

Supplemental material - Results

Content index

Tab.1	Descriptive Statistics, Number of study participants
Tab.2	Descriptive Statistics, Age eligible for study
Tab. 3	Frequencies for Age eligible for study
Tab. 4	Descriptive Statistics, Masking
Tab. 5	Frequencies for Masking
Tab. 6	Descriptive Statistics, Type of trial
Tab.7	Frequencies for Pharmacological interventional trial
Tab.8	Frequencies for Surgical interventional trial
Tab.9	Frequencies for Non-pharmacological, non-surgical interventional trial
Tab.10	Frequencies for Diagnostic trial
Tab. 11	Descriptive Statistics, Inability to give informed consent
Tab.12	Frequencies for Inability to give informed consent
Tab. 13	Descriptive Statistics, Explicit exclusion criteria
Tab.14	Frequencies for Disability
Tab.15	Frequencies for Physical impairment
Tab.16	Frequencies for Cognitive impairment
Tab.17	Frequencies for Behavioural or psychiatric disorders
Tab.18	Frequencies for Communication and language impairment
Tab.19	Frequencies for Sensory disabilities
Tab.20	Contingency Tables, Disability + Absolute exclusion criterion
Tab.21	Chi-Squared Tests, Disability + Absolute exclusion criterion
Tab.22	Contingency Tables, Disability + Relative exclusion criterion
Tab.23	Chi-Squared Tests, Disability + Relative exclusion criterion
Tab.24	Contingency Tables, Disability + Questionable exclusion criterion
Tab.25	Chi-Squared Tests, Disability + Questionable exclusion criterion
Tab.26	Contingency Tables, Physical impairment + Absolute exclusion criterion
Tab.27	Chi-Squared Tests, Physical impairment + Absolute exclusion criterion
Tab.28	Contingency Tables, Physical impairment + Relative exclusion criterion
Tab.29	Chi-Squared Tests, Physical impairment + Relative exclusion criterion
Tab.30	Contingency Tables, Physical impairment + Questionable exclusion criterion
Tab.31	Chi-Squared Tests, Physical impairment + Questionable exclusion criterion
Tab.32	Contingency Tables, Cognitive impairment + Absolute exclusion criterion
Tab.33	Chi-Squared Tests, Cognitive impairment + Absolute exclusion criterion
Tab.34	Contingency Tables, Cognitive impairment + Relative exclusion criterion
Tab.35	Chi-Squared Tests, Cognitive impairment + Relative exclusion criterion
Tab.36	Contingency Tables, Cognitive impairment + Questionable exclusion criterion
Tab.37	Chi-Squared Tests, Cognitive impairment + Questionable exclusion criterion
Tab.38	Contingency Tables, Behavioural or psychiatric disorders+ Absolute exclusion criterion
Tab.39	Chi-Squared Tests, Behavioural or psychiatric impairment + Absolute exclusion criterion
Tab.40	Contingency Tables, Behavioural or psychiatric disorders+ Relative exclusion criterion
Tab.41	Chi-Squared Tests, Behavioural or psychiatric impairment + Relative exclusion criterion
Tab.42	Contingency Tables, Behavioural or psychiatric disorders+ Questionable exclusion criterion
Tab.43	Chi-Squared Tests, Behavioural or psychiatric impairment + Questionable exclusion criterion
Tab.44	Contingency Tables, Communication and language disorders+ Absolute exclusion criterion
Tab.45	Chi-Squared Tests, Communication and language disorders + Absolute exclusion criterion
Tab.46	Contingency Tables, Communication and language disorders+ Relative exclusion criterion
Tab.47	Chi-Squared Tests, Communication and language disorders + Relative exclusion criterion
Tab.48	Contingency Tables, Communication and language disorders+ Questionable exclusion criterion
Tab.49	Chi-Squared Tests, Communication and language disorders + Questionable exclusion criterion
Tab.50	Contingency Tables, Sensory disabilities+ Absolute exclusion criterion
Tab.51	Chi-Squared Tests, Sensory disabilities + Absolute exclusion criterion

Tab.52 Contingency Tables, Sensory disabilities+ Relative exclusion criterion

Tab.53 Chi-Squared Tests, Sensory disabilities + Relative exclusion criterion

Tab.54 Contingency Tables, Sensory disabilities+ Questionable exclusion criterion

Tab.55 Chi-Squared Tests, Sensory disabilities + Questionable exclusion criterion

Tab.1 Descriptive Statistics, Number of study participants

Number of study participants	
Valid	2710
Missing	0
Mean	458.977
Std. Deviation	2290.447
Minimum	1.000
Maximum	94321.000
Sum	1.244×10 ⁺⁶

Tab.2 Descriptive Statistics, Age eligible

Age eligible for study	
Valid	2710
Missing	0

Tab. 3 Frequencies for Age eligible for study

Age eligible for study	Frequency	Percent	Valid Percent	Cumulative Percent
0	170	6.273	6.273	6.273
1	2374	87.601	87.601	93.875
2	166	6.125	6.125	100.000
Missing	0	0.000		
Total	2710	100.000		

Coding: 0= paediatric-only studies, 1= adult-only studies, 2= trials comprising subjects of all ages

Tab.4 Descriptive Statistics, Masking

Masking	
Valid	2710
Missing	0

Tab.5 Frequencies for Masking

Masking	Frequency	Percent	Valid Percent	Cumulative Percent
0	1211	44.686	44.686	44.686
1	1499	55.314	55.314	100.000
Missing	0	0.000		
Total	2710	100.000		
Masking	Frequency	Percent	Valid Percent	Cumulative Percent

Coding: 0= without masking, 1= with masking

Tab. 6 Descriptive Statistics, Type of trial

	Pharmacological interventional trial	Surgical interventional trial	Non-pharmacological non-surgical interventional trial	Diagnostic trial
Valid	2710	2710	2710	2710
Missing	0	0	0	0

Tab.7 Frequencies for Pharmacological interventional trial

Pharmacological interventional trial	Frequency	Percent	Valid Percent	Cumulative Percent
0	956	35.277	35.277	35.277
1	1754	64.723	64.723	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.8 Frequencies for Surgical interventional trial

Surgical interventional trial	Frequency	Percent	Valid Percent	Cumulative Percent
0	2646	97.638	97.638	97.638
1	64	2.362	2.362	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.9 Frequencies for Non-pharmacological, non-surgical interventional trial

Non-pharmacological, non-surgical interventional trial	Frequency	Percent	Valid Percent	Cumulative Percent
0	1951	71.993	71.993	71.993
1	759	28.007	28.007	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.10 Frequencies for Diagnostic trial

Diagnostic trial	Frequency	Percent	Valid Percent	Cumulative Percent
0	2577	95.092	95.092	95.092
1	133	4.908	4.908	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab. 11 Descriptive Statistics, Inability to give informed consent

Inability to give informed consent	
Valid	2710
Missing	0

Tab.12 Frequencies for Inability to give informed consent

Inability to give informed consent	Frequency	Percent	Valid Percent	Cumulative Percent
0	2230	82.288	82.288	82.288
1	480	17.712	17.712	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab. 13 Descriptive Statistics, Explicit exclusion criteria

	Disability	Physical impairment	Cognitive impairment	Behavioural or psychiatric disorders	Communication and language disorders	Sensory
Valid	2710	2710	2710	2710	2710	2710
Missing	0	0	0	0	0	0

Tab.14 Frequencies for Disability

Disability	Frequency	Percent	Valid Percent	Cumulative Percent
0	2648	97.712	97.712	97.712
1	62	2.288	2.288	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.15 Frequencies for Physical impairment

Physical impairment	Frequency	Percent	Valid Percent	Cumulative Percent
0	2503	92.362	92.362	92.362
1	207	7.638	7.638	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.16 Frequencies for Cognitive impairment

Cognitive impairment	Frequency	Percent	Valid Percent	Cumulative Percent
0	2246	82.878	82.878	82.878
1	464	17.122	17.122	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.17 Frequencies for Behavioural or psychiatric disorders

Behavioural or psychiatric disorders	Frequency	Percent	Valid Percent	Cumulative Percent
0	2122	78.303	78.303	78.303
1	588	21.697	21.697	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.18 Frequencies for Communication and language impairment

Communication and language	Frequency	Percent	Valid Percent	Cumulative Percent
0	2577	95.092	95.092	95.092
1	133	4.908	4.908	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.19 Frequencies for Sensory disabilities

Sensory	Frequency	Percent	Valid Percent	Cumulative Percent
0	2612	96.384	96.384	96.384
1	98	3.616	3.616	100.000
Missing	0	0.000		
Total	2710	100.000		

Tab.20 Contingency Tables, Disability + Absolute exclusion criterion

Absolute exclusion criterion	Disability		Total
	0	1	
0	2621	60	2681
1	27	2	29
Total	2648	62	2710

Tab.21 Chi-Squared Tests, Disability + Absolute exclusion criterion

	Value	df	p
X ²	2.785	1	0.095
N	2710		

Tab.22 Contingency Tables, Disability + Relative exclusion criterion

Relative exclusion criterion	Disability		Total
	0	1	
0	1787	3	1790
1	861	59	920
Total	2648	62	2710

Tab.23 Chi-Squared Tests, Disability + Relative exclusion criterion

	Value	df	p
X ²	106.030	1	< .001
N	2710		

Tab.24 Contingency Tables, Disability + Questionable exclusion criterion

Questionable exclusion criterion	Disability		Total
	0	1	
0	2640	61	2701
1	8	1	9
Total	2648	62	2710

Tab.25 Chi-Squared Tests, Disability + Questionable exclusion criterion

	Value	df	p
X ²	3.145	1	0.076
N	2710		

Tab.26 Contingency Tables, Physical impairment + Absolute exclusion criterion

Absolute exclusion criterion	Physical impairment		Total
	0	1	
0	2487	194	2681
1	16	13	29
Total	2503	207	2710

Tab.27 Chi-Squared Tests, Physical impairment + Absolute exclusion criterion

	Value	df	p
X ²	57.466	1	< .001
N	2710		

Tab.28 Contingency Tables, Physical impairment + Relative exclusion criterion

Relative exclusion criterion	Physical impairment		Total
	0	1	
0	1777	13	1790
1	726	194	920
Total	2503	207	2710

Tab.29 Chi-Squared Tests, Physical impairment + Relative exclusion criterion

	Value	df	p
X ²	357.079	1	< .001
N	2710		

Tab.30 Contingency Tables, Physical impairment + Questionable exclusion criterion

Questionable exclusion criterion	Physical impairment		Total
	0	1	
0	2494	207	2701
1	9	0	9
Total	2503	207	2710

Tab.31 Chi-Squared Tests, Physical impairment + Questionable exclusion criterion

	Value	df	p
X ²	0.747	1	0.387
N	2710		

Tab.32 Contingency Tables, Cognitive impairment + Absolute exclusion criterion

Absolute exclusion criterion	Cognitive impairment		Total
	0	1	
0	2227	454	2681
1	19	10	29
Total	2246	464	2710

Tab.33 Chi-Squared Tests, Cognitive impairment + Absolute exclusion criterion

	Value	df	p
X ²	6.226	1	0.013
N	2710		

Tab.34 Contingency Tables, Cognitive impairment + Relative exclusion criterion

Relative exclusion criterion	Cognitive impairment		Total
	0	1	
0	1774	16	1790
1	472	448	920
Total	2246	464	2710

Tab.35 Chi-Squared Tests, Cognitive impairment + Relative exclusion criterion

	Value	df	p
X ²	978.523	1	< .001
N	2710		

Tab.36 Contingency Tables, Cognitive impairment + Questionable exclusion criterion

Questionable exclusion criterion	Cognitive impairment		Total
	0	1	
0	2243	458	2701
1	3	6	9
Total	2246	464	2710

Tab.37 Chi-Squared Tests, Cognitive impairment + Questionable exclusion criterion

	Value	df	p
X ²	15.621	1	< .001
N	2710		

Tab.38 Contingency Tables, Behavioural or psychiatric disorders+ Absolute exclusion criterion

Absolute exclusion criterion	Behavioural or psychiatric impairment		Total
	0	1	
0	2102	579	2681
1	20	9	29
Total	2122	588	2710

Tab.39 Chi-Squared Tests, Behavioural or psychiatric impairment + Absolute exclusion criterion

	Value	df	p
X ²	1.504	1	0.220
N	2710		

Tab.40 Contingency Tables, Behavioural or psychiatric disorders+ Relative exclusion criterion

Relative exclusion criterion	Behavioural or psychiatric impairment		Total
	0	1	
0	1777	13	1790
1	345	575	920
Total	2122	588	2710

Tab.41 Chi-Squared Tests, Behavioural or psychiatric impairment + Relative exclusion criterion

	Value	df	p
X ²	1364.883	1	< .001
N	2710		

Tab.42 Contingency Tables, Behavioural or psychiatric disorders+ Questionable exclusion criterion

Questionable exclusion criterion	Behavioural or psychiatric impairment		Total
	0	1	
0	2117	584	2701
1	5	4	9
Total	2122	588	2710

Tab.43 Chi-Squared Tests, Behavioural or psychiatric impairment + Questionable exclusion criterion

	Value	df	p
X ²	2.750	1	0.097
N	2710		

Tab.44 Contingency Tables, Communication and language disorders+ Absolute exclusion criterion

	Communication and language disorders		
Absolute exclusion criterion	0	1	Total
0	2551	130	2681
1	26	3	29
Total	2577	133	2710

Tab.45 Chi-Squared Tests, Communication and language disorders + Absolute exclusion criterion

	Value	df	p
X ²	1.857	1	0.173
N	2710		

Tab.46 Contingency Tables, Communication and language disorders+ Relative exclusion criterion

	Communication and language disorders		
Relative exclusion criterion	0	1	Total
0	1787	3	1790
1	790	130	920
Total	2577	133	2710

Tab.47 Chi-Squared Tests, Communication and language disorders + Relative exclusion criterion

	Value	df	p
X ²	253.858	1	< .001
N	2710		

Tab.48 Contingency Tables, Communication and language disorders+ Questionable exclusion criterion

	Communication and language disorders		
Questionable exclusion criterion	0	1	Total
0	2568	133	2701
1	9	0	9
Total	2577	133	2710

Tab.49 Chi-Squared Tests, Communication and language disorders + Questionable exclusion criterion

	Value	df	p
X ²	0.466	1	0.495
N	2710		

Tab.50 Contingency Tables, Sensory disabilities+ Absolute exclusion criterion

	Sensory disabilities		
Absolute exclusion criterion	0	1	Total
0	2594	87	2681
1	18	11	29
Total	2612	98	2710

Tab.51 Chi-Squared Tests, Sensory disabilities + Absolute exclusion criterion

	Value	df	p
X ²	99.031	1	< .001
N	2710		

Tab.52 Contingency Tables, Sensory disabilities+ Relative exclusion criterion

Relative exclusion criterion	Sensory disabilities		Total
	0	1	
0	1779	11	1790
1	833	87	920
Total	2612	98	2710

Tab.53 Chi-Squared Tests, Sensory disabilities + Relative exclusion criterion

	Value	df	p
X ²	136.305	1	< .001
N	2710		

Tab.54 Contingency Tables, Sensory disabilities+ Questionable exclusion criterion

Questionable exclusion criterion	Sensory disabilities		Total
	0	1	
0	2603	98	2701
1	9	0	9
Total	2612	98	2710

Tab.55 Chi-Squared Tests, Sensory disabilities + Questionable exclusion criterion

	Value	df	p
X ²	0.339	1	0.561
N	2710		