

Appendix 5

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5.1.1. Possibly suicide-related events, adult placebo-controlled studies

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.03	0.01	0.08	<0.001
Age		1	0.97	0.95	0.99	0.008
Treatment	Paroxetine	1	1.71	0.50	5.80	0.391
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.98	0.95	1.01	0.219
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	-

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Gender	Female		1	1.11	0.64	1.92	0.716
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.90	0.50	1.62	0.726
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.86	0.41	1.81	0.691
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Race	Other		1	0.15	0.02	1.09	0.061
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.76	0.53	1.10	0.149
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	5.27	0.61	45.31	0.130
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Disease Severity	Mild to Moderate		1	0.64	0.36	1.15	0.139
	Normal/Missing		1	1.09	0.50	2.37	0.835
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.80	0.45	1.42	0.452
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	1.13	0.52	2.46	0.753
		Normal/Missing	1	0.82	0.25	2.67	0.739
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Indication	Depression		1	5.19	2.82	9.54	<0.001
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.42	0.17	0.99	0.048
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	2.10	0.80	5.48	0.129
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
CR vs IR	CR/CRIR		1	0.09	0.02	0.36	<0.001
	IR		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.74	0.50	1.07	0.112
	Placebo		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Paroxetine	CR/CRIR	1	4.45	0.93	21.27	0.062
		IR	0	1.00	1.00	1.00	.
	Placebo	CR/CRIR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Medical History

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.06	0.02	0.27	<0.001
Medical History	No		1	0.14	0.03	0.62	0.009
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.94	0.12	7.08	0.952
	Placebo		0	1.00	1.00	1.00	.
Treatment x Medical History	Paroxetine	No	1	0.88	0.11	6.84	0.901
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.03	<0.001
Prior Psychotropic Medication	No		1	0.29	0.17	0.49	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.73	0.44	1.23	0.239
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	1.36	0.66	2.81	0.406
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.08	0.05	0.12	<0.001
Baseline Suicidal Ideation	No		1	0.08	0.05	0.14	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.45	0.23	0.89	0.021
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	2.29	1.02	5.14	0.044
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Baseline Agitation	No		1	0.85	0.36	1.98	0.700
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.58	0.19	1.81	0.349
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Paroxetine	No	1	1.47	0.44	4.86	0.531
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.06	<0.001
On-therapy AE of Agitation	No		1	1.07	0.15	7.82	0.945
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.42	0.13	15.83	0.777
	Placebo		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of Agitation	Paroxetine	No	1	0.57	0.05	6.55	0.653
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia

Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.10	<0.001
On-therapy AE of Hyperkinesia	No	1	0.73	0.10	5.28	0.754
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.82	0.57	1.17	0.277
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
Treatment	Paroxetine	1	0.82	0.57	1.18	0.280
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Early Emergent Agitation
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Early Emergent Agitation	No	1	2.54	0.63	10.32	0.191
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.82	0.57	1.17	0.276
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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5.1.2. Possibly suicide-related events, adult active controlled studies

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Age		1	1.00	0.98	1.01	0.705
Treatment	Comparator	1	3.83	1.22	12.01	0.021
	Paroxetine	0	1.00	1.00	1.00	.
Treatment x Age	Comparator	1	0.98	0.95	1.00	0.091
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Gender	Female		1	1.63	0.87	3.04	0.127
	Male/Missing		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.83	1.46	5.48	0.002
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Gender	Comparator	Female	1	0.39	0.17	0.87	0.021
		Male/Missing	0	1.00	1.00	1.00	.
	Paroxetine	Female	0	1.00	1.00	1.00	.
		Male/Missing	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Race	Other		1	1.24	0.72	2.12	0.436
	White		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.61	1.03	2.51	0.038
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Race	Comparator	Other	1	0.90	0.40	2.00	0.790
		White	0	1.00	1.00	1.00	.
	Paroxetine	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Disease Severity	Mild to Moderate		1	0.36	0.16	0.77	0.009
	Normal/Missing		1	0.74	0.41	1.33	0.313
	Severe		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.45	0.84	2.50	0.178
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Comparator	Mild to Moderate	1	1.58	0.60	4.11	0.352
		Normal/Missing	1	0.78	0.32	1.90	0.584
		Severe	0	1.00	1.00	1.00	.
	Paroxetine	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Indication	Depression		1	4.34	0.60	31.43	0.146
	Other		0	1.00	1.00	1.00	.
Treatment	Comparator		1	5.12	0.57	45.97	0.145
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Indication	Comparator	Depression	1	0.28	0.03	2.62	0.265
		Other	0	1.00	1.00	1.00	.
	Paroxetine	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
CR vs IR	CR		1	0.59	0.08	4.30	0.605
	IR		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.48	1.02	2.14	0.037
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Comparator	CR	1	1.96	0.20	19.53	0.568
		IR	0	1.00	1.00	1.00	.
	Paroxetine	CR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Medical History
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
Treatment	Comparator	1	1.51	1.05	2.17	0.026
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Prior Psychotropic Medication	No		1	0.65	0.36	1.15	0.140
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.69	0.91	3.14	0.098
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Comparator	No	1	0.82	0.38	1.76	0.602
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Control Medication Class

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value	
Intercept			1	0.01	0.01	0.01	<0.001	
Control Medication Class	Other/Benzodiazepine		1	0.80	0.41	1.56	0.513	
	SSRI		1	1.33	0.69	2.55	0.394	
	Tetracyclic		1	0.43	0.10	1.81	0.250	
	Tricyclic		0	1.00	1.00	1.00	.	
Treatment	Comparator		1	1.32	0.79	2.23	0.291	
	Paroxetine		0	1.00	1.00	1.00	.	
Treatment x Control Medication Class	Comparator	Other/Benzodiazepine	1	0.67	0.17	2.62	0.565	
		SSRI	1	1.29	0.55	2.99	0.558	
		Tetracyclic	1	1.54	0.26	9.15	0.633	
		Tricyclic	0	1.00	1.00	1.00	.	
		Paroxetine	Other/Benzodiazepine	0	1.00	1.00	1.00	.
			SSRI	0	1.00	1.00	1.00	.
			Tetracyclic	0	1.00	1.00	1.00	.
Scale		Tricyclic	0	1.00	1.00	1.00	.	
			0	2.72	2.72	2.72	—	

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.03	<0.001
Baseline Suicidal Ideation	No		1	0.37	0.20	0.68	0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.36	0.65	2.85	0.411
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Comparator	No	1	1.14	0.49	2.66	0.765
		Yes	0	1.00	1.00	1.00	.
		Paroxetine	No	0	1.00	1.00	1.00
Scale		Yes	0	1.00	1.00	1.00	.
			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Baseline Agitation	No		1	0.77	0.44	1.34	0.351
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.16	0.60	2.24	0.654
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Comparator	No	1	1.46	0.66	3.21	0.350
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.04	0.02	0.08	<0.001
On-therapy AE of Agitation	No		1	0.21	0.09	0.49	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.76	0.21	2.75	0.677
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of Agitation	Comparator	No	1	2.09	0.55	8.00	0.280
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hyperkinesia

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.19	<0.001
On-therapy AE of Hyperkinesia	No		1	0.32	0.04	2.37	0.264
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.81	0.24	32.64	0.408
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of hyperkinesia	Comparator	No	1	0.53	0.04	6.30	0.614
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hostility
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
Treatment	Comparator	1	1.51	1.05	2.17	0.026
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Early Emergent Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Early Emergent Agitation	No		1	0.93	0.29	2.99	0.902
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.69	0.11	4.17	0.688
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Early emergent agitation	Comparator	No	1	2.27	0.36	14.19	0.382
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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5.1.3. Possibly suicide-related events, paediatric placebo-controlled studies

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.07	0.001
Age		1	1.19	0.89	1.58	0.237
Treatment	Paroxetine	1	0.23	0.00	54.62	0.596
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	1.17	0.81	1.68	0.408
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.02	<0.001
Gender	Female		1	6.43	0.77	53.69	0.086
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	3.13	0.32	30.27	0.324
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.61	0.05	7.18	0.696
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Race	Other		1	3.61	0.80	16.37	0.096
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	3.19	1.04	9.74	0.042
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	0.33	0.05	2.20	0.253
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.05	<0.001
Disease Severity	Mild to Moderate		1	0.46	0.08	2.77	0.397
	Normal/Missing		1	0.97	0.16	5.89	0.975
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	2.90	0.77	10.87	0.114
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	0.41	0.04	3.82	0.435
		Normal/Missing	1	1.06	0.13	8.53	0.959
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Indication
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Indication	Depression	1	5.61	1.91	16.45	0.002
	Other	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.07	0.86	5.01	0.106
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Medical History
 Note that the covariate and the interaction term have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.02	<0.001
Treatment	Paroxetine	1	2.29	0.95	5.51	0.065
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Prior Psychotropic Medication
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Prior Psychotropic Medication	No	1	4.80	0.64	35.69	0.126
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.19	0.91	5.28	0.081
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.10	0.03	0.34	<0.001
Baseline Suicidal Ideation	No		1	0.06	0.01	0.30	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.12	0.26	4.80	0.883
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	2.46	0.39	15.63	0.340
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.00	0.16	<0.001
Baseline Agitation	No		1	0.44	0.05	3.76	0.456
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	3.52	0.38	32.69	0.268
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Paroxetine	No	1	0.59	0.05	6.68	0.670
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Agitation
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.02	0.00	0.17	<0.001
On-therapy AE of Agitation	No	1	0.53	0.07	4.11	0.544
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.25	0.93	5.44	0.071
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.02	<0.001
Treatment	Paroxetine	1	2.29	0.95	5.51	0.065
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.02	0.00	0.14	<0.001
On-therapy AE of Hostility	No	1	0.67	0.09	5.20	0.704
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.25	0.93	5.45	0.072
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Early Emergent Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.18	<0.001
Early Emergent Agitation	No		1	0.40	0.05	3.40	0.402
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.11	0.07	18.42	0.941
	Placebo		0	1.00	1.00	1.00	.
Treatment x Early emergent agitation	Paroxetine	No	1	2.24	0.12	43.19	0.594
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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5.1.4. Self harm, adult placebo controlled studies

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.03	0.01	0.10	<0.001
Age		1	0.96	0.93	0.99	0.004
Treatment	Paroxetine	1	2.08	0.49	8.90	0.323
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.98	0.94	1.02	0.249
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Gender	Female		1	0.97	0.50	1.86	0.926
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.02	0.53	1.96	0.960
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.84	0.36	1.98	0.693
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Race	Other		1	0.22	0.03	1.61	0.136
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.87	0.57	1.34	0.535
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	3.06	0.33	28.65	0.327
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Disease Severity	Mild to Moderate		1	0.49	0.25	0.98	0.043
	Normal/Missing		1	0.74	0.27	1.99	0.544
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.72	0.38	1.37	0.314
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	1.61	0.65	3.99	0.300
		Normal/Missing	1	1.38	0.34	5.61	0.653
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Indication	Depression		1	11.67	4.55	29.95	<0.001
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.88	0.27	2.87	0.826
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	0.96	0.27	3.43	0.952
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = CR vs IR
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
CR vs IR	CR/CRIR	1	0.22	0.11	0.46	<0.001
	IR	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.93	0.61	1.42	0.745
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Medical History

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.23	<0.001
Medical History	No		1	0.21	0.03	1.55	0.125
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.94	0.17	22.46	0.596
	Placebo		0	1.00	1.00	1.00	.
Treatment x Medical History	Paroxetine	No	1	0.47	0.04	5.61	0.548
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.03	<0.001
Prior Psychotropic Medication	No		1	0.18	0.09	0.35	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.72	0.41	1.28	0.263
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	1.96	0.82	4.68	0.131
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.07	0.04	0.11	<0.001
Baseline Suicidal Ideation	No		1	0.06	0.03	0.11	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.39	0.18	0.83	0.015
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	3.57	1.40	9.09	0.008
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Baseline Agitation
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Baseline Agitation	No	1	10.21	1.42	73.35	0.021
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.93	0.61	1.42	0.749
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Agitation
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.03	<0.001
On-therapy AE of Agitation	No	1	0.85	0.21	3.46	0.817
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.92	0.60	1.40	0.693
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.09	<0.001
On-therapy AE of Hyperkinesia	No	1	0.54	0.07	3.94	0.545
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.92	0.60	1.40	0.683
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.01	<0.001
Treatment	Paroxetine	1	0.92	0.60	1.40	0.693
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Adult Placebo Controlled Studies, Covariate = Early Emergent Agitation
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Early Emergent Agitation	No	1	1.85	0.45	7.54	0.390
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.92	0.60	1.40	0.688
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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5.1.5. Self harm, adult active controlled studies

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Self Harm Events, Adult Active Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Age		1	1.00	0.98	1.02	0.984
Treatment	Comparator	1	5.08	1.04	24.81	0.045
	Paroxetine	0	1.00	1.00	1.00	.
Treatment x Age	Comparator	1	0.97	0.94	1.01	0.102
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Self Harm Events, Adult Active Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Gender	Female		1	4.37	1.32	14.44	0.016
	Male/Missing		0	1.00	1.00	1.00	.
Treatment	Comparator		1	5.66	1.61	19.91	0.007
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Gender	Comparator	Female	1	0.17	0.04	0.68	0.013
		Male/Missing	0	1.00	1.00	1.00	.
	Paroxetine	Female	0	1.00	1.00	1.00	.
		Male/Missing	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Active Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Race	Other		1	0.65	0.29	1.48	0.308
	White		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.14	0.63	2.07	0.657
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Race	Comparator	Other	1	2.33	0.76	7.17	0.141
		White	0	1.00	1.00	1.00	.
	Paroxetine	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Active Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Disease Severity	Mild to Moderate		1	0.18	0.05	0.63	0.007
	Normal/Missing		1	0.54	0.25	1.19	0.126
	Severe		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.29	0.65	2.57	0.470
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Comparator	Mild to Moderate	1	1.59	0.34	7.49	0.556
		Normal/Missing	1	1.23	0.39	3.85	0.725
		Severe	0	1.00	1.00	1.00	.
	Paroxetine	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Active Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Indication	Depression		1	2.24	0.30	16.50	0.429
	Other		0	1.00	1.00	1.00	.
Treatment	Comparator		1	3.83	0.40	36.95	0.246
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Indication	Comparator	Depression	1	0.36	0.03	3.65	0.385
		Other	0	1.00	1.00	1.00	.
	Paroxetine	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Self Harm Events, Adult Active Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
CR vs IR	CR		1	1.15	0.16	8.48	0.893
	IR		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.43	0.85	2.39	0.178
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Comparator	CR	1	1.35	0.11	15.83	0.812
		IR	0	1.00	1.00	1.00	.
	Paroxetine	CR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Self Harm Events, Adult Active Controlled Studies, Covariate = Medical History
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Treatment	Comparator	1	1.45	0.88	2.40	0.147
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Self Harm Events, Adult Active Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Prior Psychotropic Medication	No		1	0.76	0.34	1.73	0.517
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.44	1.05	5.67	0.038
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Comparator	No	1	0.40	0.14	1.18	0.096
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Active Controlled Studies, Covariate = Control Medication Class

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value	
Intercept			1	0.01	0.00	0.01	<0.001	
Control Medication Class	Other/Benzodiazepine		1	0.38	0.13	1.12	0.079	
	SSRI		1	0.87	0.34	2.21	0.766	
	Tetracyclic		1	0.66	0.15	2.86	0.576	
	Tricyclic		0	1.00	1.00	1.00	.	
Treatment	Comparator		1	1.39	0.74	2.62	0.309	
	Paroxetine		0	1.00	1.00	1.00	.	
Treatment x Control Medication Class	Comparator	Other/Benzodiazepine	1	1.39	0.23	8.51	0.725	
		SSRI	1	0.71	0.19	2.60	0.603	
	Paroxetine	Tetracyclic	1	0.73	0.09	5.76	0.767	
		Tricyclic	0	1.00	1.00	1.00	.	
		Other/Benzodiazepine	0	1.00	1.00	1.00	.	
	Scale	Paroxetine	SSRI	0	1.00	1.00	1.00	.
			Tetracyclic	0	1.00	1.00	1.00	.
			Tricyclic	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—	

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Self Harm Events, Adult Active Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Baseline Suicidal Ideation	No		1	0.40	0.17	0.93	0.034
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.63	0.60	4.41	0.333
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Comparator	No	1	0.85	0.27	2.68	0.775
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Adult Active Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Baseline Agitation	No		1	0.57	0.27	1.20	0.141
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.65	0.24	1.73	0.385
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Comparator	No	1	3.13	0.98	9.96	0.053
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Self Harm Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.07	<0.001
On-therapy AE of Agitation	No		1	0.16	0.06	0.47	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.28	0.03	2.56	0.261
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of Agitation	Comparator	No	1	5.79	0.60	55.75	0.129
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Self Harm Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.09	<0.001
On-therapy AE of Hyperkinesia	No	1	0.35	0.05	2.58	0.305
	Yes	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.45	0.88	2.40	0.147
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hostility
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Treatment	Comparator	1	1.45	0.88	2.40	0.147
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Adult Active Controlled Studies, Covariate = Early Emergent Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Early Emergent Agitation	No		1	0.46	0.14	1.54	0.208
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.34	0.04	3.33	0.358
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Early Emergent Agitation	Comparator	No	1	4.61	0.45	47.32	0.198
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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5.1.6. Self harm, paediatric placebo controlled studies

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.15	0.006
Age		1	1.13	0.82	1.55	0.463
Treatment	Paroxetine	1	0.03	0.00	17.69	0.284
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	1.34	0.88	2.05	0.170
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Gender
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Gender	Female	1	7.70	1.78	33.39	0.006
	Male	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.38	0.86	6.61	0.096
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Race	Other		1	1.18	0.13	10.69	0.881
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	2.49	0.79	7.87	0.120
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	1.30	0.11	15.68	0.835
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.05	<0.001
Disease Severity	Mild to Moderate/Normal/ Missing		1	0.31	0.05	1.87	0.202
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.91	0.47	7.72	0.366
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate/Normal/ Missing	1	2.03	0.25	16.24	0.504
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate/Normal/ Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Indication
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Indication	Depression	1	20.19	2.69	151.42	0.003
	Other	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.35	0.84	6.52	0.103
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Medical History
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Prior Psychotropic Medication
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Prior Psychotropic Medication	No	1	3.74	0.50	28.14	0.200
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.56	0.93	7.10	0.070
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.07	0.02	0.28	<0.001
Baseline Suicidal Ideation	No		1	0.07	0.01	0.46	0.005
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.73	0.33	9.12	0.518
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	1.58	0.19	13.13	0.672
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Agitation
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.02	0.01	0.08	<0.001
Baseline Agitation	No	1	0.30	0.10	0.92	0.036
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.65	0.96	7.35	0.061
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Agitation
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.13	<0.001
On-therapy AE of Hostility	No	1	0.55	0.07	4.29	0.566
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.60	0.93	7.23	0.068
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Early Emergent Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.06	<0.001
Early Emergent Agitation	No	1	1.07	0.14	8.16	0.945
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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5.1.7. Hostility, adult placebo controlled studies

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.03	<0.001
Age		1	0.98	0.94	1.02	0.386
Treatment	Paroxetine	1	2.21	0.26	18.56	0.465
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.98	0.93	1.03	0.457
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Gender	Female		1	1.39	0.48	4.01	0.540
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.67	0.59	4.74	0.338
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.44	0.12	1.68	0.231
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Race	Other		1	1.17	0.27	5.16	0.835
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.93	0.47	1.86	0.843
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	1.79	0.30	10.64	0.522
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Disease Severity	Mild to Moderate		1	0.95	0.31	2.91	0.928
	Normal/Missing		1	1.59	0.38	6.69	0.524
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.82	0.25	2.68	0.739
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	1.57	0.37	6.79	0.543
		Normal/Missing	1	0.81	0.09	6.92	0.844
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Indication	Depression		1	1.36	0.50	3.65	0.545
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.05	0.45	2.47	0.904
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	0.92	0.26	3.30	0.902
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Hostility Events, Adult Placebo Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
CR vs IR	CR/CRIR		1	0.16	0.02	1.18	0.072
	IR		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.89	0.45	1.74	0.725
	Placebo		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Paroxetine	CR/CRIR	1	3.69	0.39	35.12	0.256
		IR	0	1.00	1.00	1.00	.
	Placebo	CR/CRIR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	-

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Medical History
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
Treatment	Paroxetine	1	1.03	0.55	1.94	0.934
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Prior Psychotropic Medication	No		1	2.44	0.55	10.76	0.238
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.18	0.20	7.09	0.854
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	0.83	0.12	5.63	0.849
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Baseline Suicidal Ideation	No	1	0.49	0.17	1.37	0.173
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	1.03	0.54	1.93	0.939
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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5.1.8. Hostility, adult active controlled studies

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Hostility Events, Adult Active Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Age		1	0.99	0.96	1.02	0.424
Treatment	Comparator	1	1.76	0.24	12.89	0.580
	Paroxetine	0	1.00	1.00	1.00	.
Treatment x Age	Comparator	1	1.00	0.95	1.04	0.848
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Hostility Events, Adult Active Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Gender	Female		1	0.50	0.20	1.26	0.142
	Male/Missing		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.16	0.44	3.00	0.767
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Gender	Comparator	Female	1	1.53	0.42	5.53	0.521
		Male/Missing	0	1.00	1.00	1.00	.
	Paroxetine	Female	0	1.00	1.00	1.00	.
		Male/Missing	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Active Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Race	Other		1	1.09	0.42	2.83	0.852
	White		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.62	0.76	3.45	0.216
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Race	Comparator	Other	1	0.62	0.13	2.95	0.553
		White	0	1.00	1.00	1.00	.
	Paroxetine	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Active Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Disease Severity	Mild to Moderate		1	2.07	0.64	6.72	0.228
	Normal/Missing		1	0.93	0.25	3.47	0.913
	Severe		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.07	0.27	4.29	0.922
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Comparator	Mild to Moderate	1	1.38	0.27	7.05	0.696
		Normal/Missing	1	1.22	0.17	8.93	0.848
		Severe	0	1.00	1.00	1.00	.
	Paroxetine	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Active Controlled Studies, Covariate = Indication
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Indication	Depression	1	0.69	0.24	1.95	0.485
	Other	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.46	0.77	2.76	0.246
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Hostility Events, Adult Active Controlled Studies, Covariate = CR vs IR
 Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
CR vs IR	CR	1	0.72	0.10	5.27	0.746
	IR	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.46	0.77	2.77	0.241
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

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Hostility Events, Adult Active Controlled Studies, Covariate = Medical History
 Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
Treatment	Comparator	1	1.46	0.77	2.76	0.245
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Hostility Events, Adult Active Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Prior Psychotropic Medication	No		1	2.33	0.54	10.16	0.259
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.86	0.55	14.74	0.210
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Comparator	No	1	0.45	0.08	2.69	0.383
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Adult Active Controlled Studies, Covariate = Control Medication Class

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Control Medication Class	Other/Benzodiazepine		1	1.60	0.46	5.55	0.455
	SSRI		1	3.46	1.10	10.92	0.034
	Tetracyclic		1	1.12	0.13	9.61	0.917
	Tricyclic		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.07	0.31	3.71	0.912
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Control Medication Class	Comparator	Other/Benzodiazepine	1	2.16	0.32	14.39	0.426
		SSRI	1	1.05	0.21	5.23	0.952
	Paroxetine	Tetracyclic	1	3.82	0.31	47.49	0.298
		Tricyclic	0	1.00	1.00	1.00	.
		Other/Benzodiazepine	0	1.00	1.00	1.00	.
		SSRI	0	1.00	1.00	1.00	.
	Scale	Tetracyclic	0	1.00	1.00	1.00	.
		Tricyclic	0	2.72	2.72	2.72	—

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Hostility Events, Adult Active Controlled Studies, Covariate = Baseline Suicidal Ideation

Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
Baseline Suicidal Ideation	No	1	4.82	0.66	35.19	0.121
	Yes	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.47	0.77	2.77	0.240
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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5.1.9. Hostility, paediatric placebo controlled studies

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.78	0.038
Age		1	0.95	0.69	1.31	0.763
Treatment	Paroxetine	1	58.97	0.68	5089.0	0.073
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.83	0.59	1.17	0.287
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Gender	Female		1	0.35	0.04	3.38	0.363
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	5.77	1.67	20.00	0.006
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	1.47	0.13	16.20	0.753
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.02	<0.001
Race	Other		1	4.79	0.67	34.39	0.119
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	11.16	2.62	47.45	0.001
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	0.11	0.01	1.09	0.059
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.05	<0.001
Disease Severity	Mild to Moderate/Normal/ Missing		1	0.15	0.02	1.50	0.107
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	2.90	0.77	10.87	0.114
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate/Normal/ Missing	1	5.45	0.49	60.76	0.168
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate/Normal/ Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Indication	Depression		1	0.42	0.04	4.07	0.455
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	7.04	2.07	23.90	0.002
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	0.76	0.07	8.65	0.826
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Medical History

Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	6.10	2.12	17.54	<0.001
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	—

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.06	<0.001
Prior Psychotropic Medication	No		1	0.74	0.08	7.16	0.794
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	4.75	0.52	43.12	0.166
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	1.38	0.11	17.07	0.802
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—

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Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.24	<0.001
Baseline Suicidal Ideation	No		1	0.15	0.02	1.50	0.107
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.54	0.03	9.00	0.671
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	14.91	0.70	315.51	0.083
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	—