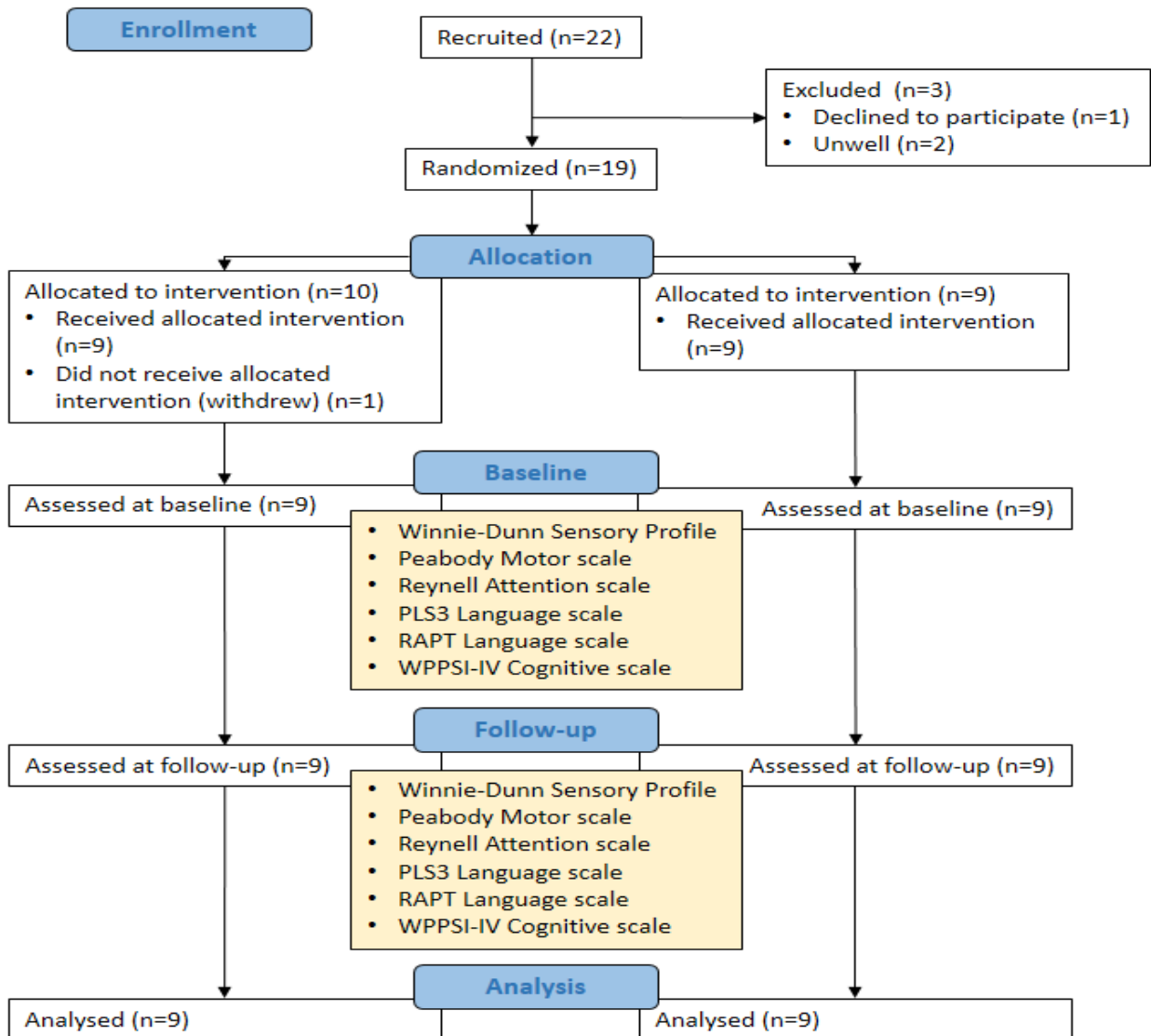


Participant Flow

Diagram 1: Recruitment, randomization, allocation of TL and Control Groups and assessment process.



Baseline Characteristics

Table 1. Infant Characteristics of TL and Controls

Characteristic	Intervention Group	Control Group
Mean GA: (wks)	26.5	26.6
Mean BW: (g)	851	1034.4
Mean Age: 1 st assessment (mths/days)	38/11	37/6
Male sex (n)	5	4
Female sex (n)	4	5
Delivery SVD (n)	2	3
Delivery EM C- section (n)	7	6
Apgar Score @ 1min	6	6
Apgar Score @ 5min	8	7
ANS Dexamethasone use (n)	7	9
PNS Surfactant use (n)	8	4
MgSO ₄ given (n)	4	5
Ventilation days (n)	107 (8)	110 (2)
CLD (n)	5	4
ROP requiring laser surgery (n)	2	0
Patent Ductus Arteriosus (n)	4	3
Intraventricular Haemorrhage 1-2 (n)	4	1
Intraventricular Haemorrhage 3-4 (n)	0	1
Periventricular Leukomalacia (n)	0	1

Outcome Measures

Primary: Winnie-Dunn Sensory Profile; Peabody Developmental Motor Scales (2nd ed); Reynell Attention Scale; Preschool Language Scales – 3; RAPT (Renfrew Action Picture Test); WPPSI – IV (4th ed). Secondary: Home Listening Follow-up Forms.

Table 2: Sensory Profile: Pre and Post TL : (Winnie-Dunn SPS)

Sensory Processing		Group				Risk Ratio (95% CI)
		Control		Intervention		
		Pre	Post	Pre	Post	
Sensation Seeking	Normal	6 (67%)	2 (22%)	4 (44%)	5 (71%)	
	Probable Disability	2 (22%)	5 (56%)	3 (33%)	1 (14%)	
	Definite Disability	1 (11%)	2 (22%)	2 (22%)	1 (14%)	
	Improvers:	1 (11%)		5 (71%)		6.4 (1.0, 43.3)
Auditory	Normal	4 (44%)	2 (22%)	2 (22%)	6 (67%)	
	Probable Disability	3 (33%)	2 (22%)	1 (11%)	1 (11%)	
	Definite Disability	2 (22%)	5 (56%)	6 (67%)	2 (22%)	
	Improvers:	1 (11%)		5 (56%)		5.0 (0.7, 34.7)
Visual	Normal	7 (78%)	6 (67%)	5 (56%)	7 (78%)	
	Probable Disability	1 (11%)	2 (22%)	4 (44%)	1 (11%)	
	Definite Disability	1 (11%)	1 (11%)	0 (0%)	1 (11%)	
	Improvers:	0 (0%)		2 (22%)		N/A
Tactile	Normal	4 (44%)	5 (56%)	4 (44%)	7 (78%)	
	Probable Disability	4 (44%)	1 (11%)	1 (11%)	2 (22%)	
	Definite Disability	1 (11%)	3 (33%)	4 (44%)	0 (0%)	
	Improvers:	1 (11%)		4 (44%)		4.0 (0.5, 29.1)
Vestibular	Normal	4 (44%)	3 (33%)	2 (22%)	8 (89%)	
	Probable Disability	5 (56%)	2 (22%)	4 (44%)	0 (0%)	

	Definite Disability	0 (0%)	4 (44%)	3 (33%)	1 (11%)	
	Improvers:	0 (0%)		6 (67%)		N/A
Oral Sensory	Normal	6 (67%)	4 (44%)	5 (56%)	4 (44%)	
	Probable Disability	1 (11%)	3 (33%)	1 (11%)	2 (22%)	
	Definite Disability	2 (22%)	2 (22%)	3 (33%)	3 (33%)	
	Improvers:	1 (11%)		2 (22%)		2.0 (0.2, 18.3)

Table 3: Attention Levels: Pre and Post TL (Reynell Attention Scale: 1978)

Attention Level	Group				Cumulative Risk Ratio
	Control		Intervention		
	Pre	Post			
1 (0-1 yrs)	1 (11%)	0 (0%)	4 (44%)	0 (0%)	
2 (1-2 yrs)	4 (44%)	0 (0%)	3 (33%)	0 (0%)	
3 (2-3 yrs)	3 (33%)	5 (56%)	2 (22%)	5 (56%)	
4 (3-4 yrs)	1 (11%)	4 (44%)	0 (0%)	3 (33%)	
5 (4-5 yrs)	0 (0%)	0 (0%)	0 (0%)	1 (11%)	
6 (5-6 yrs)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Improved 1 level:	5 (56%)		2 (22%)		0.4
Improved 2 levels:	2 (22%)		7 (78%)		3.5

Table 4: Peabody Motor Scores: Pre and Post TL: (PDMS 2nd Edition)

PEABODY	Control		Intervention		Group Diff (95% CI) †	Cohen's d
	Pre	Post	Pre	Post		
Gross Motor Quotient	66.6 (3.3)	74.8 (4.8)	64.1 (8.1)	68.8 (9.9)		
Change:		8.2 (5.1)		4.7 (6.0)	-3.5	0.63
GMQ centile	1.1 (0.6)	5.3 (4.0)	1.2 (1.2)	3.6 (4.4)		
Fine Motor Quotient	70.4 (10.2)	77.7 (7.7)	67.6 (12.6)	71.3 (8.9)		
Change:		7.2 (15.9)		3.8 (14.7)	-3.4	0.22
FMQ centile	6.6 (7.8)	8.9 (8.4)	3.8 (4.4)	4.6 (6.7)		
Total Motor Quotient	66.0 (5.5)	73.6 (5.1)	63.8 (8.0)	66.6 (9.6)		
Change:		7.6 (6.8)		2.8 (8.1)	-4.8	0.64

TMQ centile	1.4 (1.8)	4.6 (3.8)	1.4 (1.5)	2.7 (4.2)		
Stationary scaled score	5.0 (1.3)	5.4 (1.0)	5.0 (1.2)	5.1 (0.8)		
Change:		0.4 (1.3)		0.1 (1.3)	-0.3	0.23
S centile	5.9 (3.3)	7.3 (4.4)	6.0 (4.7)	5.7 (2.8)		
Locomotion scaled score	4.1 (.6)	6.2 (1.4)	4.3 (1.2)	4.9 (2.0)		
Change:		2.1 (1.3)		0.6 (1.4)	-1.5	1.11
L centile	2.6 (1.4)	12.4 (10.2)	3.9 (3.3)	7.2 (7.8)		
Object Manipulation scaled score	5.2 (0.4)	6.6 (0.9)	4.7 (1.3)	5.3 (2.3)		
Change:		1.3 (0.9)		0.7 (2.1)	-0.6	0.37
OM centile	5.9 (1.8)	13.4 (6.0)	4.9 (3.0)	10.1 (9.6)		
Grasp scaled score	4.8 (3.4)	6.4 (2.1)	3.3 (2.5)	5.2 (1.6)		
Change:		1.7 (4.4)		1.9 (3.2)	0.2	0.05
G centile	9.6 (13.0)	16.4 (15.4)	4.2 (5.8)	7.1 (8.5)		
Visual-Motor Integration scaled score	6.1 (1.3)	6.1 (0.9)	5.9 (1.5)	5.7 (1.3)		
Change:		0 (1.1)		-0.2 (0.8)	-0.2	0.21
VMI Centile	11.4 (7.3)	10.7 (6.2)	9.1 (7.4)	9.1 (7.4)		

† A negative Group Difference indicates that the Intervention group score improved less than the Control group; a positive Group Difference indicates that the intervention group improved more than the control group.

Table 5: Language: Auditory Comprehension (AC) and Expressive Communication (EC) Scores: Pre and Post TL: (PLS 3)

Preschool Language Scale - 3	Control		Intervention		Group Diff	Cohen's d
	Pre	Post	Pre	Post		
Auditory comprehension	74.9 (9.3)	82.9 (12.1)	67.9 (10.6)	71.1 (15.8)		
Change:		8.0 (11.2)		3.2 (10.9)	-4.8	0.43
AC raw score	20.3 (6.0)	28.3 (7.7)	17.1 (6.2)	21.9 (9.2)		
AC centile	7.7 (9.5)	18.3 (20.0)	3.6 (3.8)	9.2 (11.7)		
Expressive communication	78.0 (8.9)	78.1 (7.6)	66.2 (9.7)	69.3 (13.1)		
Change:		0.1 (6.6)		3.1 (8.6)	3.0	0.39
EC raw score	19.9 (3.4)	23.9 (4.1)	15.3 (5.2)	19.3 (7.3)		
EC centile	10.4 (10.1)	9.4 (8.4)	2.8 (3.1)	5.4 (5.1)		

Table 6: Language: RAPT: Information (verbal formulation) and Grammer Scores: Pre and Post TL

Renfrew Action Picture Test: RAPT	Control		Intervention		Group Diff	Cohen's d
	Pre	Post	Pre	Post		
R/AE/I	6.9 (7.0)	16.7 (9.7)	4.0 (8.3)	6.9 (10.5)		
Change:		*7.4 (3.6)		2.9 (7.2)	-4.5	0.78
R/AE/G	2.9 (4.7)	9.4 (8.2)	1.7 (3.7)	4.8 (7.6)		
Change:		*5.0 (4.6)		3.1 (5.8)	-1.9	0.36

* N = 8

Table 7: Cognitive Scores: Pre and Post TL: (WPPSI – IV)

WPPSI – IV^{UK}	Control		Intervention		Group Diff	Cohen's d
	Pre	Post	Pre	Post		
Verbal Comprehension index	81.4 (12.8)	85.3 (11.2)	70.9 (18.1)	76.0 (16.5)		
Change:		3.9 (14.1)		5.1 (17.6)	1.2	0.08
VCI centile	16.8 (14.9)	21.4 (19.1)	10.4 (14.5)	14.1 (17.1)		
Receptive vocabulary scaled score	7.1 (3.1)	7.8 (2.9)	5.1 (3.4)	6.6 (3.3)		
Change:		0.7 (4.1)		1.4 (2.8)	0.7	0.20
Information scaled score	6.1 (2.3)	6.7 (1.8)	3.8 (2.7)	5.2 (3.3)		
Change:		0.6 (1.7)		1.4 (2.1)	0.8	0.42
Visuo-Spatial Index	90.7 (6.9)	85.4 (6.6)	86.3 (12.2)	85.2 (15.6)		
Change:		-5.2 (8.8)		-1.1 (13.9)	4.1	0.35
VSI centile	28.4 (14.8)	18.6 (12.1)	24.1 (19.4)	24.7 (25.6)		
Block design scaled score	9.0 (1.4)	6.8 (1.0)	7.6 (2.0)	7.2 (2.3)		
Change:		-2.2 (1.6)		-0.3 (1.9)	1.9	1.08
Object assembly scaled score	7.9 (1.3)	8.3 (2.3)	6.9 (2.8)	7.8 (3.8)		
Change:		0.4 (2.1)		0.9 (2.8)	0.5	0.20
Working Memory Index	85.9 (11.1)	90.7 (16.1)	86.4 (21.6)	90.9 (24.5)		
Change:		4.8 (14.4)		4.4 (13.8)	-0.4	0.03
WM centile	22.2 (17.5)	35.2 (30.1)	30.1 (37.5)	34.5 (41.3)		
Picture memory scaled score	7.2 (2.3)	7.2 (2.3)	6.4 (3.5)	7.7 (4.1)		
Change:		0 (2.6)		1.2 (2.3)	1.2	0.49
Zoo location scaled score	8.1 (2.9)	9.4 (3.6)	8.8 (4.3)	8.9 (4.6)		
Change:		1.3 (3.2)		0.1 (2.9)	-1.2	0.39
Full Scale Intelligence Quotient	83.2 (10.3)	84.2 (10.8)	77.6 (14.7)	77.3 (18.8)		
Change:		1.0 (13.7)		-0.2 (15.4)	-1.2	0.08
FSIQ centile	17.4 (14.4)	19.3 (18.9)	14.5 (17.1)	17.8 (23.7)		

Secondary Outcome Measure**Table 8: Therapeutic Home Listening Reviews: Descriptive Summary Analyses**

Levels of arousal /emotional tone	More animated/relaxed/affectionate/independent; improved empathy; happier; more mature and assertive; calmer; more regulated
Social skills	Improved eye-contact / social engagement;
Attention Skills	Improved attention/focus and concentration
Motor Skills	Improved coordination/balance; better at running/ using the scooter/jumping; improved drawing; now seeking painting/drawing/play doh activities;
Language Skills	Increase in sound production/variety of sounds; more speech imitation; better at listening/ following instructions; improved expressive language; improved articulation; making efforts to talk more; increasing vocabulary/sentences; louder more confident expressions; more chat
General Observations	Better at eating/ sleeping/completing tasks; improved play skills; increased energy levels; improved independent dressing ability to stick to task improved as they were more modulated Their improved sensory profile led to improvement in their attention abilities /skills. They went from being “very busy kids to quieter kids”.

Adverse Events

There were no adverse events.