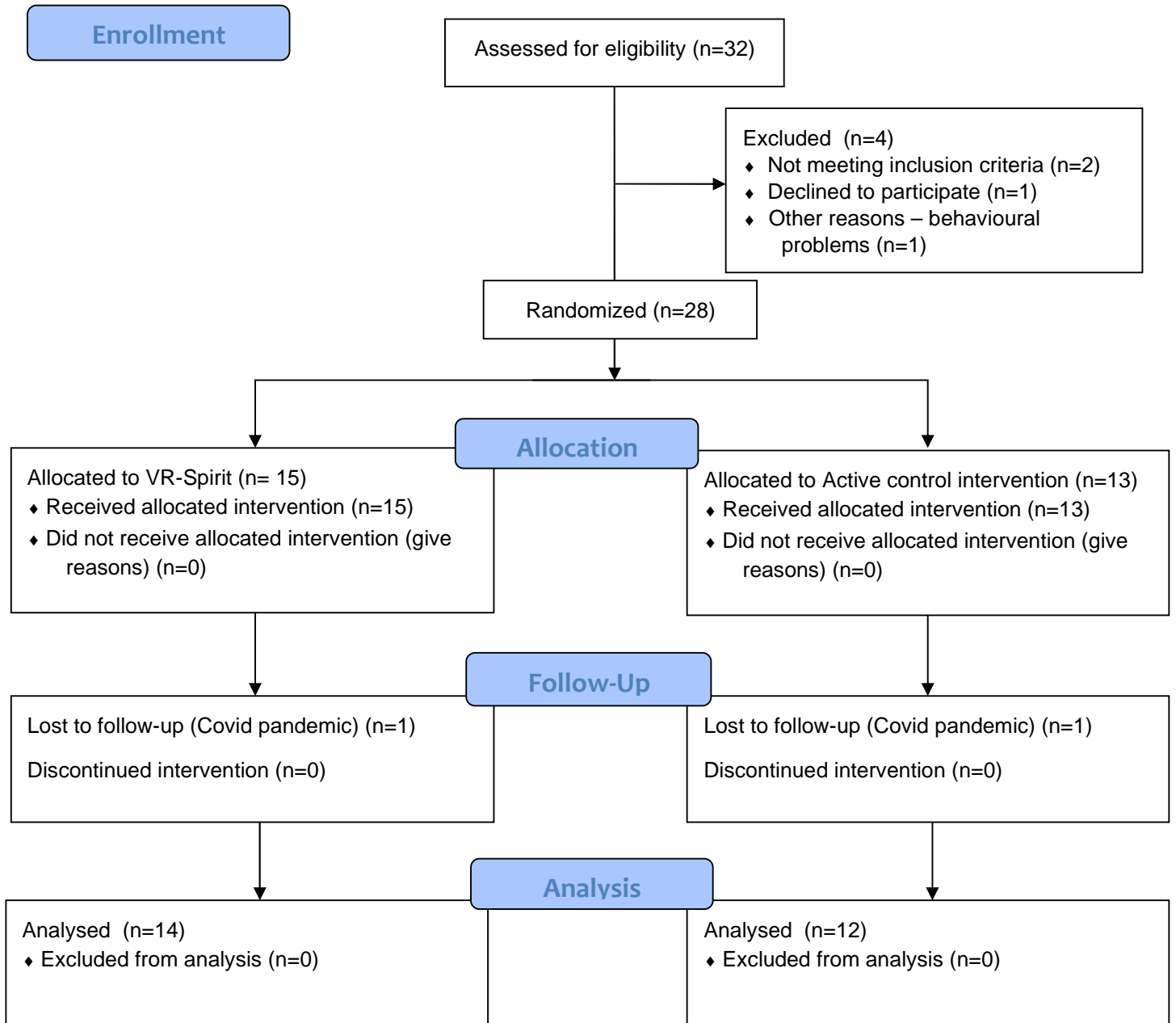Results trial ISRCTN22332873: "Virtual reality social prediction training for pediatric patients with cerebellar diseases"

Enrollment

Assessed for eligibility (n=32)

Excluded (n=4)
- Not meeting inclusion criteria (n=2)
- Declined to participate (n=1)
- Other reasons – behavioural problems (n=1)

Randomized (n=28)

Allocation

Allocated to VR-Spirit (n= 15)
- Received allocated intervention (n=15)
- Did not receive allocated intervention (give reasons) (n=0)

Allocated to Active control intervention (n=13)
- Received allocated intervention (n=13)
- Did not receive allocated intervention (give reasons) (n=0)

Follow-Up

Lost to follow-up (Covid pandemic) (n=1)

Discontinued intervention (n=0)

Lost to follow-up (Covid pandemic) (n=1)

Discontinued intervention (n=0)

Analysis

Analysed (n=14)
- Excluded from analysis (n=0)

Analysed (n=12)
- Excluded from analysis (n=0)

Baseline Characteristics of the two samples

		VR-Spirit	**Active Control Group**
Gender	M:F	11:4	10:3
Age			
	Range	7.4-25.6	7.4-25.6

	Mean (SD)	13.4 (3.8)	12.8 (5.2)
IQ	Range	46-137	46-120
	Mean (SD)	72 (26)	67 (21)

Outcome measures

Primary outcome measures

	VR-Spirit			Active Control Group		
	T0	**T2**	**T3**	**T0**	**T2**	**T3**
VR-Prediction score: Mean (SD)	32.9 (8.4)	51.3 (5.2)		34.4 (10.5)	37.5 (8.1)	
Action prediction Beta: Mean (SD)	-0-03 (0.71)	0.25 (0.51)	0.26 (0.52)	-0.08 (0.53)	-0.05 (0.59)	-0.21 (0.54)

Secondary outcome measures

	VR-Spirit			Active Control Group		
	T0	**T2**	**T3**	**T0**	**T2**	**T3**
Implicit learning (Action prediction task)						
Familiarization phase (accuracy)	93%	94%	93%	91%	91%	92%
NEPSY-II scaled scores: Mean (SD)						
Social cognition						
Theory of Mind	4.7 (3.8)	7.3 (3.8)	7.7 (4.3)	6.2 (4.5)	6.8 (3.9)	5.5 (4.3)
Affect recognition	5.8 (4.1)	7.3 (4.5)	7.6 (3.6)	5.4 (3.1)	6.5 (3.3)	5.5 (3.6)
Executive functions						
Visual attention	4.3 (4.0)	5.7 (5.1)	7.0 (5.6)	4.5 (3.7)	6.3 (4.0)	5.8 (4.8)
Inhibition	5.6 (3.7)	7.9 (3.4)	8.7 (3.6)	4.8 (2.4)	5.8 (3.3)	6.3 (3.4)
Visuospatial processing						
Picture and Geometric puzzles Mean	5.5 (4.2)	7.0 (4.9)	7.7 (5.2)	5.6 (3.2)	7.3 (4.1)	7.3 (4.2)
Memory						
Memory for drawings	3.4 (3.7)	6.0 (4.8)	6.4 (5.1)	3.5 (3.9)	6.6 (4.6)	6.5 (4.6)
Sensorimotor functions						
Tapping	8.2 (4.6)	8.5 (4.7)	9.4 (4.5)	8.5 (3.5)	8.3 (3.5)	8.7 (3.5)
CBCL T-scores: Mean (SD)						
Anxious/Depressed	60 (6)		57 (8)	59 (10)		59 (8)

Social withdrawal	58 (9)	61 (11)	58 (7)	60 (7)
Somatic complaints	59 (9)	56 (8)	58 (8)	57 (7)
Social problems	63 (10)	61 (9)	63 (6)	63 (7)
Thought problems	59 (10)	57 (10)	59 (10)	57 (8)
attention problems	60 (11)	60 (10)	60 (5)	60 (6)
Rule-breaking behaviours	55 (7)	55 (7)	58 (9)	60 (8)
Aggressive behaviours	57 (9)	54 (7)	54 (18)	60 (11)
Quality of Life (TACQOL)	Non-available			

Note: TACQOL results are non-available since most patients had intellectual delay and were not able to provide reliable answers and to fulfil the questionnaire.

Adverse Events

There were no adverse events associated with this trial.