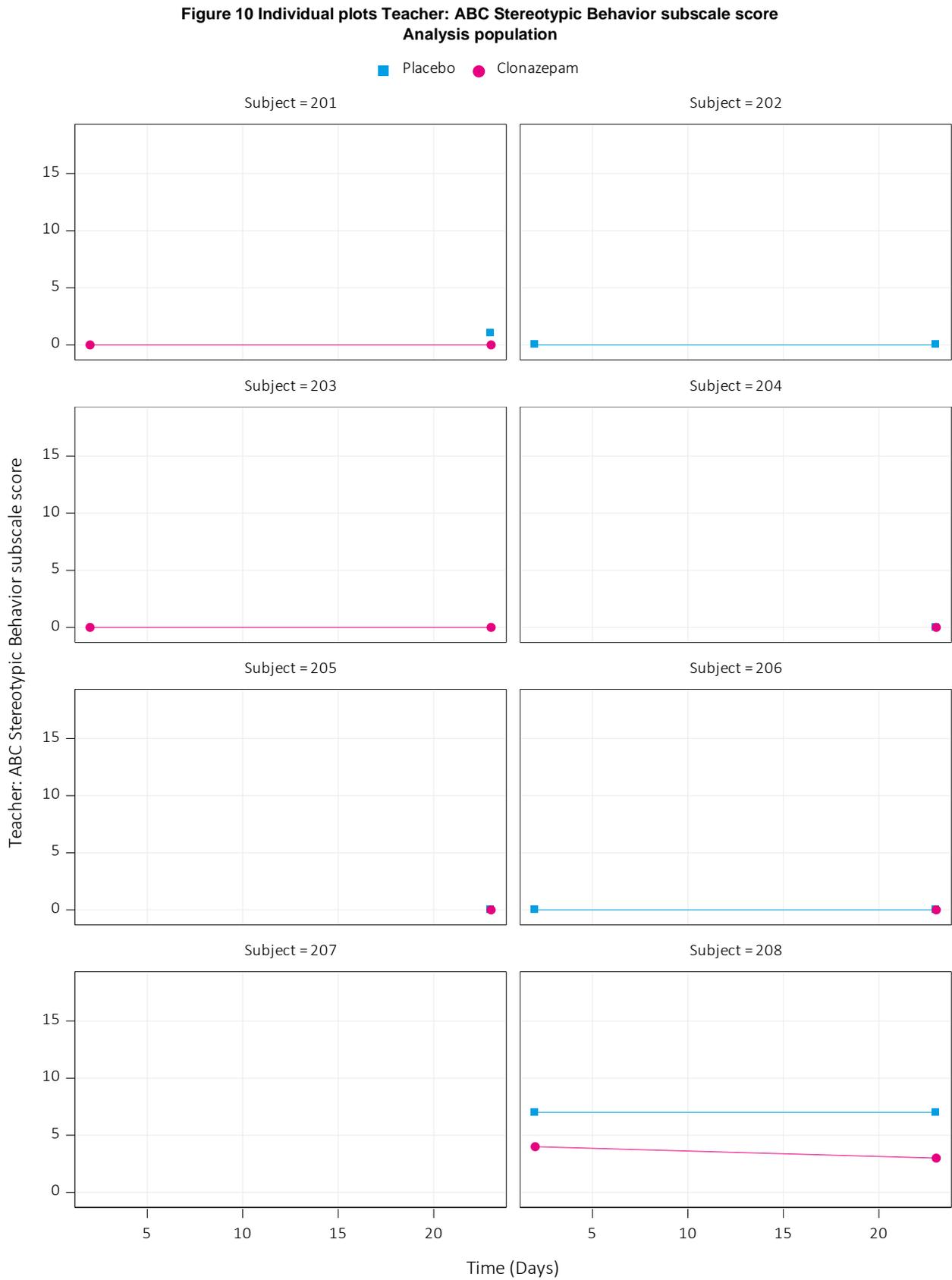
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18JAN2023 12:43 - produced by Maria Joanna Juachon

**Figure 9 Individual plots Teacher: ABC Social Withdrawal subscale score
Analysis population**



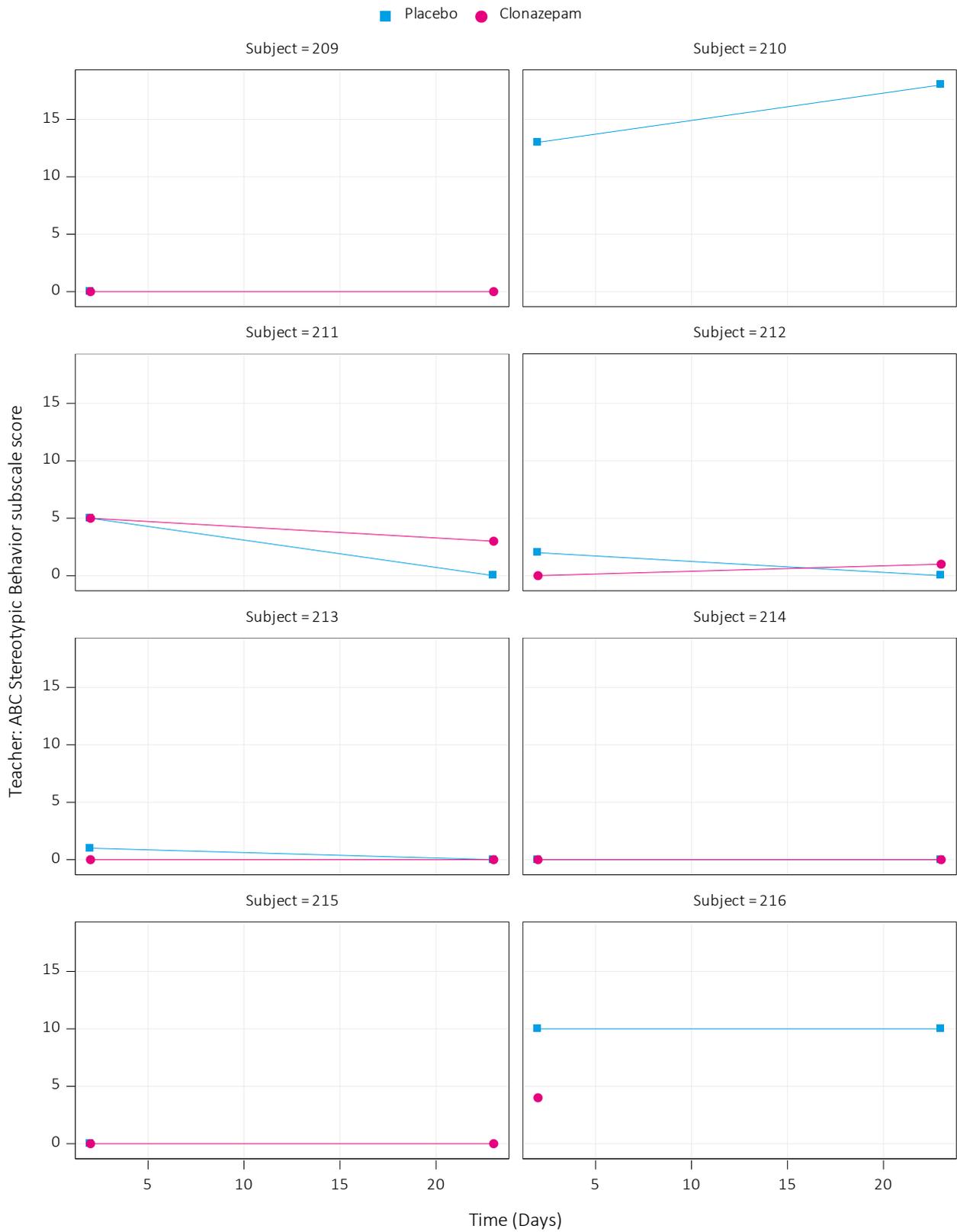
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Figure 10 Individual plots Teacher: ABC Stereotypic Behavior subscale score



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**Figure 10 Individual plots Teacher: ABC Stereotypic Behavior subscale score
Analysis population**



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
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Summary pharmacodynamic response tables and graphs

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Summaries 1 Parents: ABC Hyperactive/Noncompliance subscale score

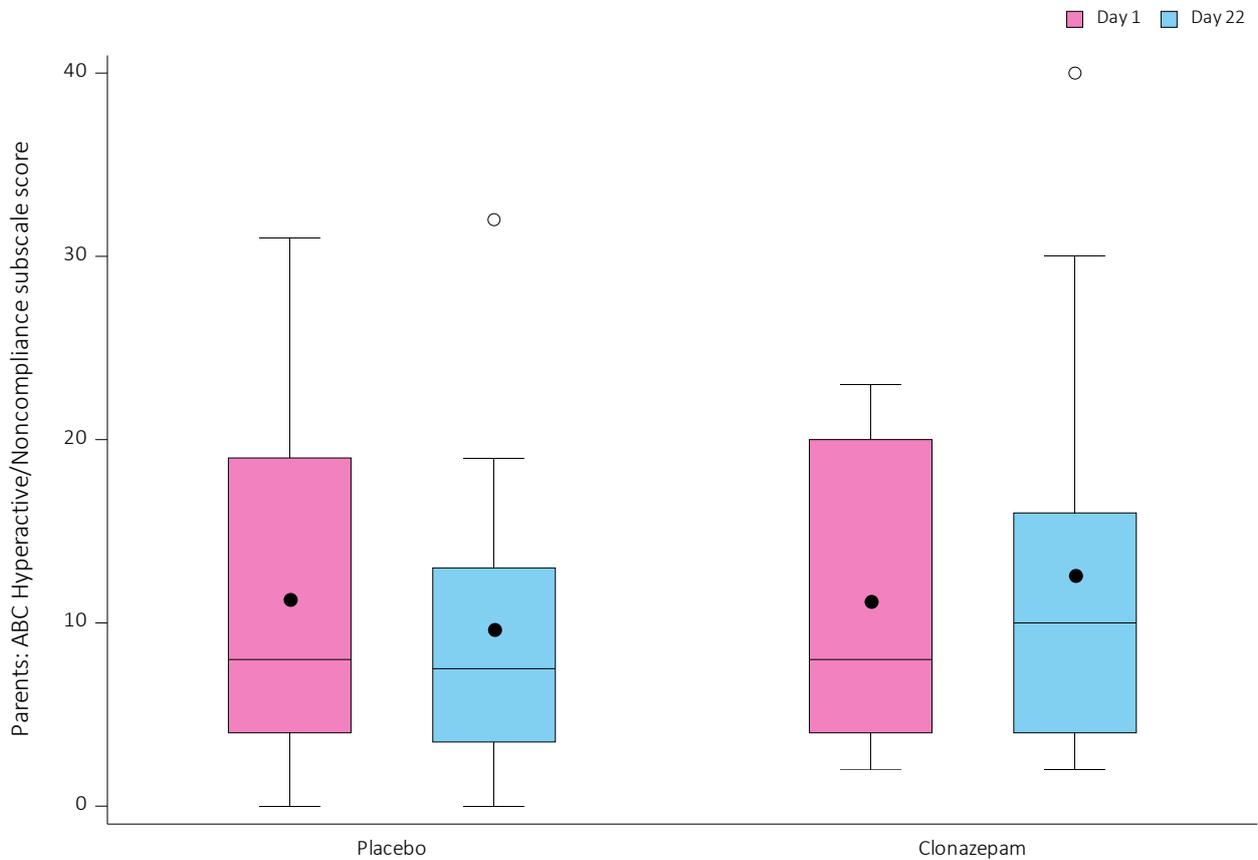
Summary Table: Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	-0:18	13	11.3	10.10	2.80	89.3	8	0	31
	503:42	12	9.7	8.90	2.57	92.0	8	0	32
Clonazepam	-0:18	15	11.2	7.86	2.03	70.2	8	2	23
	503:42	13	12.6	11.52	3.20	91.3	10	2	40

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
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Summary Graph: Summary graph Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 2 Parents: ABC Inappropriate Speech subscale score

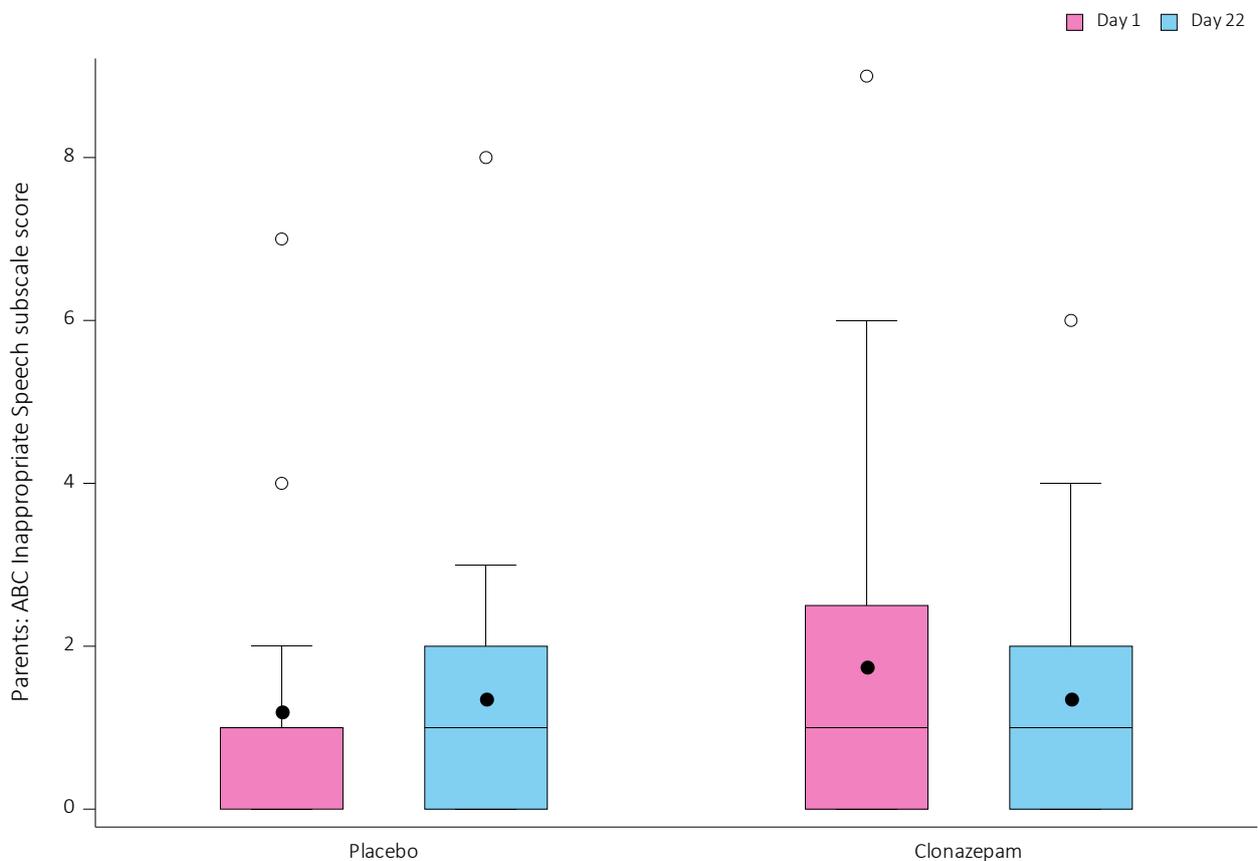
Summary Table: Parents: ABC Inappropriate Speech subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	-0:18	15	1.2	1.93	0.50	161.2	1	0	7
	503:42	14	1.4	2.13	0.57	157.3	1	0	8
Clonazepam	-0:18	16	1.8	2.52	0.63	143.8	1	0	9
	503:42	14	1.4	1.78	0.48	131.2	1	0	6

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Parents: ABC Inappropriate Speech subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 3 Parents: ABC Irritability subscale score

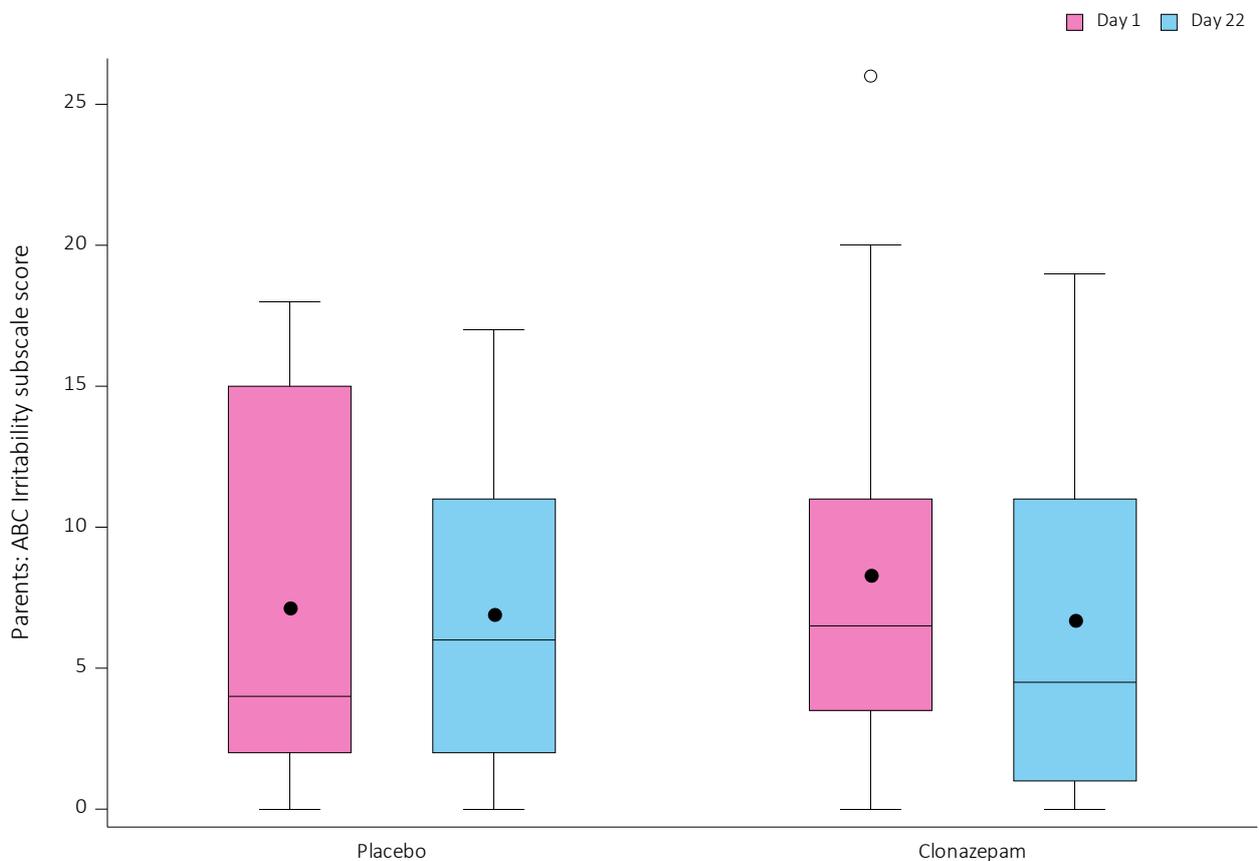
Summary Table: Parents: ABC Irritability subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	-0:18	13	7.2	6.94	1.92	97.0	4	0	18
	503:42	13	6.9	5.96	1.65	86.2	6	0	17
Clonazepam	-0:18	16	8.3	7.23	1.81	86.9	7	0	26
	503:42	14	6.7	6.45	1.72	96.1	5	0	19

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Parents: ABC Irritability subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
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Summaries 4 Parents: ABC Social Withdrawal subscale score

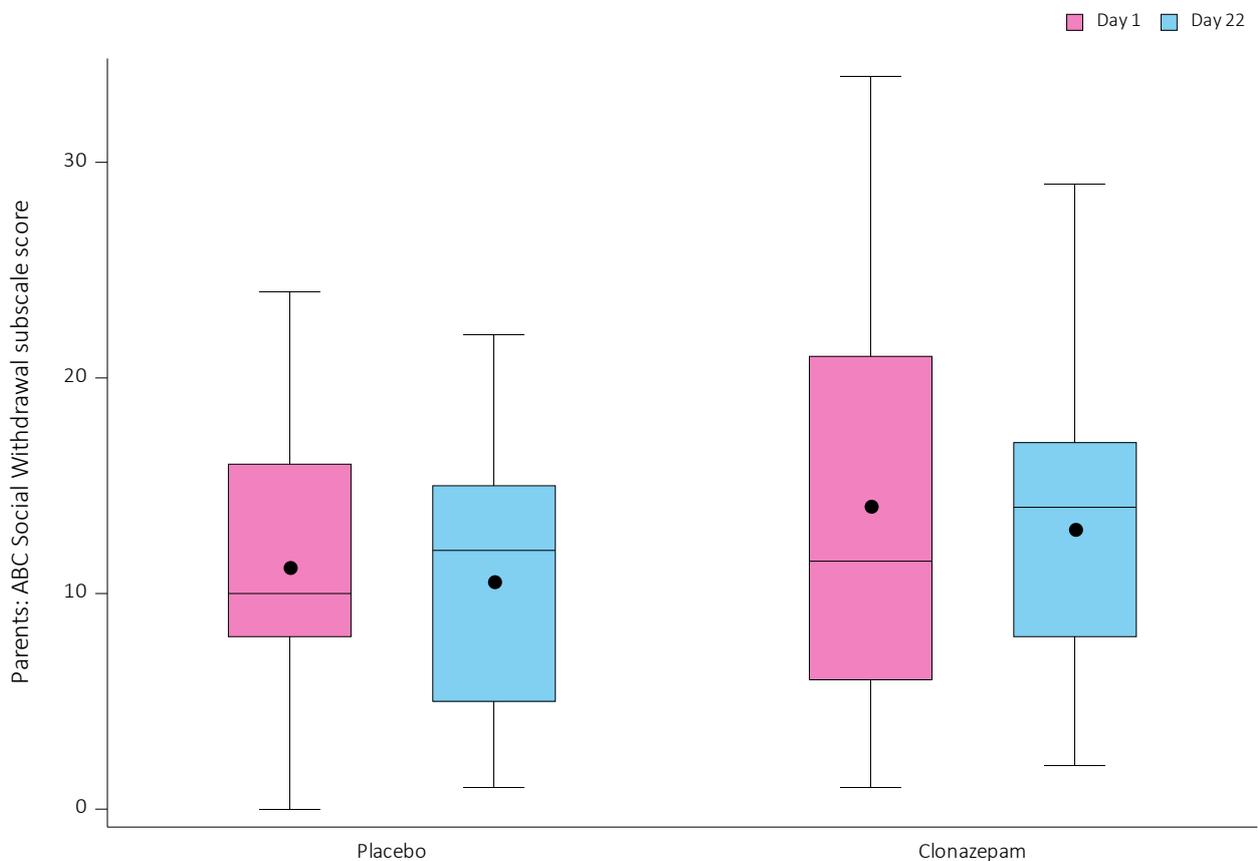
Summary Table: Parents: ABC Social Withdrawal subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	-0:18	13	11.2	7.24	2.01	64.4	10	0	24
	503:42	7	10.6	7.09	2.68	67.1	12	1	22
Clonazepam	-0:18	14	14.1	10.08	2.69	71.6	12	1	34
	503:42	13	13.0	7.91	2.19	60.8	14	2	29

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
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Summary Graph: Summary graph Parents: ABC Social Withdrawal subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 5 Parents: ABC Stereotypic Behavior subscale score

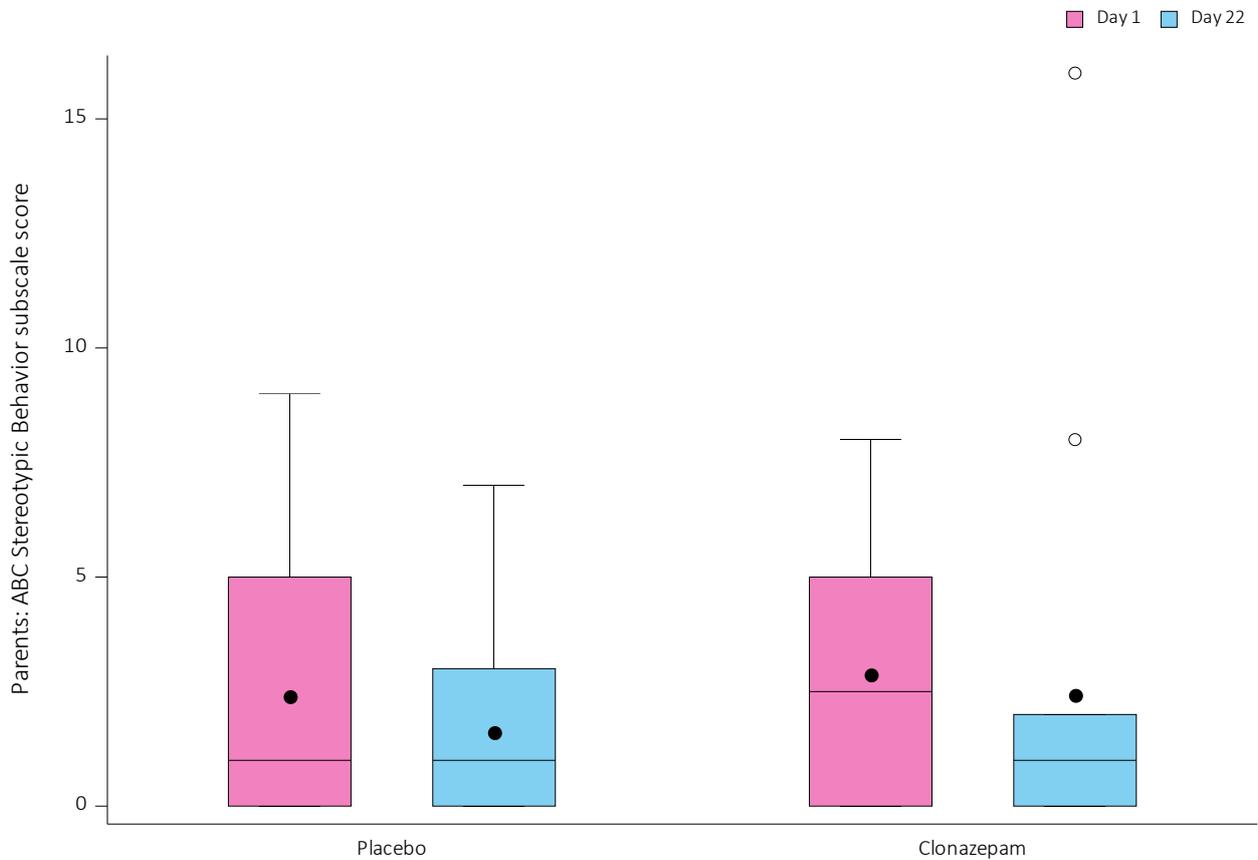
Summary Table: Parents: ABC Stereotypic Behavior subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	-0:18	15	2.4	2.69	0.70	112.2	1	0	9
	503:42	13	1.6	2.22	0.62	137.4	1	0	7
Clonazepam	-0:18	16	2.9	2.90	0.72	100.7	3	0	8
	503:42	14	2.4	4.43	1.18	182.5	1	0	16

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Parents: ABC Stereotypic Behavior subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 6 Teacher: ABC Hyperactive/Noncompliance subscale score

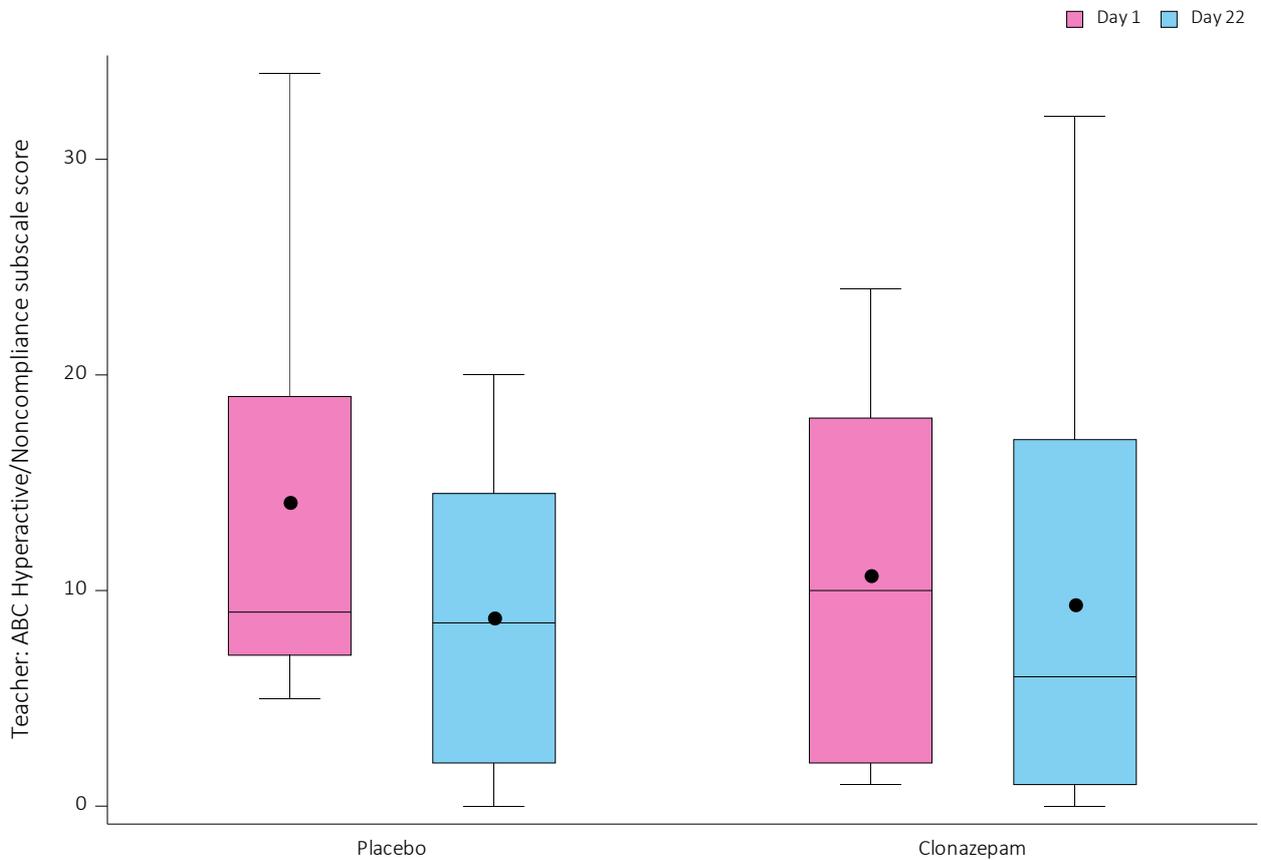
Summary Table: Teacher: ABC Hyperactive/Noncompliance subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	24:07	9	14.1	9.69	3.23	68.7	9	5	34
	528:06	8	8.8	7.23	2.55	82.6	9	0	20
Clonazepam	24:07	7	10.7	8.36	3.16	78.0	10	1	24
	528:06	11	9.4	10.27	3.10	109.7	6	0	32

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Teacher: ABC Hyperactive/Noncompliance subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 7 Teacher: ABC Inappropriate Speech subscale score

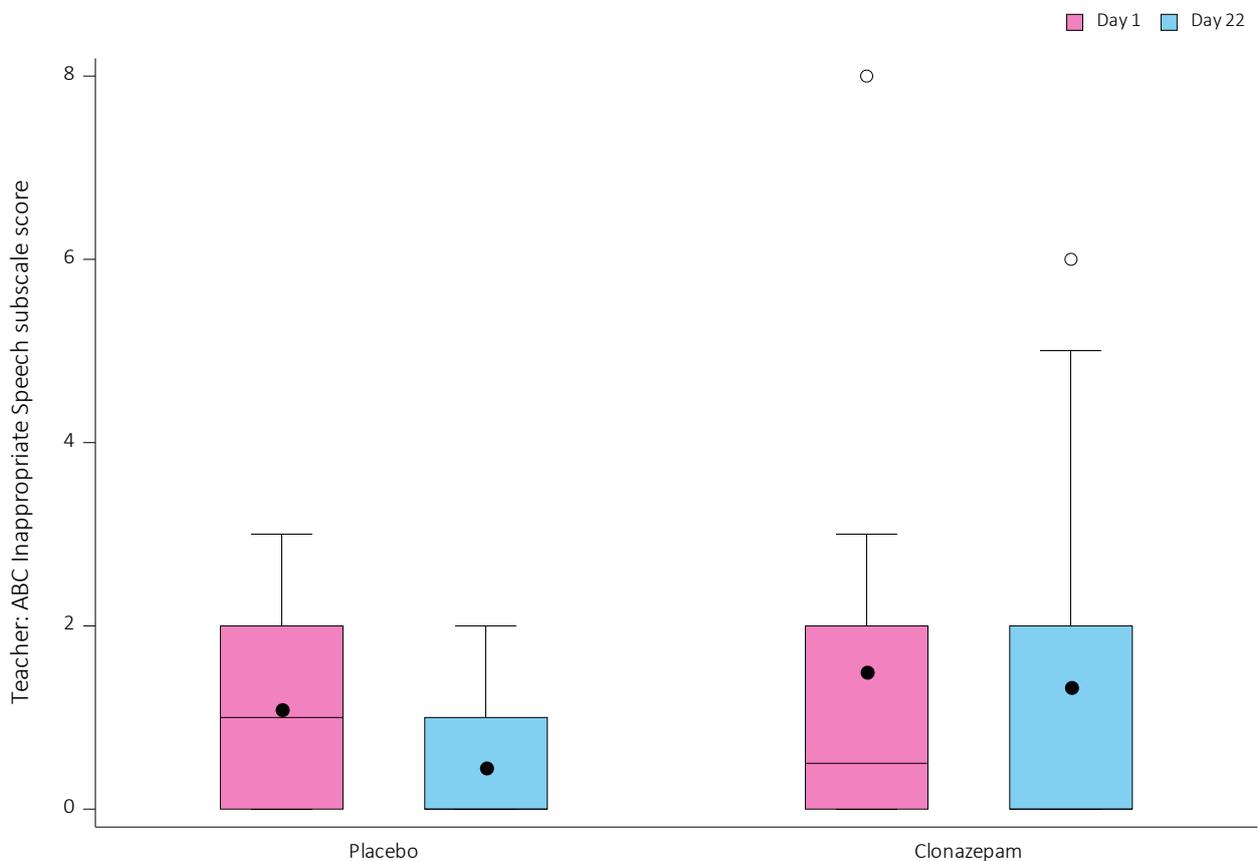
Summary Table: Teacher: ABC Inappropriate Speech subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	24:07	11	1.1	1.14	0.34	104.1	1	0	3
	528:06	11	0.5	0.69	0.21	151.3	0	0	2
Clonazepam	24:07	10	1.5	2.51	0.79	167.0	1	0	8
	528:06	12	1.3	2.15	0.62	161.0	0	0	6

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Teacher: ABC Inappropriate Speech subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 8 Teacher: ABC Irritability subscale score

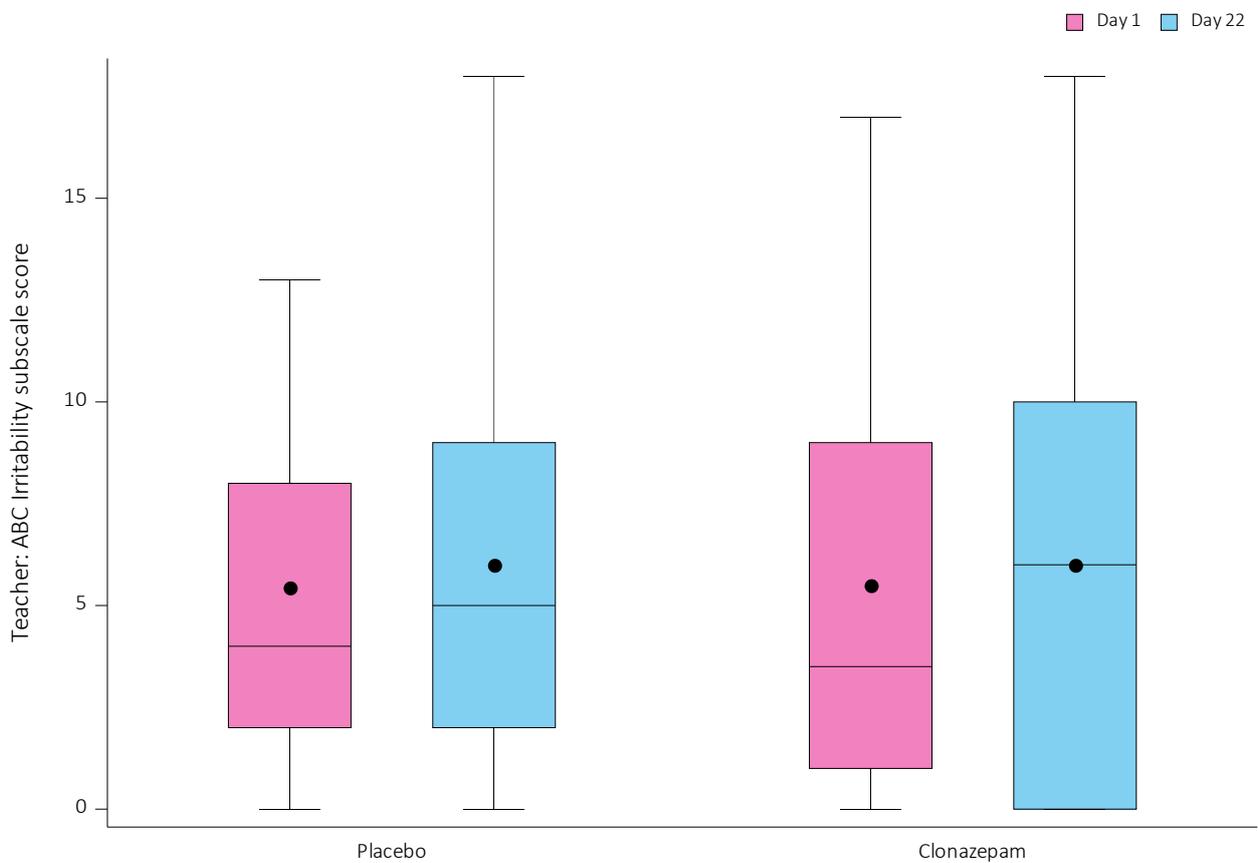
Summary Table: Teacher: ABC Irritability subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	24:07	9	5.4	4.13	1.38	75.8	4	0	13
	528:06	11	6.0	5.57	1.68	92.8	5	0	18
Clonazepam	24:07	8	5.5	5.83	2.06	106.0	4	0	17
	528:06	11	6.0	6.15	1.85	102.5	6	0	18

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Teacher: ABC Irritability subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 9 Teacher: ABC Social Withdrawal subscale score

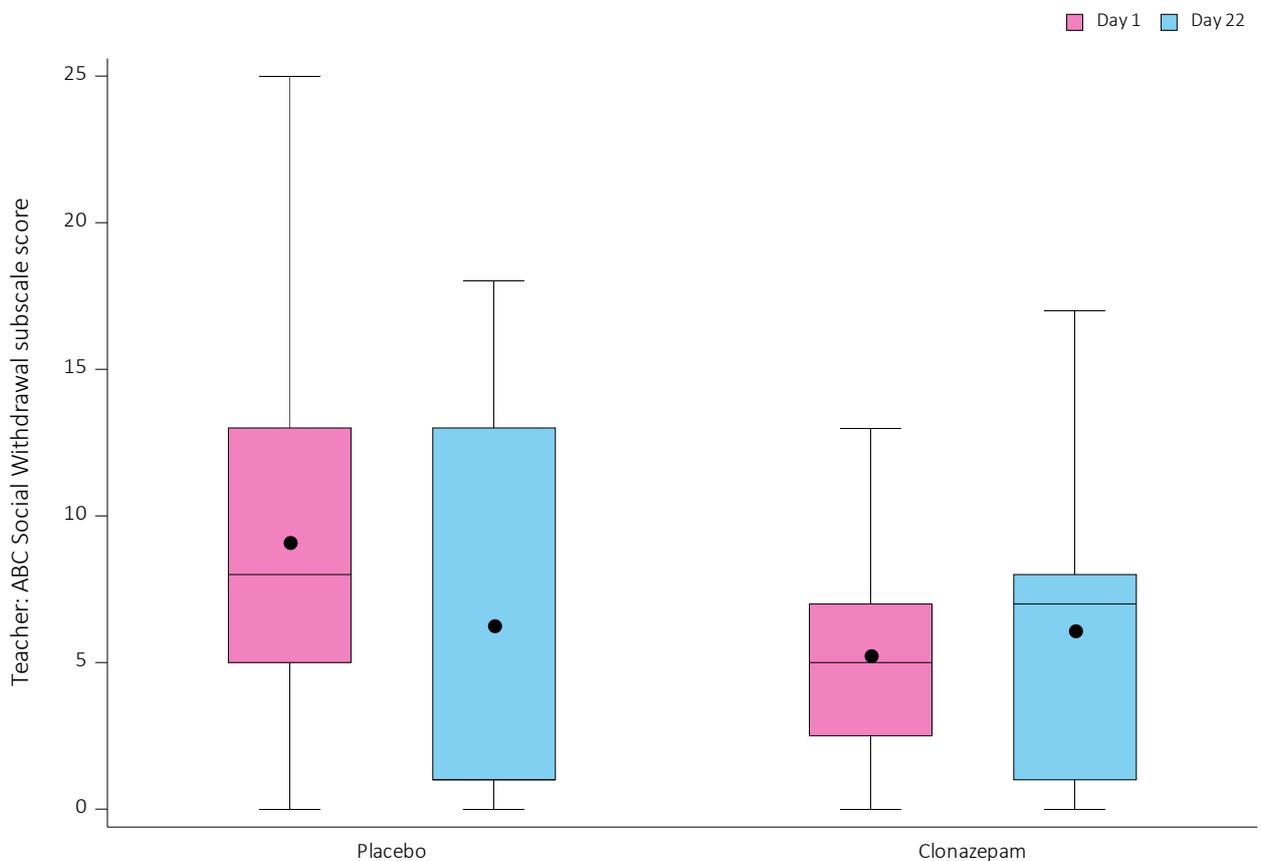
Summary Table: Teacher: ABC Social Withdrawal subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	24:07	9	9.1	7.79	2.60	85.4	8	0	25
	528:06	11	6.3	6.84	2.06	109.1	1	0	18
Clonazepam	24:07	8	5.3	3.96	1.40	75.3	5	0	13
	528:06	10	6.1	5.45	1.72	89.3	7	0	17

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Teacher: ABC Social Withdrawal subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summaries 10 Teacher: ABC Stereotypic Behavior subscale score

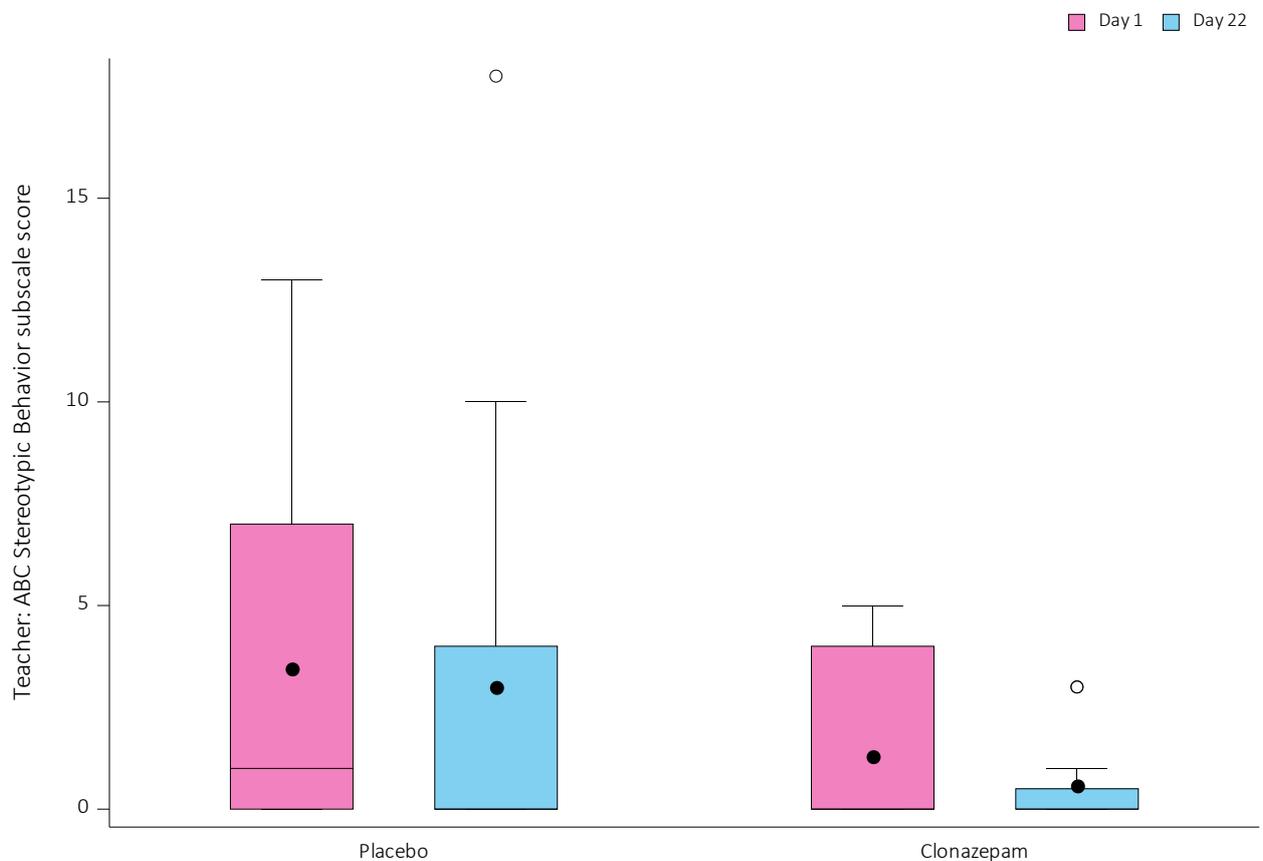
Summary Table: Teacher: ABC Stereotypic Behavior subscale score
Analysis population

Treatment	Time (hh:mm)	N	Mean	SD	SEM	CV (%)	Median	Min	Max
Placebo	24:07	11	3.5	4.66	1.40	134.8	1	0	13
	528:06	12	3.0	5.77	1.67	192.3	0	0	18
Clonazepam	24:07	10	1.3	2.11	0.67	162.4	0	0	5
	528:06	12	0.6	1.16	0.34	199.6	0	0	3

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Summary Graph: Summary graph Teacher: ABC Stereotypic Behavior subscale score
Analysis population

Tukey boxplot: Black dot = Mean Black circle = Outlier



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Analysis results pharmacodynamic response table, LSM table and graphs

DRAFT

Analysis results 1 Parents: ABC Hyperactive/Noncompliance subscale score

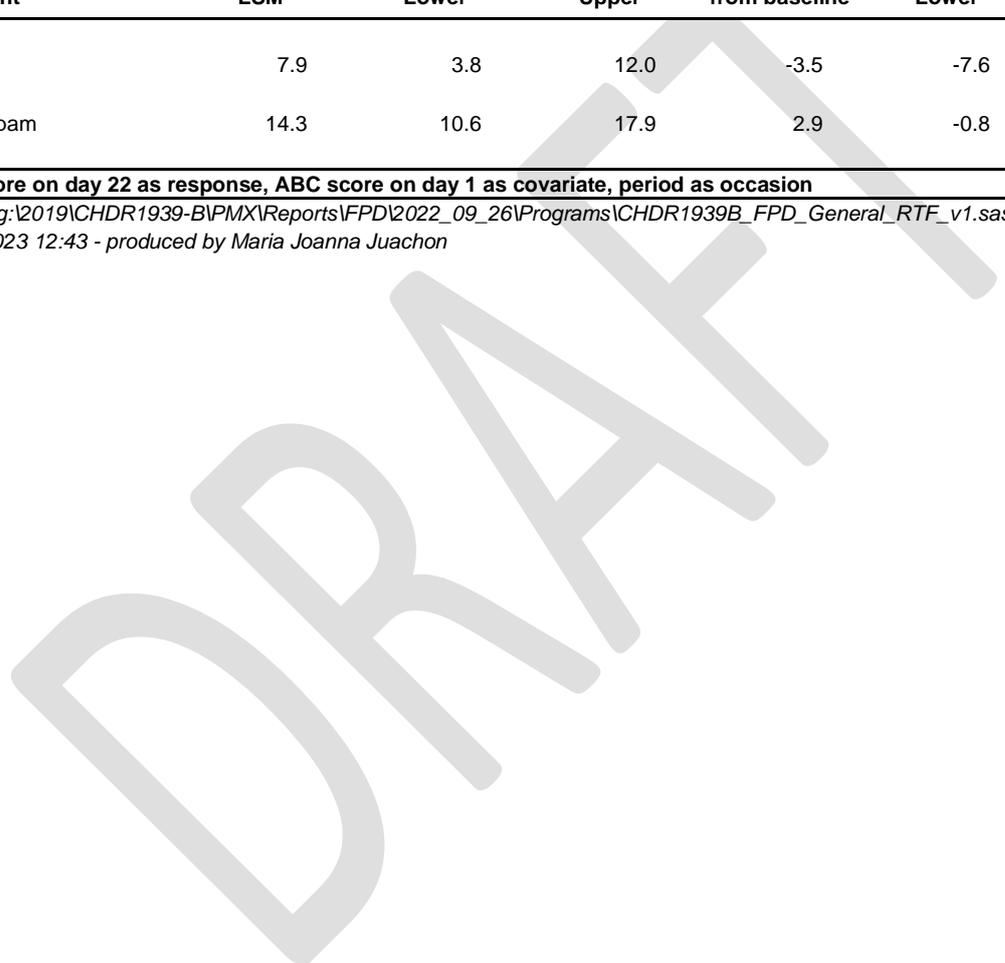
Analysis results 1 Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population

Effect/Contrast	P-value	First LSM of contrast	Second LSM of contrast	Estimate of the difference	95% CI	
					Lower	Upper
Prevalue	<.0001					
Treatment	0.0464					
Period	0.9498					
Clonazepam - Placebo	0.0464	14.3	7.9	6.3	0.1	12.6

Treatment	LSM	95% CI		LSM change from baseline	95% CI	
		Lower	Upper		Lower	Upper
Placebo	7.9	3.8	12.0	-3.5	-7.6	0.7
Clonazepam	14.3	10.6	17.9	2.9	-0.8	6.5

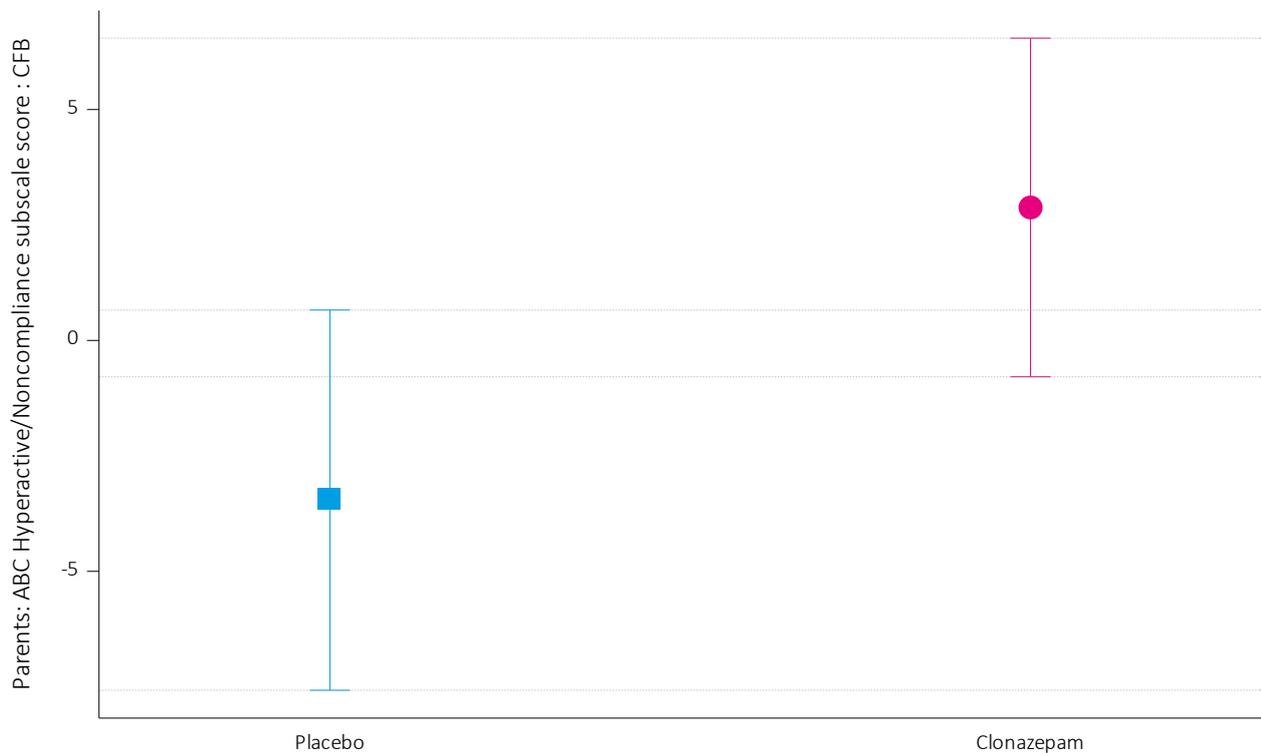
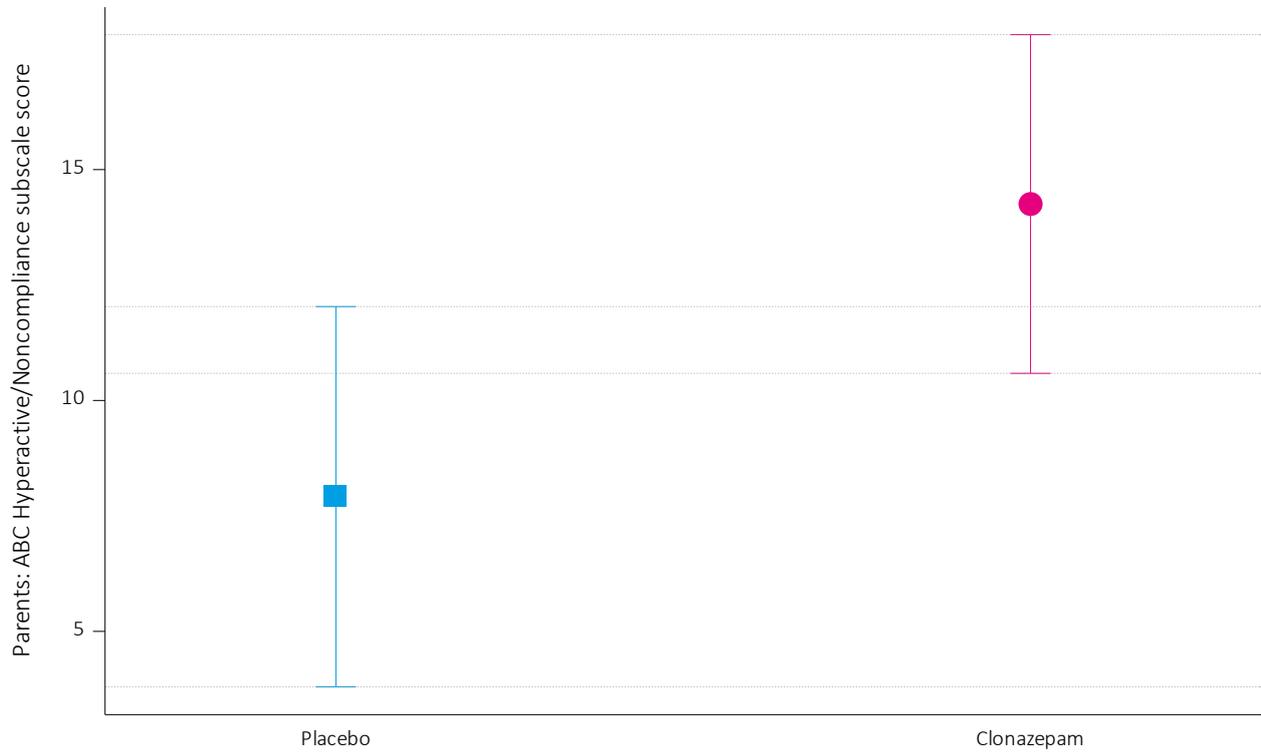
ABC Score on day 22 as response, ABC score on day 1 as covariate, period as occasion

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
 18JAN2023 12:43 - produced by Maria Joanna Juachon



Estimated means 1 Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population

Estimated means (95% CI error bars)



Source: g:\2019\CHDR1939-B\PMX\Reports\VPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Analysis results 2 Parents: ABC Inappropriate Speech subscale score

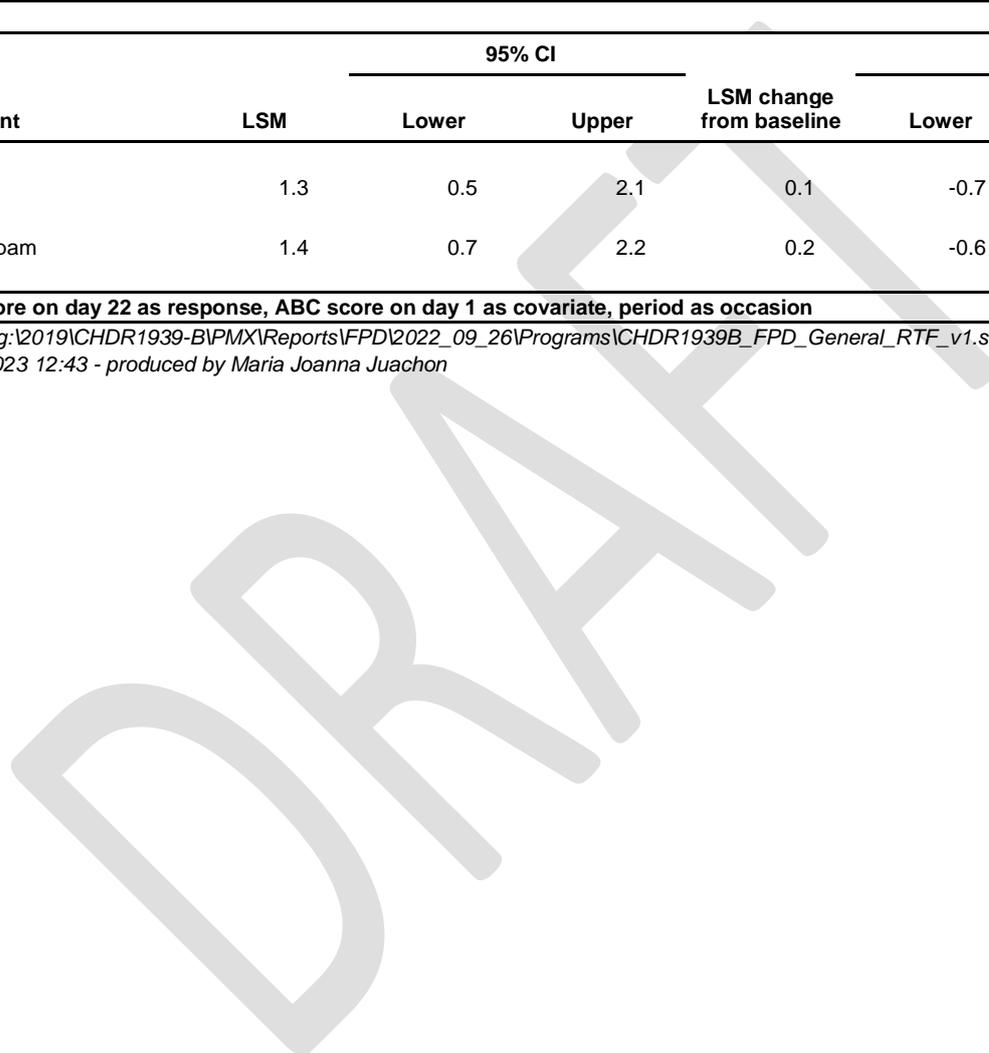
**Analysis results 2 Parents: ABC Inappropriate Speech subscale score
Analysis population**

Effect/Contrast	P-value	First LSM of contrast	Second LSM of contrast	Estimate of the difference	95% CI	
					Lower	Upper
Prevalue	0.0013					
Treatment	0.7254					
Period	0.0891					
Clonazepam - Placebo	0.7254	1.4	1.3	0.2	-0.8	1.1

Treatment	LSM	95% CI		LSM change from baseline	95% CI	
		Lower	Upper		Lower	Upper
Placebo	1.3	0.5	2.1	0.1	-0.7	0.9
Clonazepam	1.4	0.7	2.2	0.2	-0.6	1.0

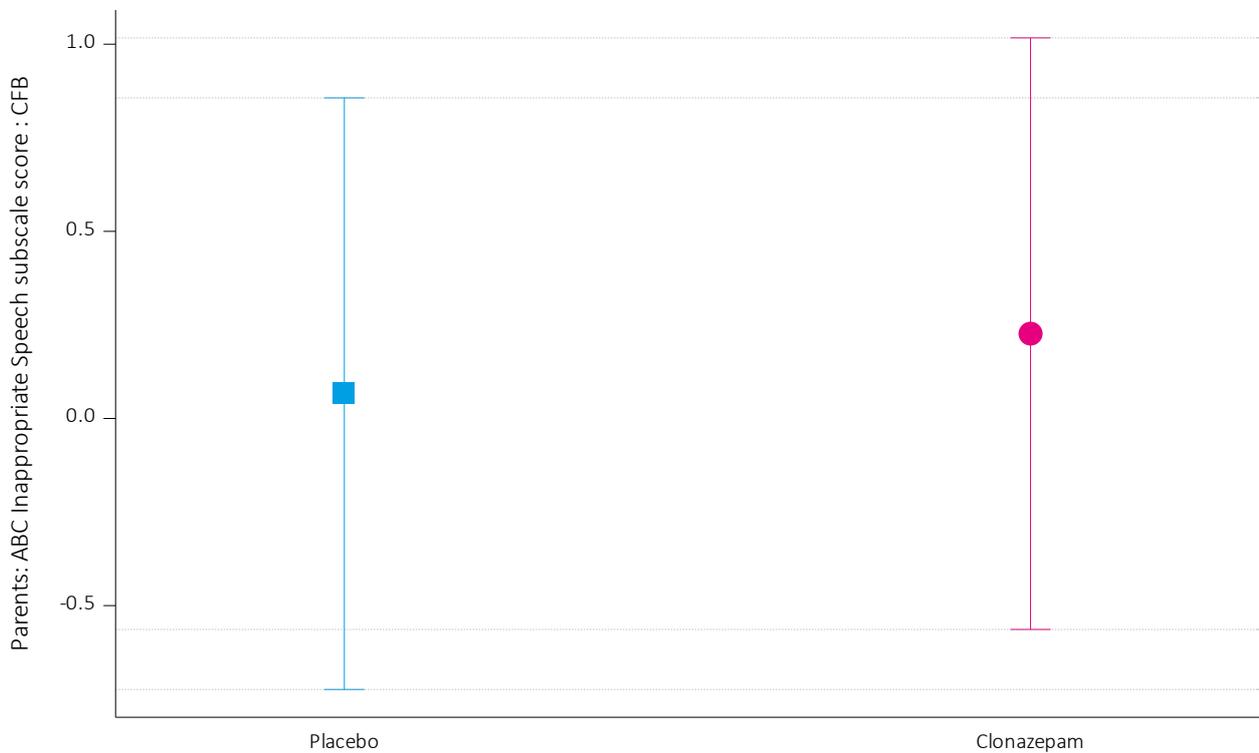
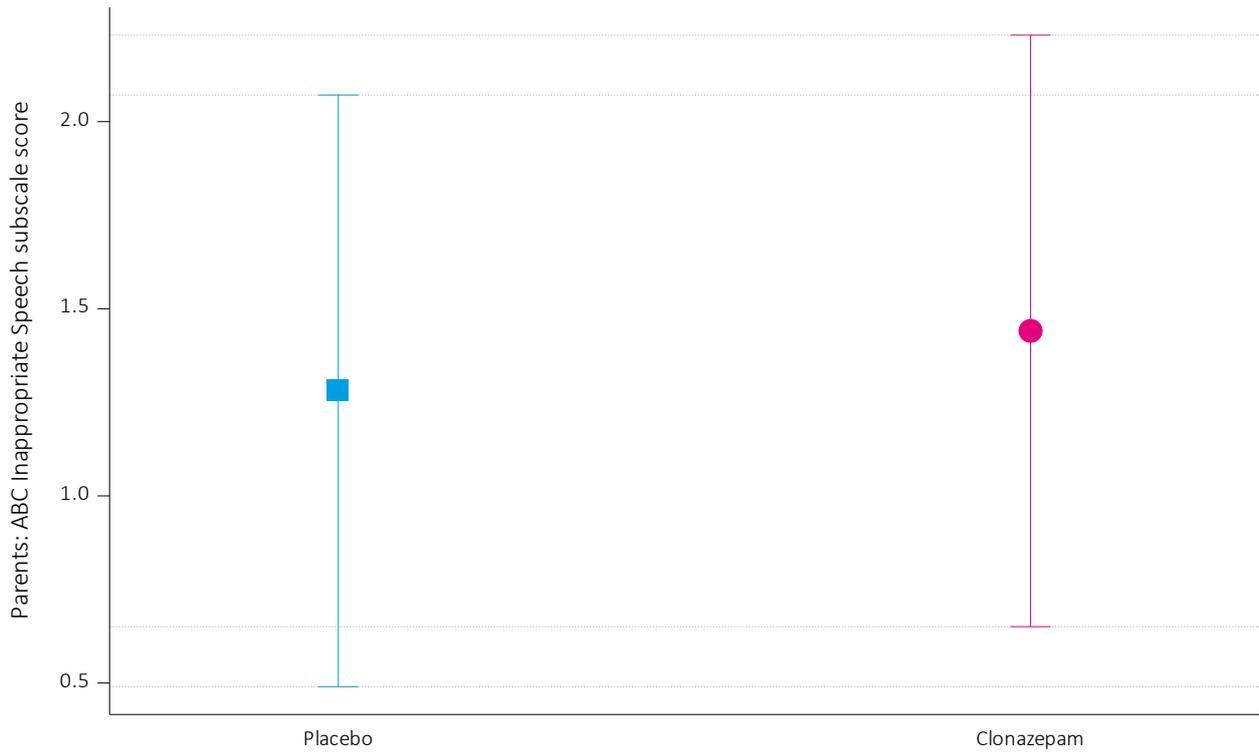
ABC Score on day 22 as response, ABC score on day 1 as covariate, period as occasion

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon



**Estimated means 2 Parents: ABC Inappropriate Speech subscale score
Analysis population**

Estimated means (95% CI error bars)



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Analysis results 3 Parents: ABC Irritability subscale score

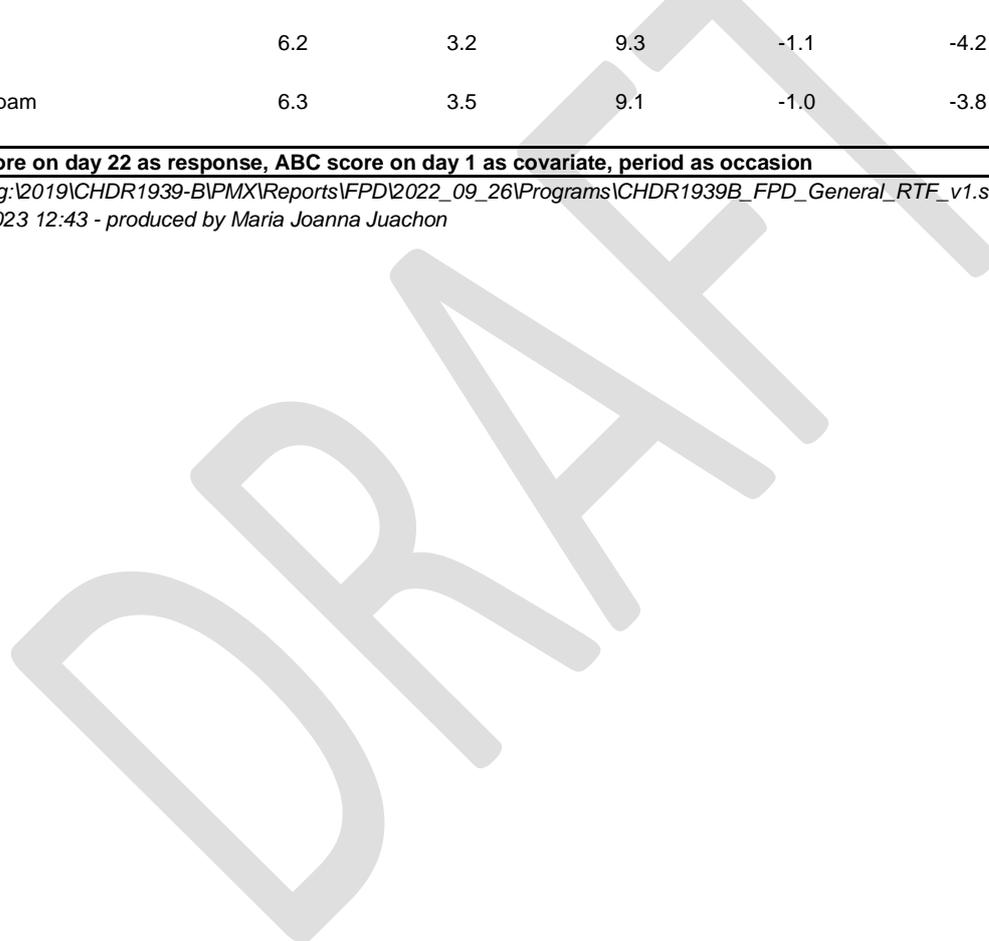
**Analysis results 3 Parents: ABC Irritability subscale score
Analysis population**

Effect/Contrast	P-value	First LSM of contrast	Second LSM of contrast	Estimate of the difference	95% CI	
					Lower	Upper
Prevalue	0.0059					
Treatment	0.9531					
Period	0.0659					
Clonazepam - Placebo	0.9531	6.3	6.2	0.1	-3.1	3.3

Treatment	LSM	95% CI		LSM change from baseline	95% CI	
		Lower	Upper		Lower	Upper
Placebo	6.2	3.2	9.3	-1.1	-4.2	2.0
Clonazepam	6.3	3.5	9.1	-1.0	-3.8	1.8

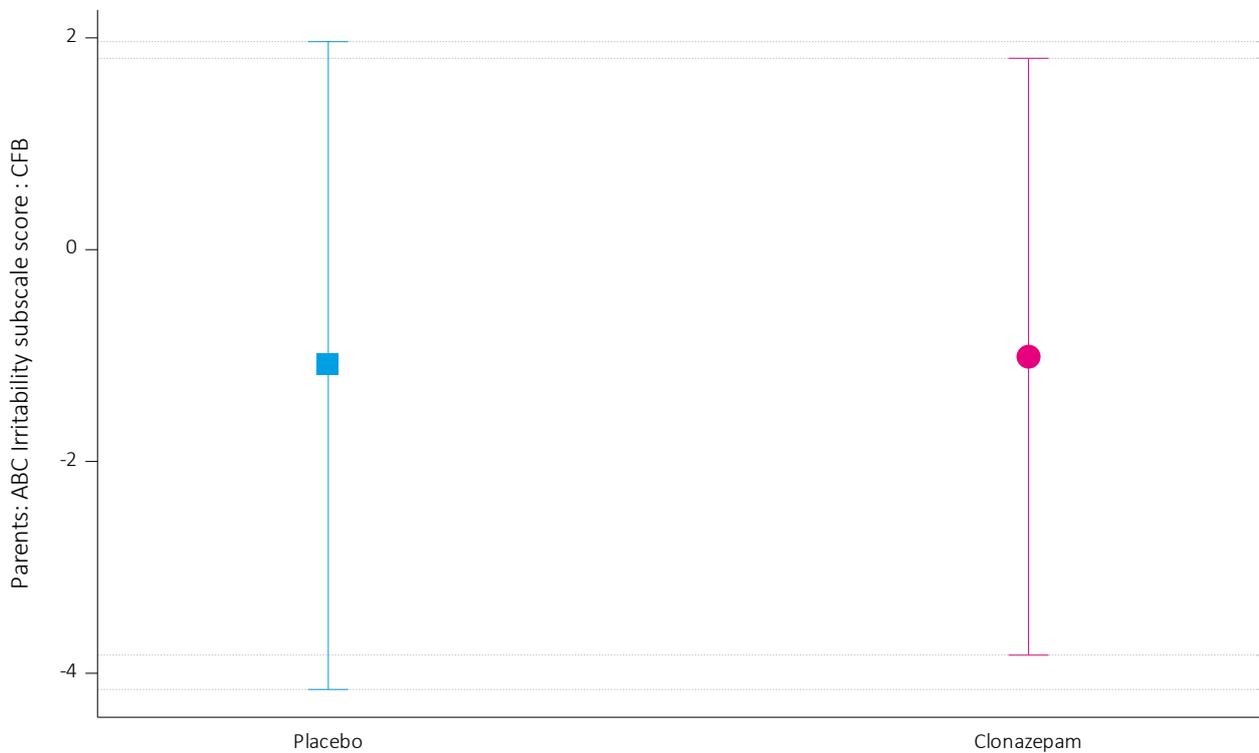
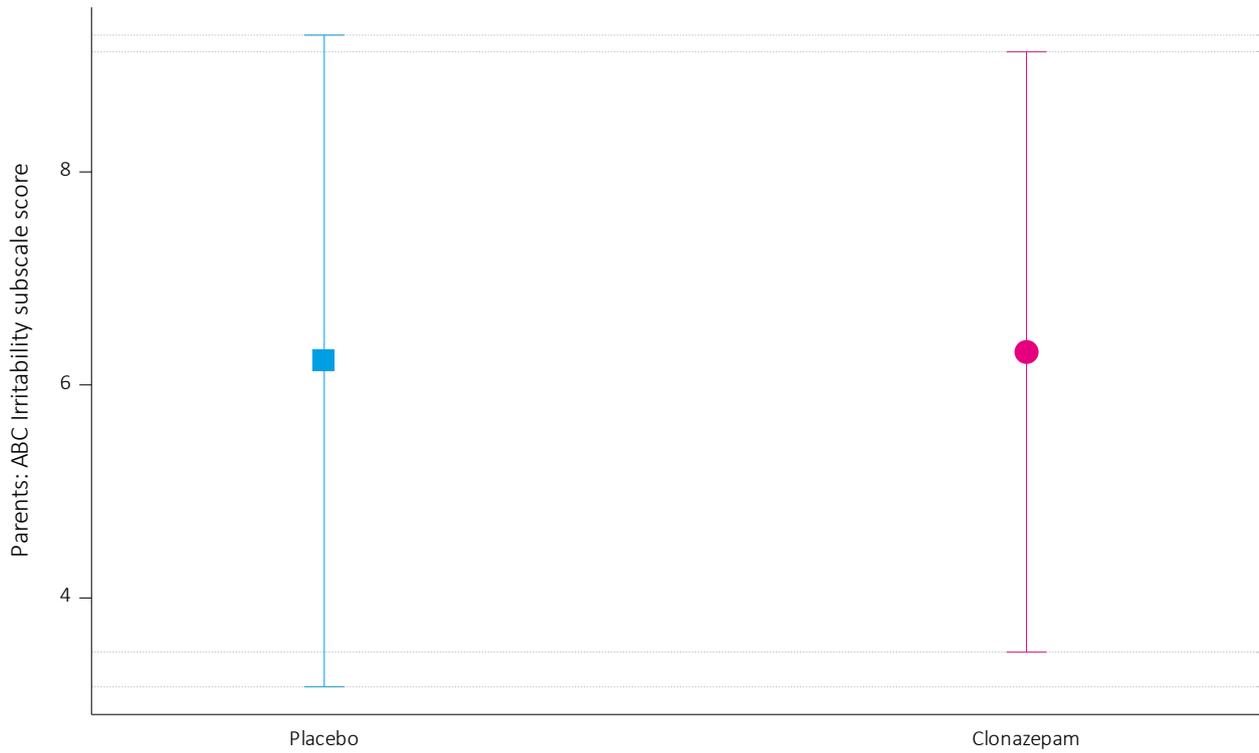
ABC Score on day 22 as response, ABC score on day 1 as covariate, period as occasion

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
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Estimated means 3 Parents: ABC Irritability subscale score Analysis population

Estimated means (95% CI error bars)



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Analysis results 4 Parents: ABC Social Withdrawal subscale score

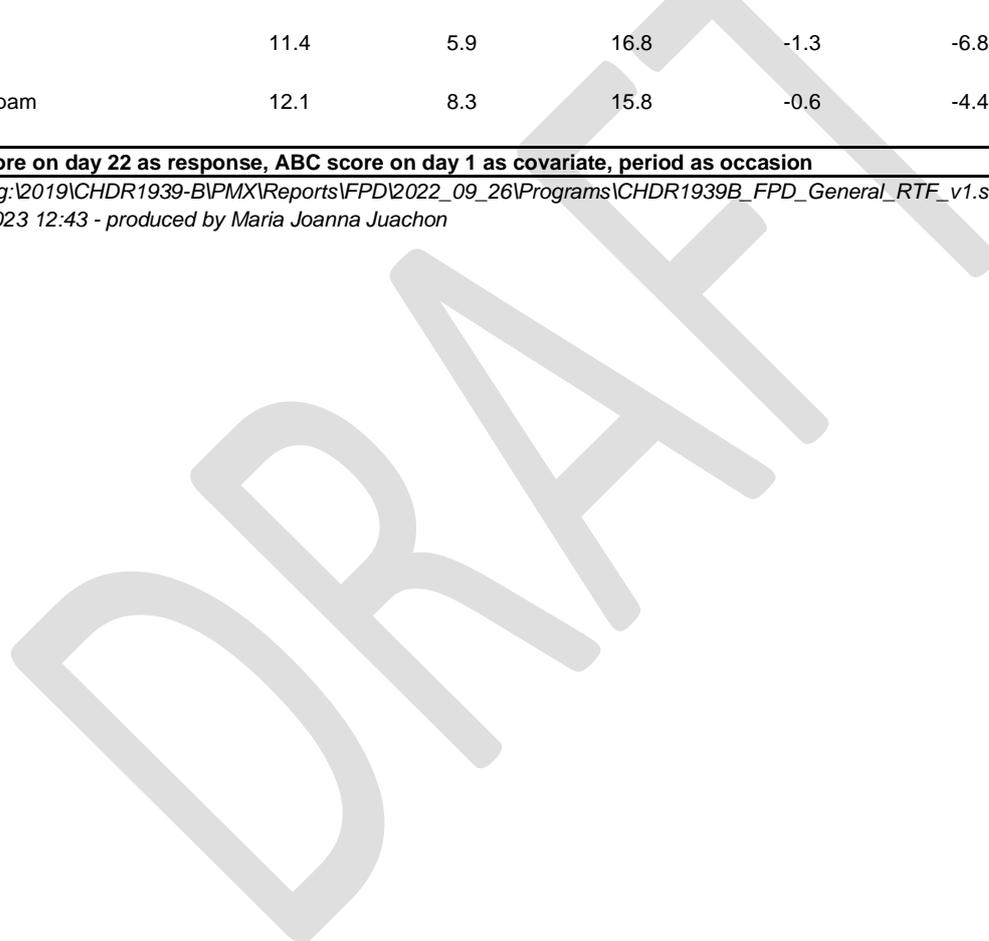
Analysis results 4 Parents: ABC Social Withdrawal subscale score
Analysis population

Effect/Contrast	P-value	First LSM of contrast	Second LSM of contrast	Estimate of the difference	95% CI	
					Lower	Upper
Prevalue	0.0053					
Treatment	0.8407					
Period	0.9213					
Clonazepam - Placebo	0.8407	12.1	11.4	0.7	-6.9	8.3

Treatment	LSM	95% CI		LSM change from baseline	95% CI	
		Lower	Upper		Lower	Upper
Placebo	11.4	5.9	16.8	-1.3	-6.8	4.2
Clonazepam	12.1	8.3	15.8	-0.6	-4.4	3.1

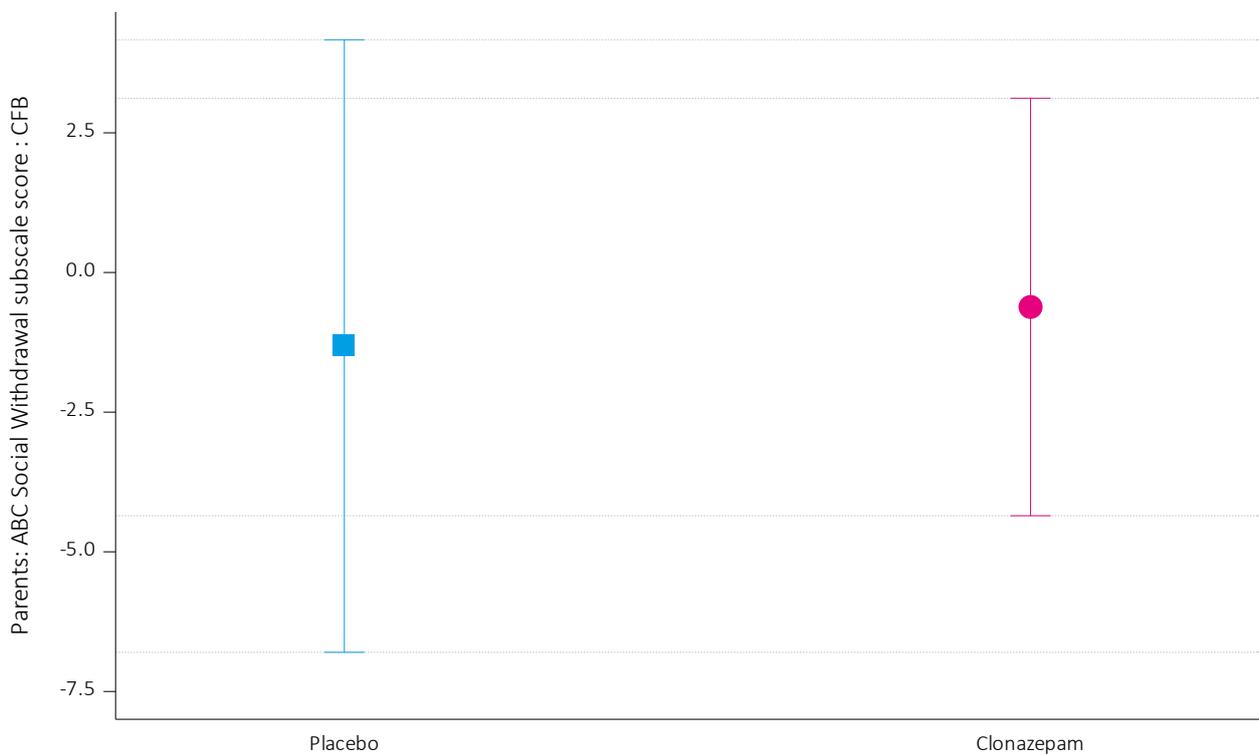
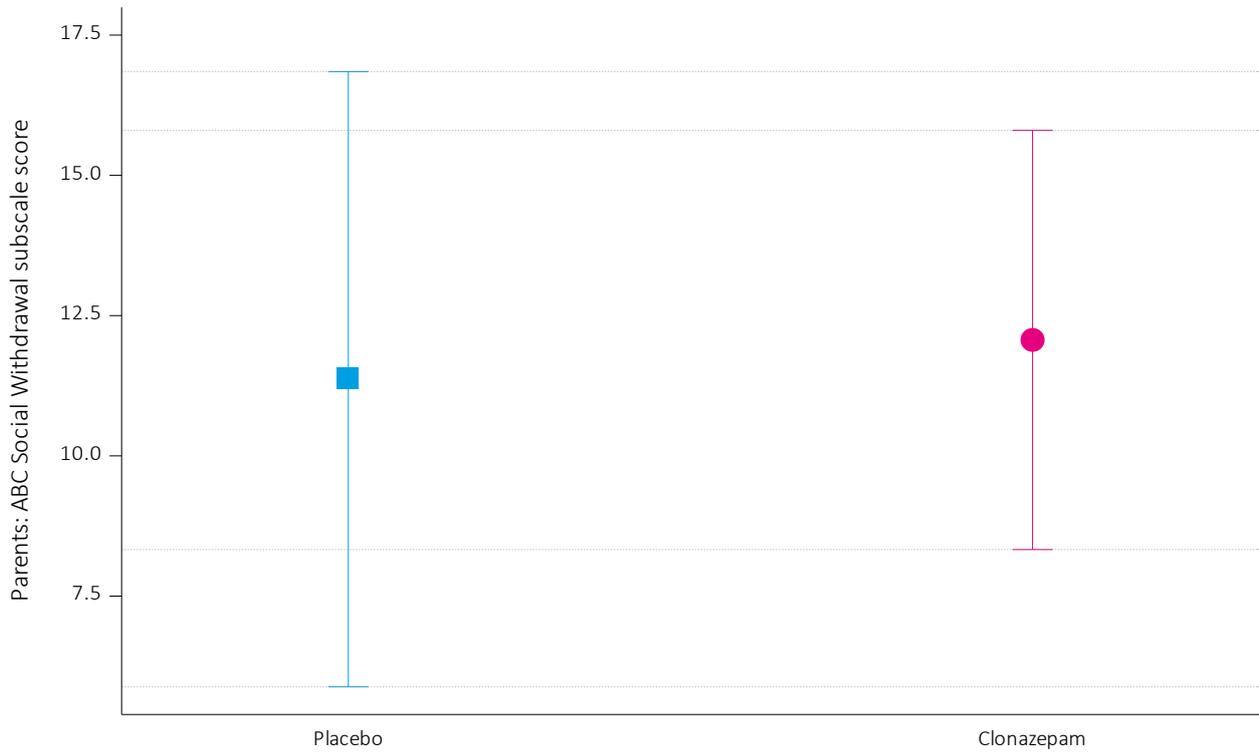
ABC Score on day 22 as response, ABC score on day 1 as covariate, period as occasion

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
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**Estimated means 4 Parents: ABC Social Withdrawal subscale score
Analysis population**

Estimated means (95% CI error bars)



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18JAN2023 12:43 - produced by Maria Joanna Juachon

Analysis results 5 Parents: ABC Stereotypic Behavior subscale score

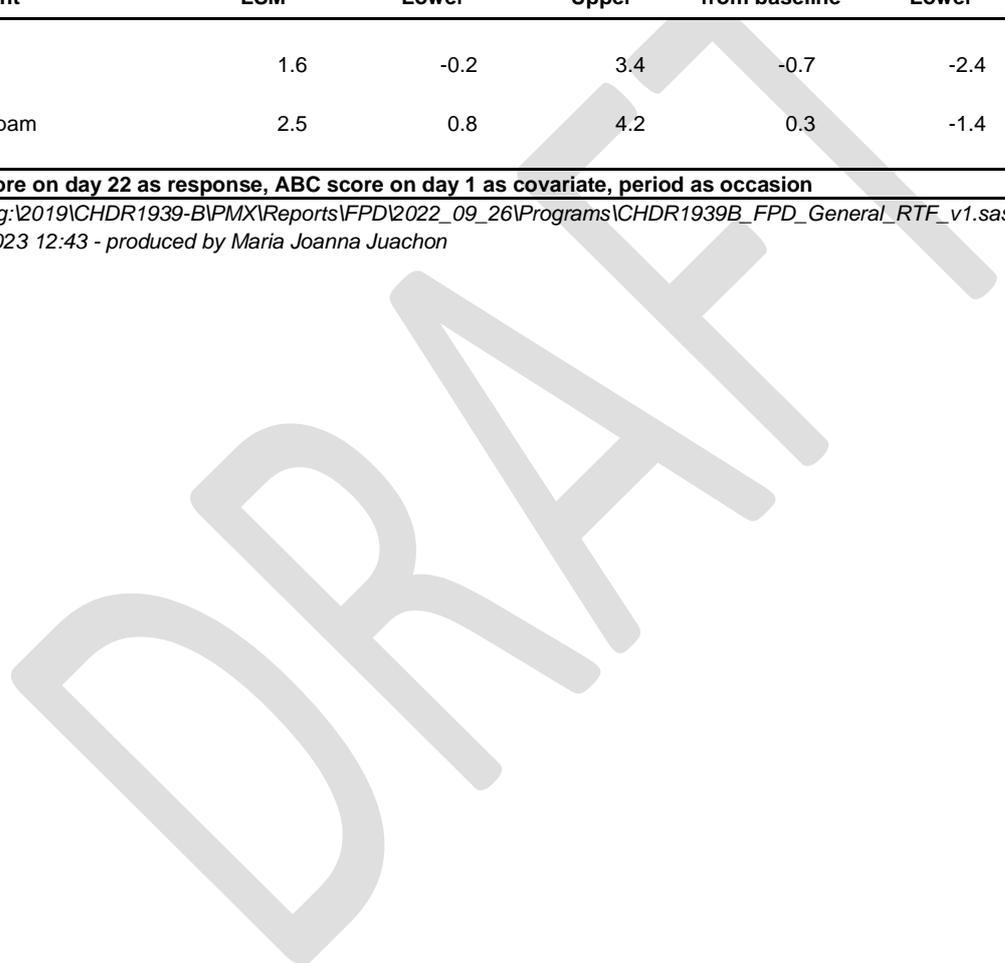
**Analysis results 5 Parents: ABC Stereotypic Behavior subscale score
Analysis population**

Effect/Contrast	P-value	First LSM of contrast	Second LSM of contrast	Estimate of the difference	95% CI	
					Lower	Upper
Prevalue	0.0150					
Treatment	0.4377					
Period	0.7835					
Clonazepam - Placebo	0.4377	2.5	1.6	0.9	-1.6	3.4

Treatment	LSM	95% CI		LSM change from baseline	95% CI	
		Lower	Upper		Lower	Upper
Placebo	1.6	-0.2	3.4	-0.7	-2.4	1.1
Clonazepam	2.5	0.8	4.2	0.3	-1.4	2.0

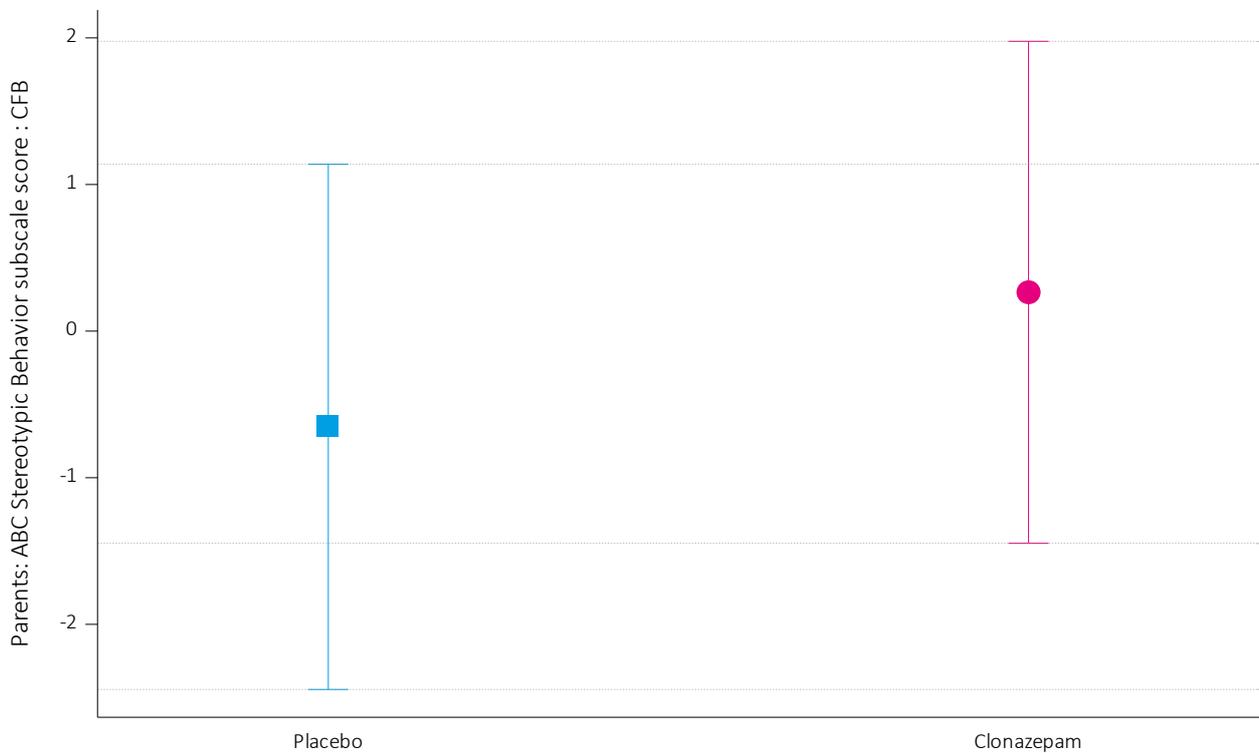
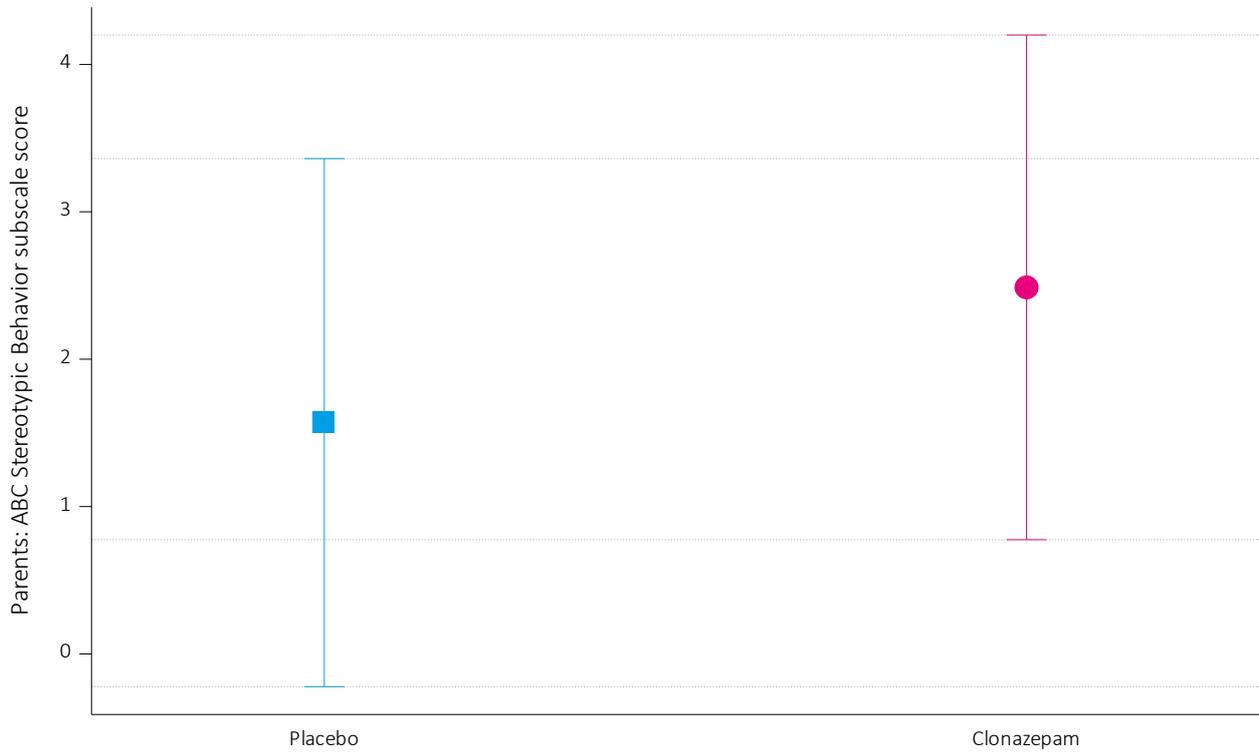
ABC Score on day 22 as response, ABC score on day 1 as covariate, period as occasion

Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon



Estimated means 5 Parents: ABC Stereotypic Behavior subscale score
Analysis population

Estimated means (95% CI error bars)



Source: g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\Programs\CHDR1939B_FPD_General_RTF_v1.sas
18JAN2023 12:43 - produced by Maria Joanna Juachon

Unedited SAS output

DRAFT

SAS output 1.1 Parents: ABC Hyperactive/Noncompliance subscale score

Proc MIXED analysis of Parents: ABC Hyperactive/Noncompliance subscale score 1
 Analysis population

Model Information

Data Set	WORK.MIX
Dependent Variable	P_Hyperactivity
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	15	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	15
Subjects	1
Max Obs per Subject	24

Number of Observations

Number of Observations Read	31
Number of Observations Used	24
Number of Observations Not Used	7

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	144.22615377	
1	2	144.01534784	0.00000010
2	1	144.01534267	0.00000000

Convergence criteria met.

Estimated G matrix is not positive definite.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	-5.7136
Residual	44.8905

Fit Statistics

-2 Res Log Likelihood	144.0
AIC (Smaller is Better)	148.0
AICC (Smaller is Better)	148.7
BIC (Smaller is Better)	149.4

Proc MIXED analysis of Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population

2

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	0.21	0.6461

Type 3 Tests of Fixed Effects

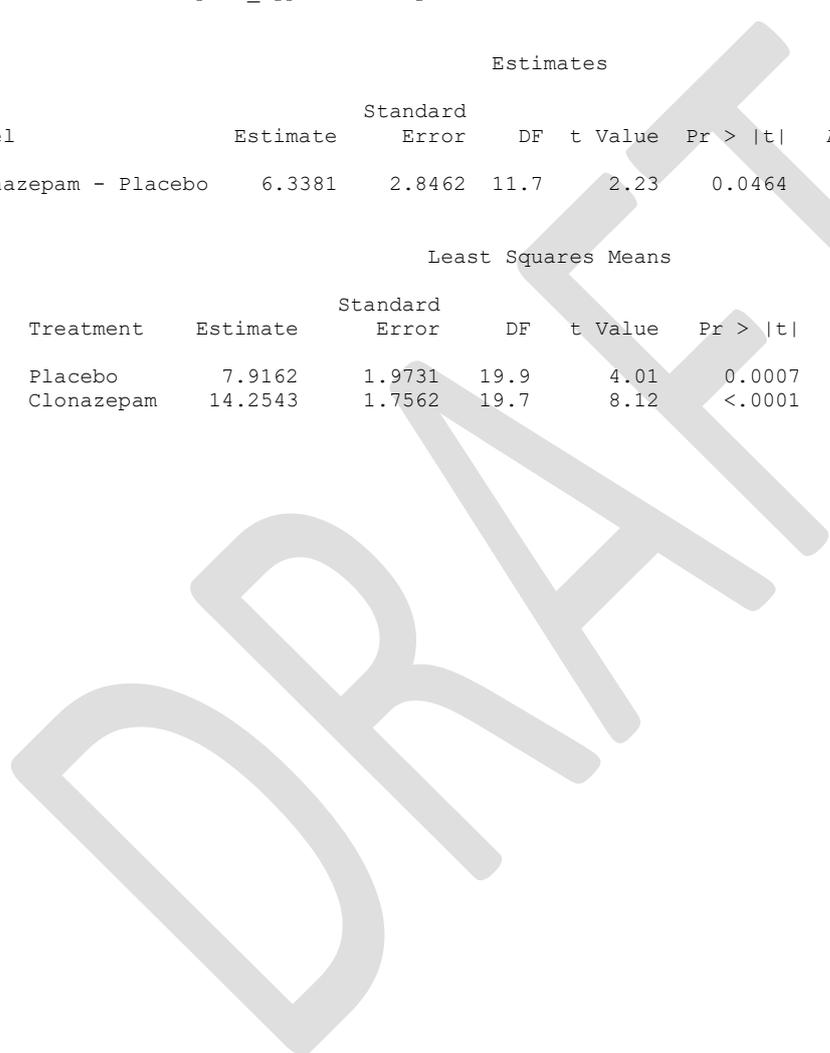
Effect	Num DF	Den DF	F Value	Pr > F
by1	1	11.7	4.96	0.0464
Occasion	1	11.2	0.00	0.9498
preP_Hyperactivity	1	11.8	46.35	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
Clonazepam - Placebo	6.3381	2.8462	11.7	2.23	0.0464	0.05	0.1202	12.5559

Least Squares Means

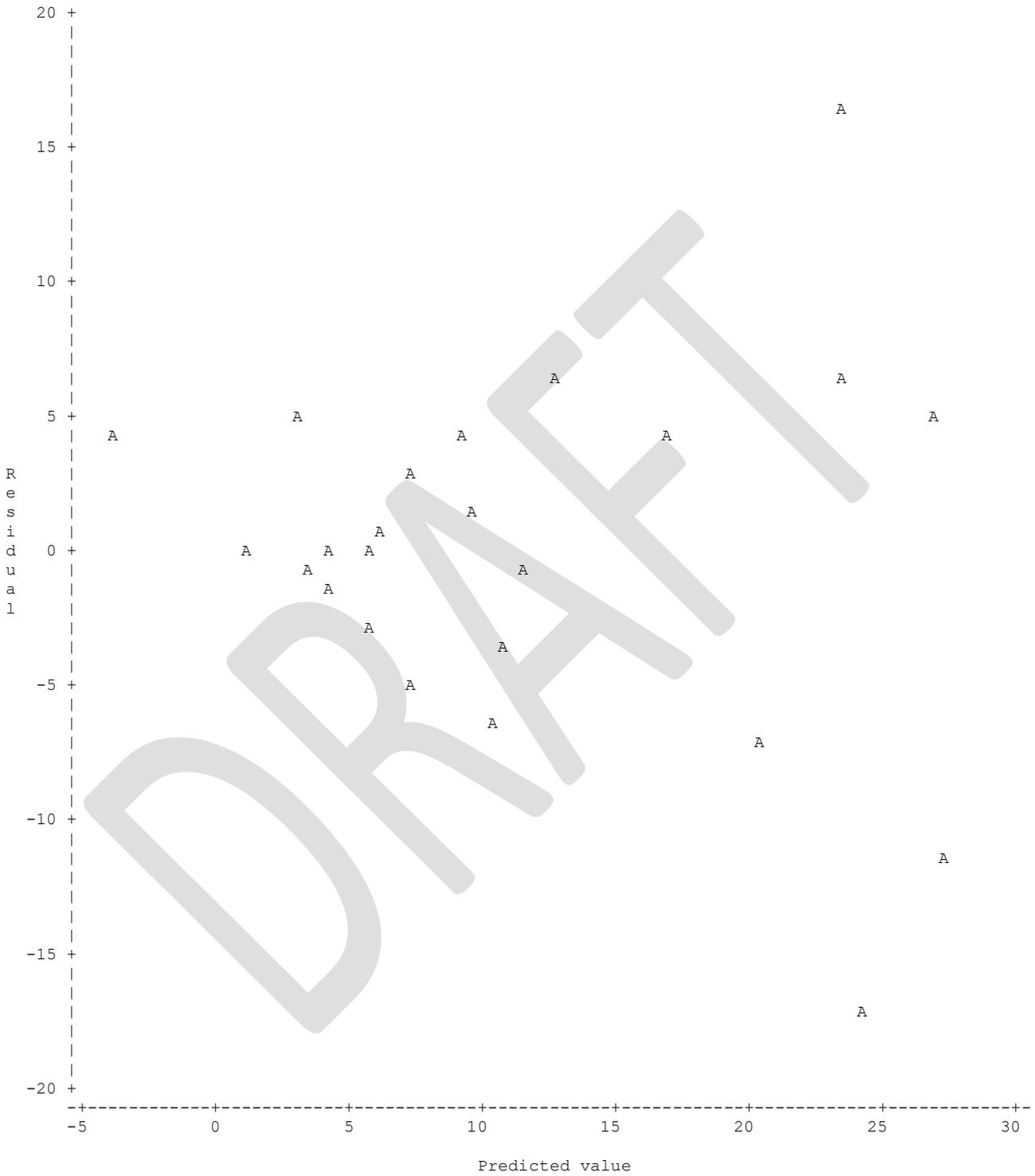
Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	7.9162	1.9731	19.9	4.01	0.0007	0.05	3.7992	12.0333
by1	Clonazepam	14.2543	1.7562	19.7	8.12	<.0001	0.05	10.5874	17.9212



Proc MIXED analysis of Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population

Residuals vs Predicted values

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



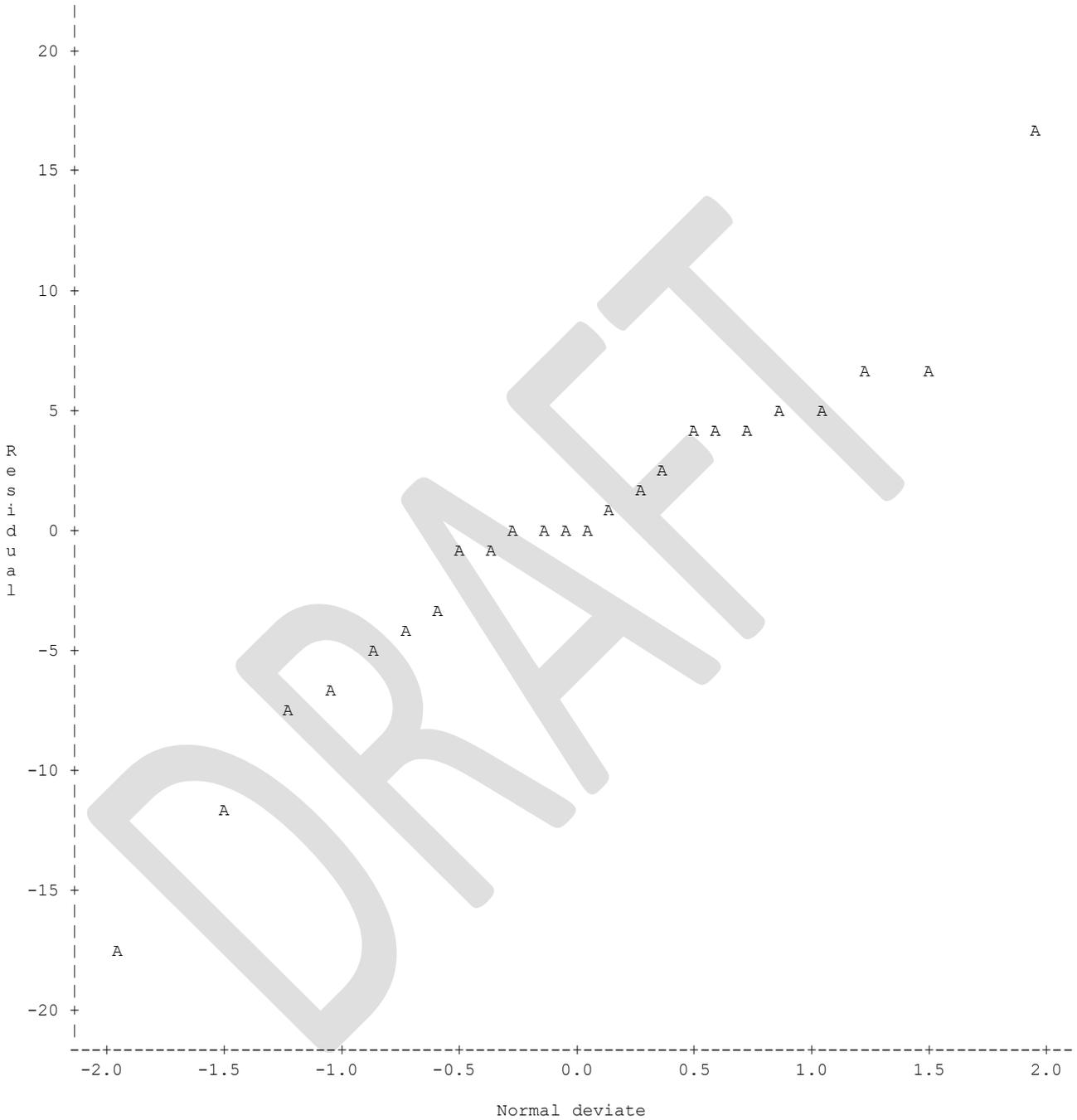
NOTE: 7 obs had missing values.

Proc MIXED analysis of Parents: ABC Hyperactive/Noncompliance subscale score
Analysis population

4

Normal probability plot for residuals P_Hyperactivity
(Shapiro-Wilk Test Statistic = 0.952 : P-value=0.3023)

Plot of Resid*rankres. Legend: A = 1 obs, B = 2 obs, etc.



NOTE: 7 obs had missing values.

SAS output 1.2 Parents: ABC Hyperactive/Noncompliance subscale score change from baseline

Proc MIXED analysis of Parents: ABC Hyperactive/Noncompliance subscale score , change from baseline 1
Analysis population

Model Information

Data Set	WORK.MIX
Dependent Variable	dP_Hyperactivity
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	15	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	15
Subjects	1
Max Obs per Subject	24

Number of Observations

Number of Observations Read	31
Number of Observations Used	24
Number of Observations Not Used	7

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	144.22615377	
1	2	144.01534784	0.00000010
2	1	144.01534267	0.00000000

Convergence criteria met.

Estimated G matrix is not positive definite.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	-5.7136
Residual	44.8905

Fit Statistics

-2 Res Log Likelihood	144.0
AIC (Smaller is Better)	148.0
AICC (Smaller is Better)	148.7
BIC (Smaller is Better)	149.4

Proc MIXED analysis of Parents: ABC Hyperactive/Noncompliance subscale score , change from baselin 2
Analysis population

Null Model Likelihood Ratio Test

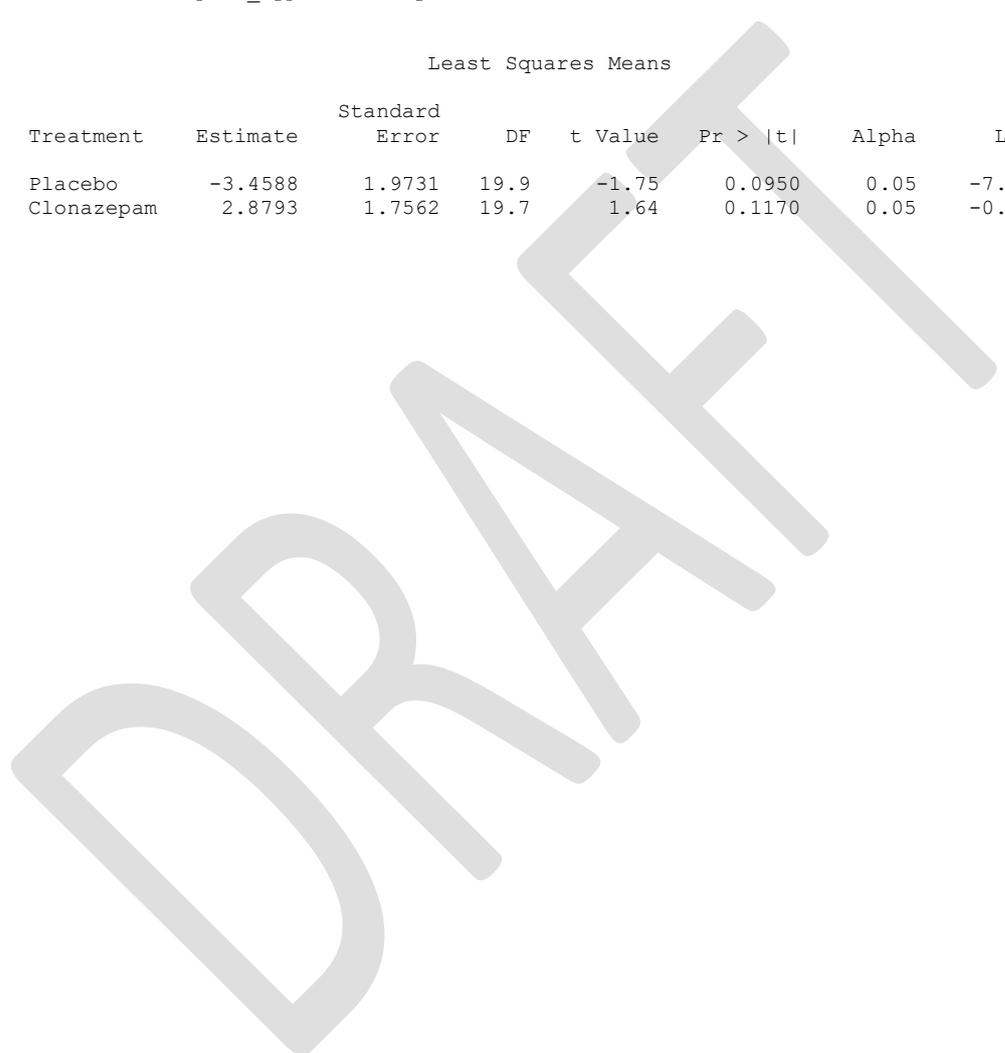
DF	Chi-Square	Pr > ChiSq
1	0.21	0.6461

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
by1	1	11.7	4.96	0.0464
Occasion	1	11.2	0.00	0.9498
preP_Hyperactivity	1	11.8	0.03	0.8712

Least Squares Means

Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	-3.4588	1.9731	19.9	-1.75	0.0950	0.05	-7.5758	0.6583
by1	Clonazepam	2.8793	1.7562	19.7	1.64	0.1170	0.05	-0.7876	6.5462



SAS output 2.1 Parents: ABC Inappropriate Speech subscale score

Proc MIXED analysis of Parents: ABC Inappropriate Speech subscale score
 Analysis population

1

Model Information

Data Set	WORK.MIX
Dependent Variable	P_Inappropriate
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	16	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	16
Subjects	1
Max Obs per Subject	28

Number of Observations

Number of Observations Read	31
Number of Observations Used	28
Number of Observations Not Used	3

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	96.72970565	
1	2	95.09851978	0.00001550
2	1	95.09812029	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	0.7157
Residual	1.2964

Fit Statistics

-2 Res Log Likelihood	95.1
AIC (Smaller is Better)	99.1
AICC (Smaller is Better)	99.7
BIC (Smaller is Better)	100.6

Proc MIXED analysis of Parents: ABC Inappropriate Speech subscale score
Analysis population

2

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	1.63	0.2015

Type 3 Tests of Fixed Effects

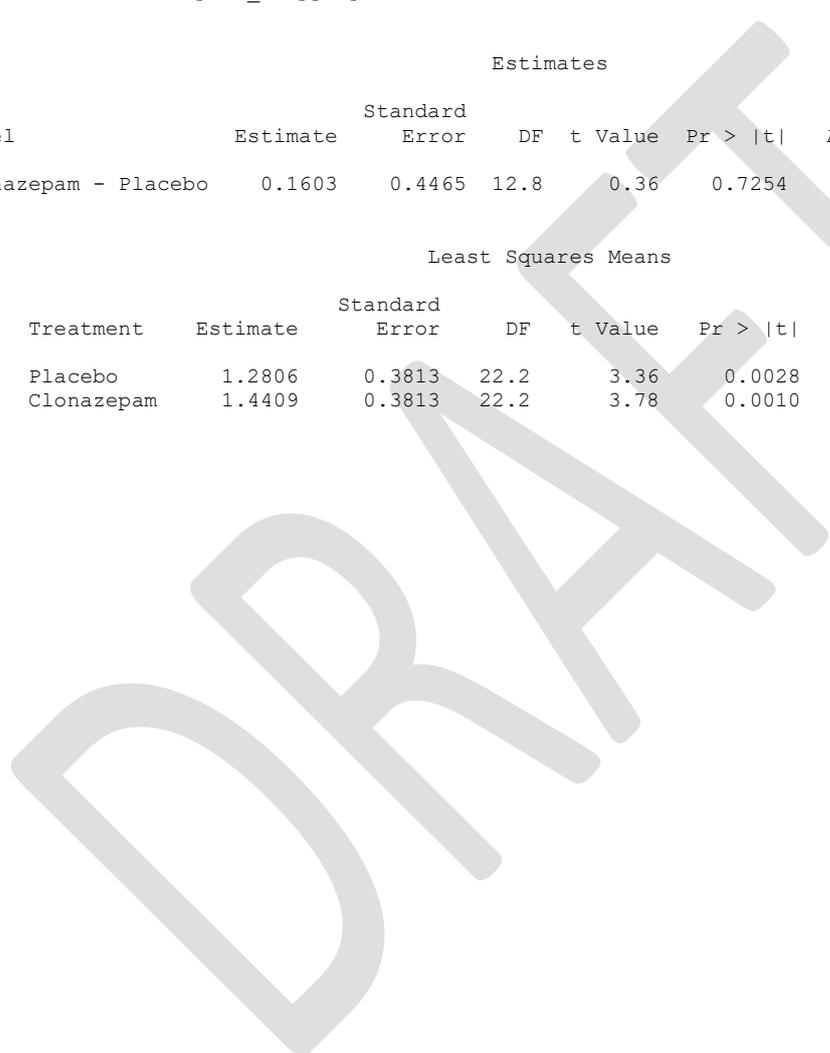
Effect	Num DF	Den DF	F Value	Pr > F
by1	1	12.8	0.13	0.7254
Occasion	1	12.8	3.39	0.0891
preP_Inappropriate	1	13.4	16.39	0.0013

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
Clonazepam - Placebo	0.1603	0.4465	12.8	0.36	0.7254	0.05	-0.8059	1.1265

Least Squares Means

Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	1.2806	0.3813	22.2	3.36	0.0028	0.05	0.4902	2.0709
by1	Clonazepam	1.4409	0.3813	22.2	3.78	0.0010	0.05	0.6506	2.2312



Proc MIXED analysis of Parents: ABC Inappropriate Speech subscale score
Analysis population

Residuals vs Predicted values

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



NOTE: 3 obs had missing values.

Proc MIXED analysis of Parents: ABC Inappropriate Speech subscale score
Analysis population

Normal probability plot for residuals P_Inappropriate
(Shapiro-Wilk Test Statistic = 0.926 : P-value=0.0490)

Plot of Resid*rankres. Legend: A = 1 obs, B = 2 obs, etc.



NOTE: 3 obs had missing values.

SAS output 2.2 Parents: ABC Inappropriate Speech subscale score change from baseline

Proc MIXED analysis of Parents: ABC Inappropriate Speech subscale score , change from baseline 1
 Analysis population

Model Information

Data Set	WORK.MIX
Dependent Variable	dP_Inappropriate
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	16	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	16
Subjects	1
Max Obs per Subject	28

Number of Observations

Number of Observations Read	31
Number of Observations Used	28
Number of Observations Not Used	3

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	96.72970565	
1	2	95.09851978	0.00001550
2	1	95.09812029	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	0.7157
Residual	1.2964

Fit Statistics

-2 Res Log Likelihood	95.1
AIC (Smaller is Better)	99.1
AICC (Smaller is Better)	99.7
BIC (Smaller is Better)	100.6

Proc MIXED analysis of Parents: ABC Inappropriate Speech subscale score , change from baseline 2
Analysis population

Null Model Likelihood Ratio Test

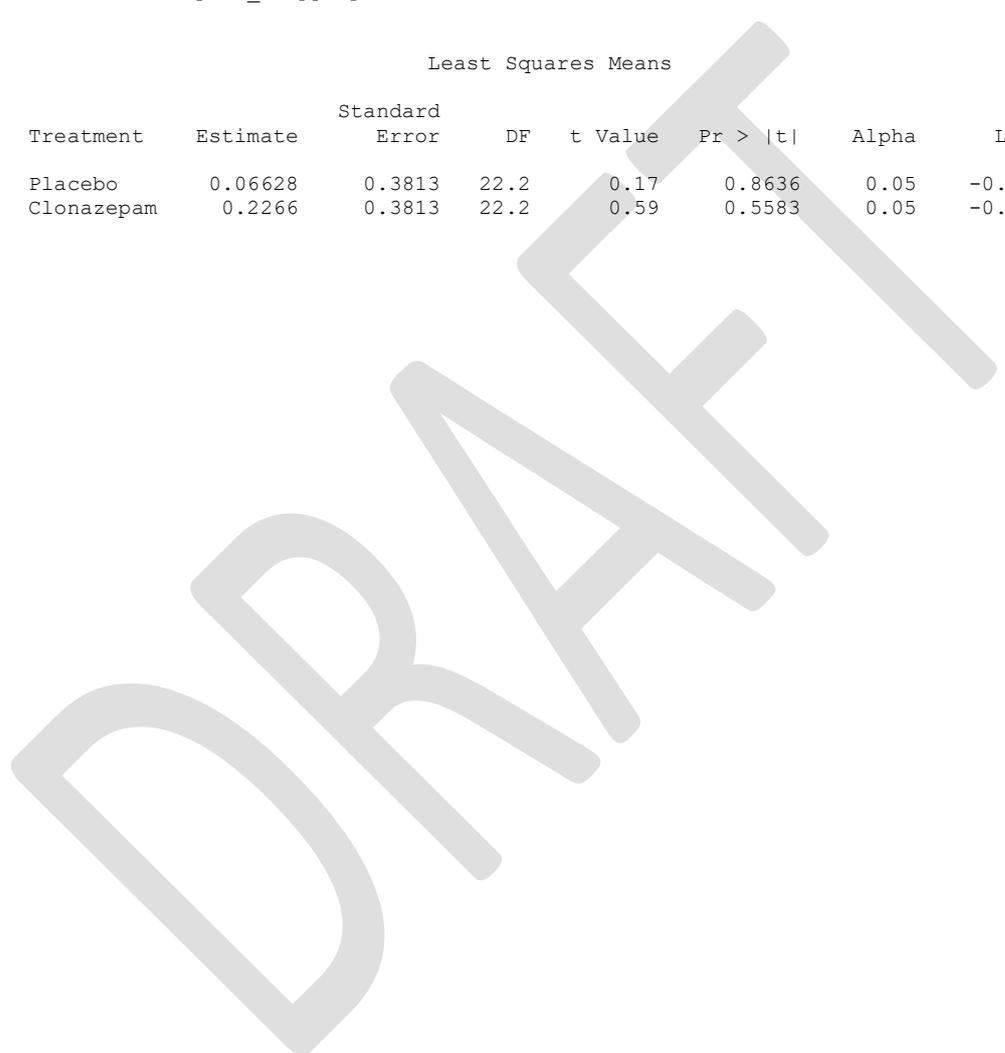
DF	Chi-Square	Pr > ChiSq
1	1.63	0.2015

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
by1	1	12.8	0.13	0.7254
Occasion	1	12.8	3.39	0.0891
preP_Inappropriate	1	13.4	2.95	0.1088

Least Squares Means

Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	0.06628	0.3813	22.2	0.17	0.8636	0.05	-0.7241	0.8566
by1	Clonazepam	0.2266	0.3813	22.2	0.59	0.5583	0.05	-0.5637	1.0169



SAS output 3.1 Parents: ABC Irritability subscale score

Proc MIXED analysis of Parents: ABC Irritability subscale score
 Analysis population

1

Model Information

Data Set	WORK.MIX
Dependent Variable	P_Irritability
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	16	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	16
Subjects	1
Max Obs per Subject	25

Number of Observations

Number of Observations Read	31
Number of Observations Used	25
Number of Observations Not Used	6

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	139.90463324	
1	2	137.14322645	0.00115917
2	1	137.07922725	0.00005127
3	1	137.07662748	0.00000011
4	1	137.07662204	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	15.7673
Residual	9.3223

Fit Statistics

-2 Res Log Likelihood	137.1
AIC (Smaller is Better)	141.1
AICC (Smaller is Better)	141.7
BIC (Smaller is Better)	142.6

Proc MIXED analysis of Parents: ABC Irritability subscale score
Analysis population

2

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	2.83	0.0926

Type 3 Tests of Fixed Effects

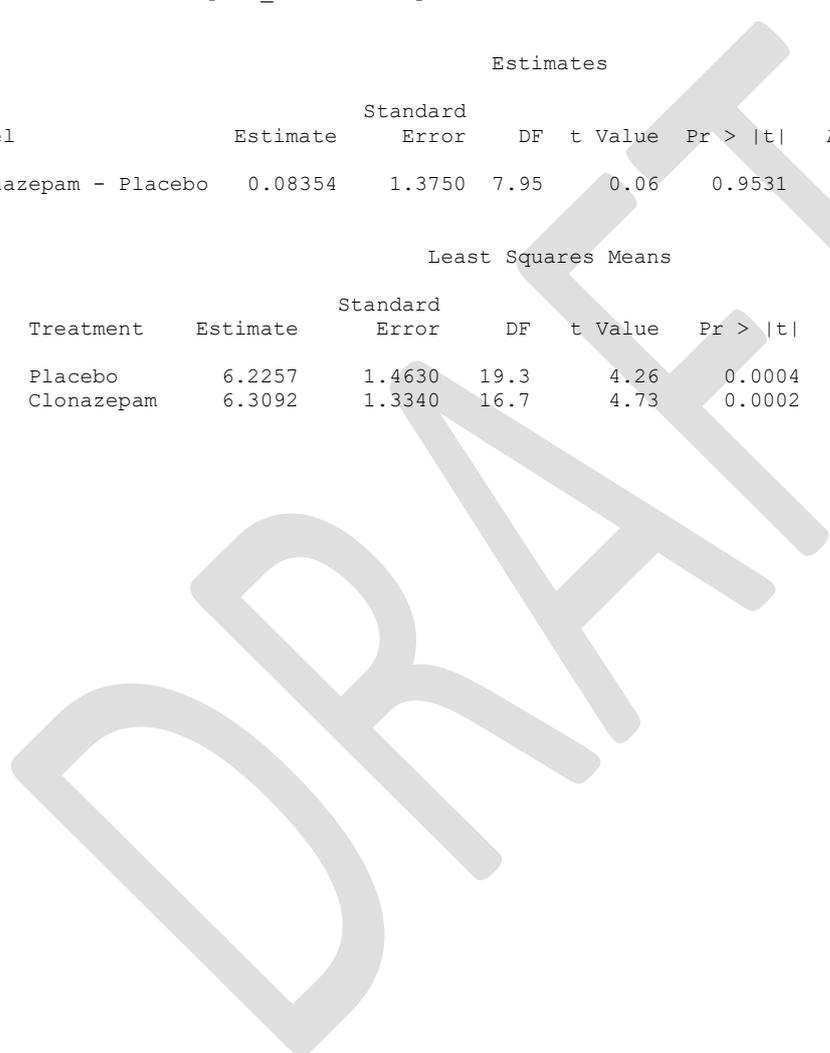
Effect	Num DF	Den DF	F Value	Pr > F
by1	1	7.95	0.00	0.9531
Occasion	1	11.4	4.14	0.0659
preP_Irritability	1	18.2	9.73	0.0059

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
Clonazepam - Placebo	0.08354	1.3750	7.95	0.06	0.9531	0.05	-3.0906	3.2577

Least Squares Means

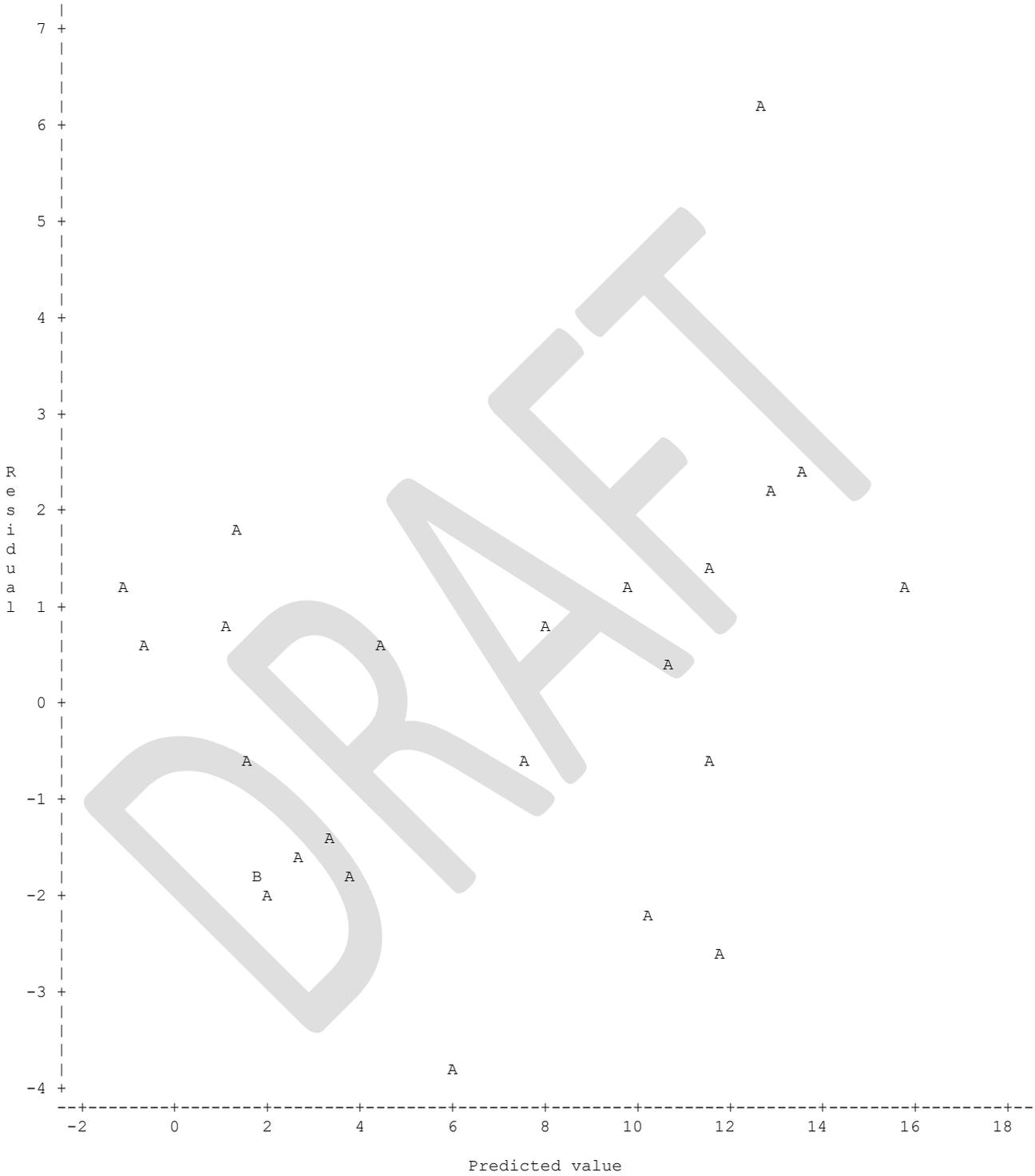
Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	6.2257	1.4630	19.3	4.26	0.0004	0.05	3.1669	9.2845
by1	Clonazepam	6.3092	1.3340	16.7	4.73	0.0002	0.05	3.4911	9.1274



Proc MIXED analysis of Parents: ABC Irritability subscale score
Analysis population

Residuals vs Predicted values

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



NOTE: 6 obs had missing values.

g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\CHDR1939B_FPD_General_RTF_v1.sas
Produced by Maria Joanna Juachon

18JAN2023 12:43

Proc MIXED analysis of Parents: ABC Irritability subscale score
Analysis population

Normal probability plot for residuals P_Irritability
(Shapiro-Wilk Test Statistic = 0.940 : P-value=0.1518)

Plot of Resid*rankres. Legend: A = 1 obs, B = 2 obs, etc.



NOTE: 6 obs had missing values.

g:\2019\CHDR1939-B\PMX\Reports\FPD\2022_09_26\CHDR1939B_FPD_General_RTF_v1.sas
Produced by Maria Joanna Juachon

18JAN2023 12:43

SAS output 3.2 Parents: ABC Irritability subscale score change from baseline

Proc MIXED analysis of Parents: ABC Irritability subscale score , change from baseline 1
 Analysis population

Model Information

Data Set	WORK.MIX
Dependent Variable	dP_Irritability
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	16	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	16
Subjects	1
Max Obs per Subject	25

Number of Observations

Number of Observations Read	31
Number of Observations Used	25
Number of Observations Not Used	6

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	139.90463324	
1	2	137.14322645	0.00115917
2	1	137.07922725	0.00005127
3	1	137.07662748	0.00000011
4	1	137.07662204	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	15.7673
Residual	9.3223

Fit Statistics

-2 Res Log Likelihood	137.1
AIC (Smaller is Better)	141.1
AICC (Smaller is Better)	141.7
BIC (Smaller is Better)	142.6

Proc MIXED analysis of Parents: ABC Irritability subscale score , change from baseline Analysis population 2

Null Model Likelihood Ratio Test

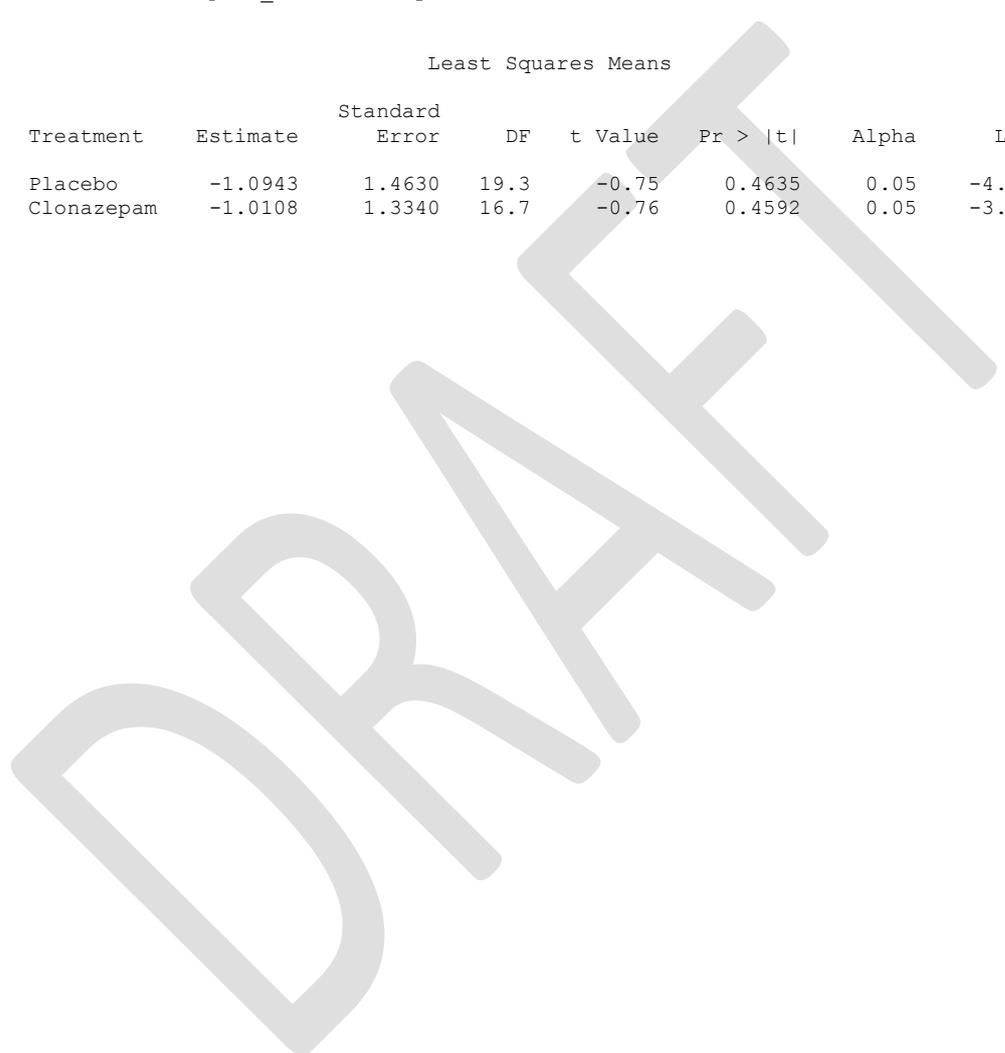
DF	Chi-Square	Pr > ChiSq
1	2.83	0.0926

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
by1	1	7.95	0.00	0.9531
Occasion	1	11.4	4.14	0.0659
preP_Irritability	1	18.2	3.84	0.0655

Least Squares Means

Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	-1.0943	1.4630	19.3	-0.75	0.4635	0.05	-4.1531	1.9645
by1	Clonazepam	-1.0108	1.3340	16.7	-0.76	0.4592	0.05	-3.8289	1.8074



SAS output 4.1 Parents: ABC Social Withdrawal subscale score

Proc MIXED analysis of Parents: ABC Social Withdrawal subscale score
 Analysis population

1

Model Information

Data Set	WORK.MIX
Dependent Variable	P_Lethargy
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	15	201 202 203 204 205 206 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	15
Subjects	1
Max Obs per Subject	19

Number of Observations

Number of Observations Read	31
Number of Observations Used	19
Number of Observations Not Used	12

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	109.15032510	
1	2	108.94790856	0.00051288
2	1	108.92422239	0.00003027
3	1	108.92293928	0.00000013
4	1	108.92293380	0.00000000

Convergence criteria met.

Estimated G matrix is not positive definite.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	-9.2903
Residual	45.2094

Fit Statistics

-2 Res Log Likelihood	108.9
AIC (Smaller is Better)	112.9
AICC (Smaller is Better)	113.9

Proc MIXED analysis of Parents: ABC Social Withdrawal subscale score
Analysis population

2

Fit Statistics

BIC (Smaller is Better) 114.3

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	0.23	0.6335

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
by1	1	9.12	0.04	0.8407
Occasion	1	9.54	0.01	0.9213
preP_Lethargy	1	9.71	12.76	0.0053

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
Clonazepam - Placebo	0.7000	3.3859	9.12	0.21	0.8407	0.05	-6.9439	8.3440

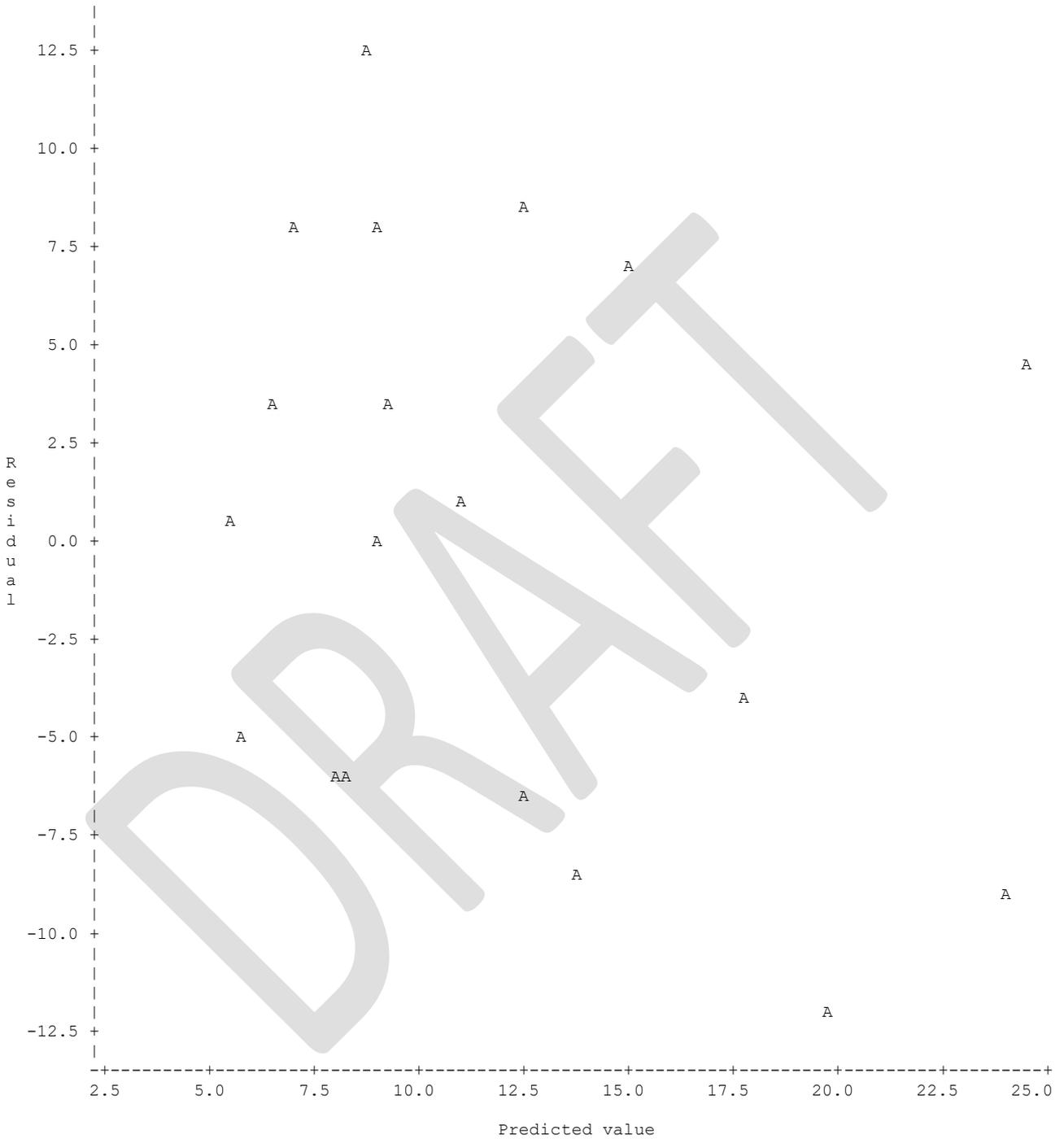
Least Squares Means

Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	11.3666	2.5677	14.7	4.43	0.0005	0.05	5.8854	16.8478
by1	Clonazepam	12.0667	1.7434	14.1	6.92	<.0001	0.05	8.3297	15.8036

Proc MIXED analysis of Parents: ABC Social Withdrawal subscale score
Analysis population

Residuals vs Predicted values

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.

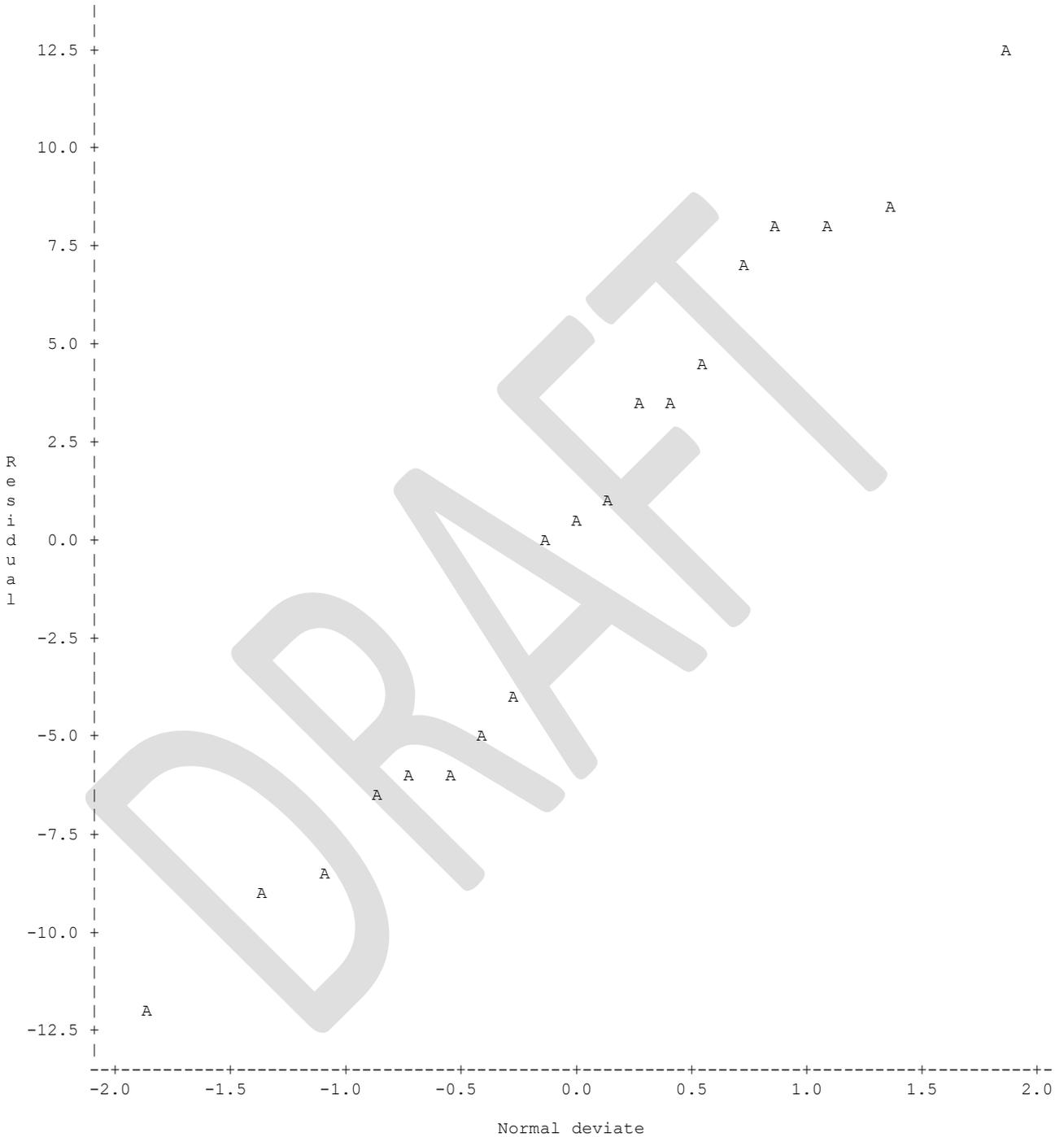


NOTE: 12 obs had missing values.

Proc MIXED analysis of Parents: ABC Social Withdrawal subscale score
Analysis population

Normal probability plot for residuals P_Lethargy
(Shapiro-Wilk Test Statistic = 0.954 : P-value=0.4639)

Plot of Resid*rankres. Legend: A = 1 obs, B = 2 obs, etc.



NOTE: 12 obs had missing values.

SAS output 4.2 Parents: ABC Social Withdrawal subscale score change from baseline

Proc MIXED analysis of Parents: ABC Social Withdrawal subscale score , change from baseline 1
 Analysis population

Model Information

Data Set	WORK.MIX
Dependent Variable	dP_Lethargy
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	15	201 202 203 204 205 206 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	15
Subjects	1
Max Obs per Subject	19

Number of Observations

Number of Observations Read	31
Number of Observations Used	19
Number of Observations Not Used	12

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	109.15032510	
1	2	108.94790856	0.00051288
2	1	108.92422239	0.00003027
3	1	108.92293928	0.00000013
4	1	108.92293380	0.00000000

Convergence criteria met.

Estimated G matrix is not positive definite.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	-9.2903
Residual	45.2094

Fit Statistics

-2 Res Log Likelihood	108.9
AIC (Smaller is Better)	112.9
AICC (Smaller is Better)	113.9

Proc MIXED analysis of Parents: ABC Social Withdrawal subscale score , change from baseline 2
 Analysis population

Fit Statistics

BIC (Smaller is Better) 114.3

Null Model Likelihood Ratio Test

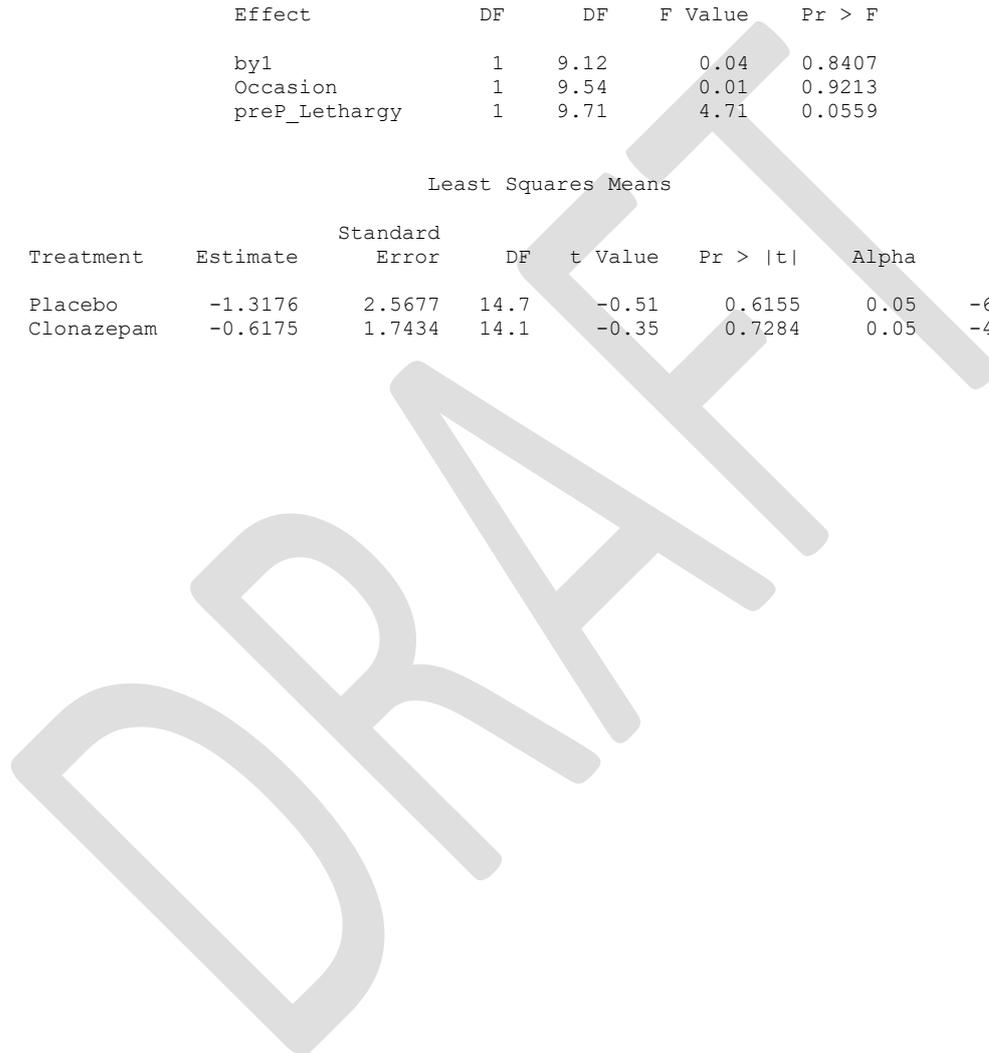
DF	Chi-Square	Pr > ChiSq
1	0.23	0.6335

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
by1	1	9.12	0.04	0.8407
Occasion	1	9.54	0.01	0.9213
preP_Lethargy	1	9.71	4.71	0.0559

Least Squares Means

Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	-1.3176	2.5677	14.7	-0.51	0.6155	0.05	-6.7988	4.1636
by1	Clonazepam	-0.6175	1.7434	14.1	-0.35	0.7284	0.05	-4.3545	3.1194



SAS output 5.1 Parents: ABC Stereotypic Behavior subscale score

Proc MIXED analysis of Parents: ABC Stereotypic Behavior subscale score
 Analysis population

1

Model Information

Data Set	WORK.MIX
Dependent Variable	P_Stereotypic
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	16	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	16
Subjects	1
Max Obs per Subject	27

Number of Observations

Number of Observations Read	31
Number of Observations Used	27
Number of Observations Not Used	4

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	129.40304526	
1	2	129.30358462	0.00000001

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	0.9589
Residual	8.6132

Fit Statistics

-2 Res Log Likelihood	129.3
AIC (Smaller is Better)	133.3
AICC (Smaller is Better)	133.9
BIC (Smaller is Better)	134.8

Proc MIXED analysis of Parents: ABC Stereotypic Behavior subscale score
Analysis population

2

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	0.10	0.7525

Type 3 Tests of Fixed Effects

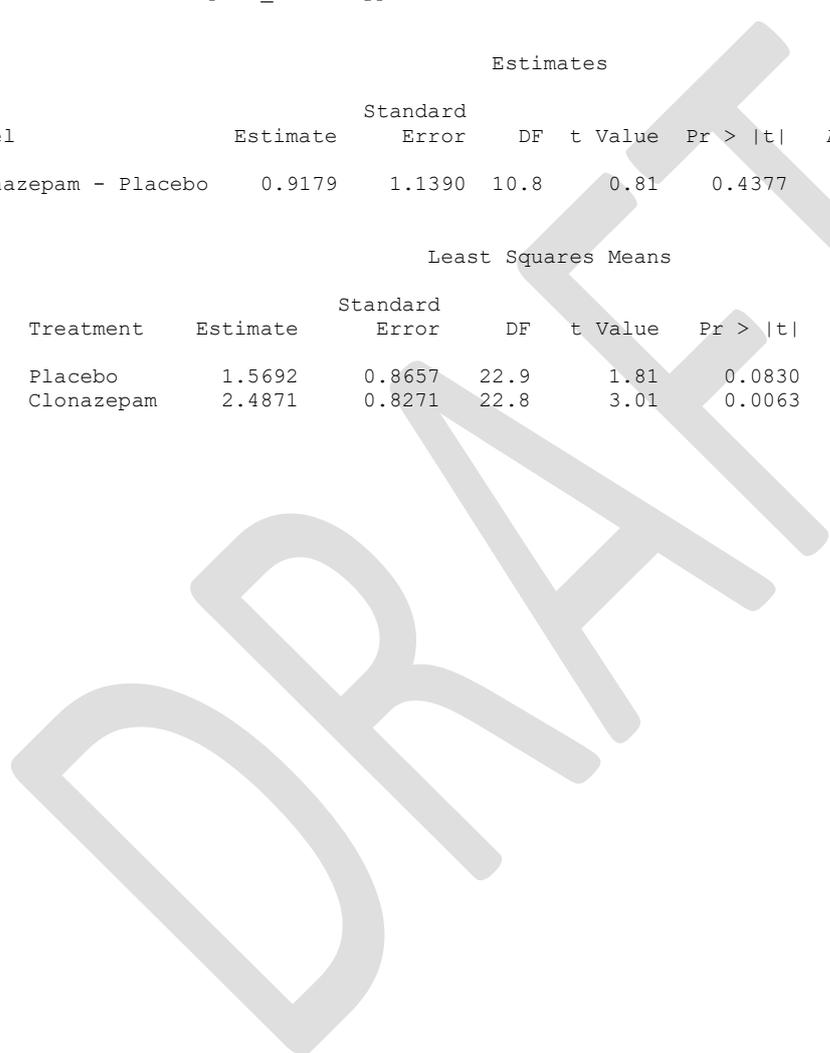
Effect	Num DF	Den DF	F Value	Pr > F
by1	1	10.8	0.65	0.4377
Occasion	1	11.2	0.08	0.7835
preP_Stereotypic	1	15.4	7.49	0.0150

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
Clonazepam - Placebo	0.9179	1.1390	10.8	0.81	0.4377	0.05	-1.5956	3.4314

Least Squares Means

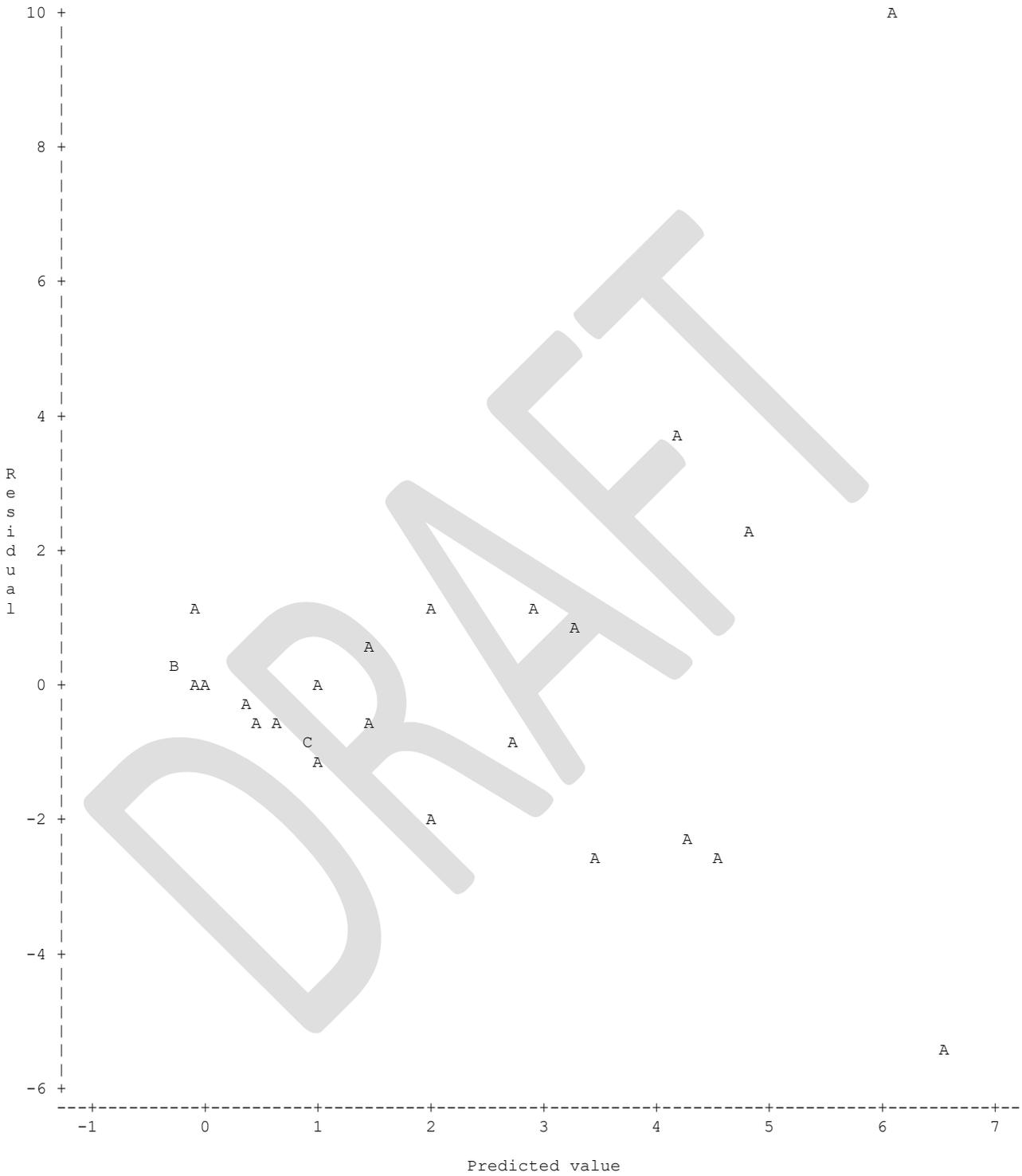
Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	1.5692	0.8657	22.9	1.81	0.0830	0.05	-0.2221	3.3606
by1	Clonazepam	2.4871	0.8271	22.8	3.01	0.0063	0.05	0.7753	4.1990



Proc MIXED analysis of Parents: ABC Stereotypic Behavior subscale score
Analysis population

Residuals vs Predicted values

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



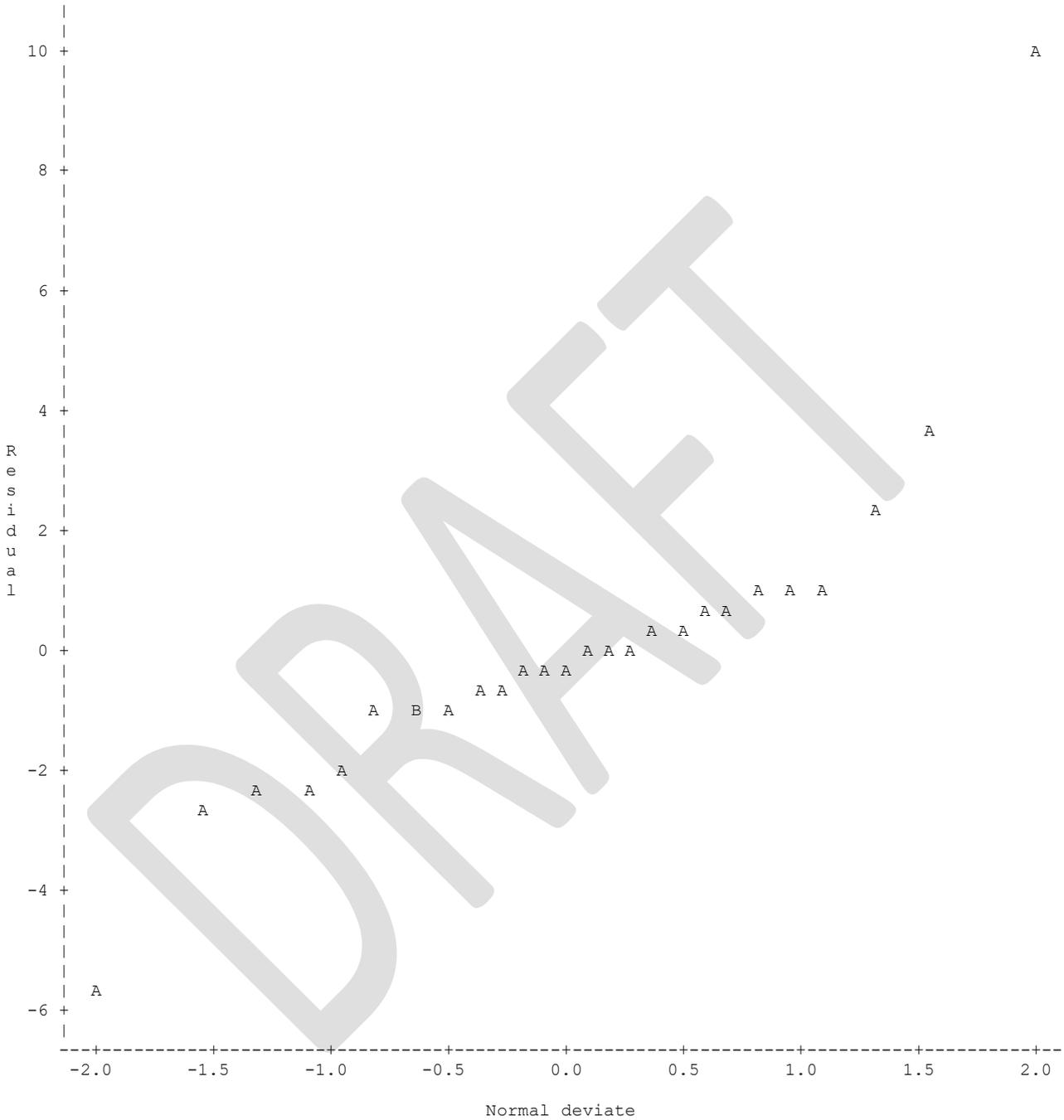
NOTE: 4 obs had missing values.

Proc MIXED analysis of Parents: ABC Stereotypic Behavior subscale score
Analysis population

4

Normal probability plot for residuals P_Stereotypic
(Shapiro-Wilk Test Statistic = 0.807 : P-value=0.0002)

Plot of Resid*rankres. Legend: A = 1 obs, B = 2 obs, etc.



NOTE: 4 obs had missing values.

SAS output 5.2 Parents: ABC Stereotypic Behavior subscale score change from baseline

Proc MIXED analysis of Parents: ABC Stereotypic Behavior subscale score , change from baseline 1
 Analysis population

Model Information

Data Set	WORK.MIX
Dependent Variable	dP_Stereotypic
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
by1	2	Placebo Clonazepam
Occasion	2	1 2
SubjectNr	16	201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216

Dimensions

Covariance Parameters	2
Columns in X	6
Columns in Z	16
Subjects	1
Max Obs per Subject	27

Number of Observations

Number of Observations Read	31
Number of Observations Used	27
Number of Observations Not Used	4

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	129.40304526	
1	2	129.30358462	0.00000001

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SubjectNr	0.9589
Residual	8.6132

Fit Statistics

-2 Res Log Likelihood	129.3
AIC (Smaller is Better)	133.3
AICC (Smaller is Better)	133.9
BIC (Smaller is Better)	134.8

Proc MIXED analysis of Parents: ABC Stereotypic Behavior subscale score , change from baseline 2
Analysis population

Null Model Likelihood Ratio Test

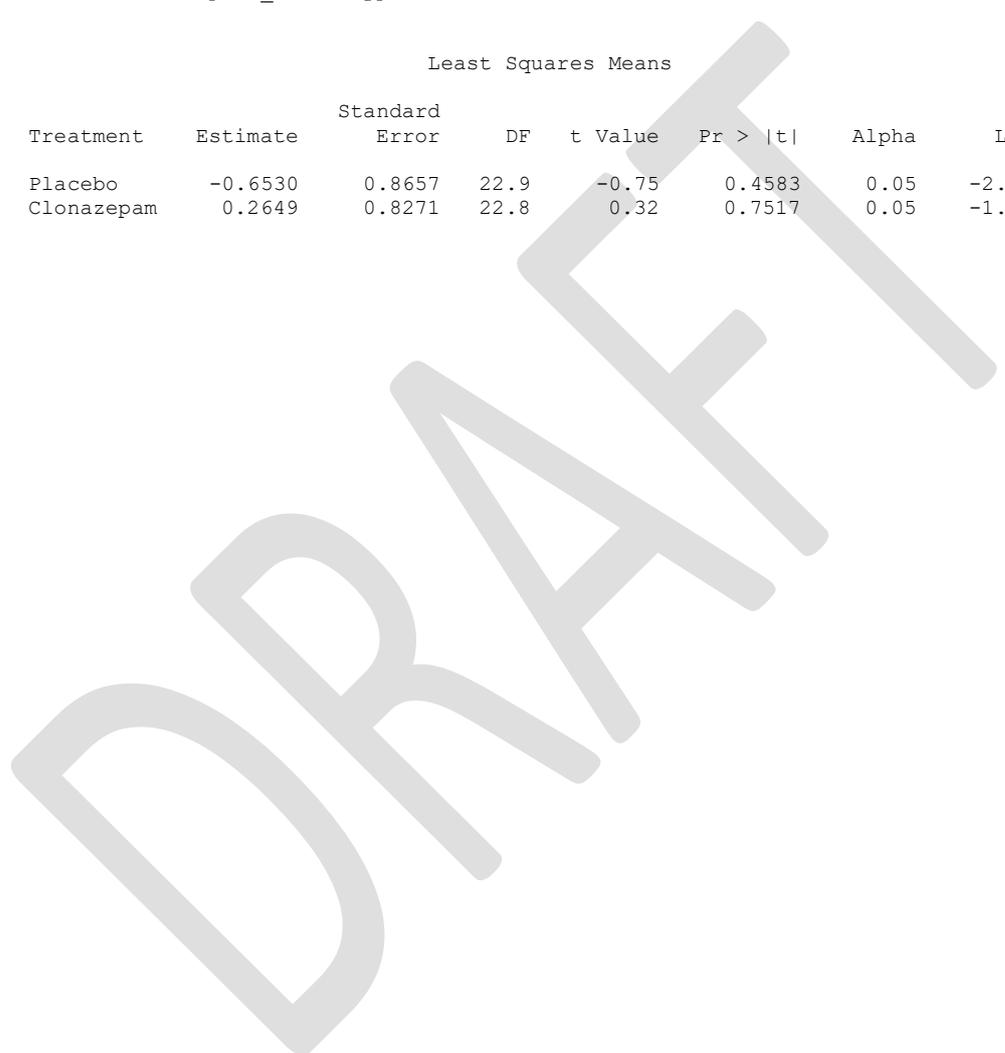
DF	Chi-Square	Pr > ChiSq
1	0.10	0.7525

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
by1	1	10.8	0.65	0.4377
Occasion	1	11.2	0.08	0.7835
preP_Stereotypic	1	15.4	0.95	0.3456

Least Squares Means

Effect	Treatment	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
by1	Placebo	-0.6530	0.8657	22.9	-0.75	0.4583	0.05	-2.4444	1.1383
by1	Clonazepam	0.2649	0.8271	22.8	0.32	0.7517	0.05	-1.4470	1.9768



DRAFT