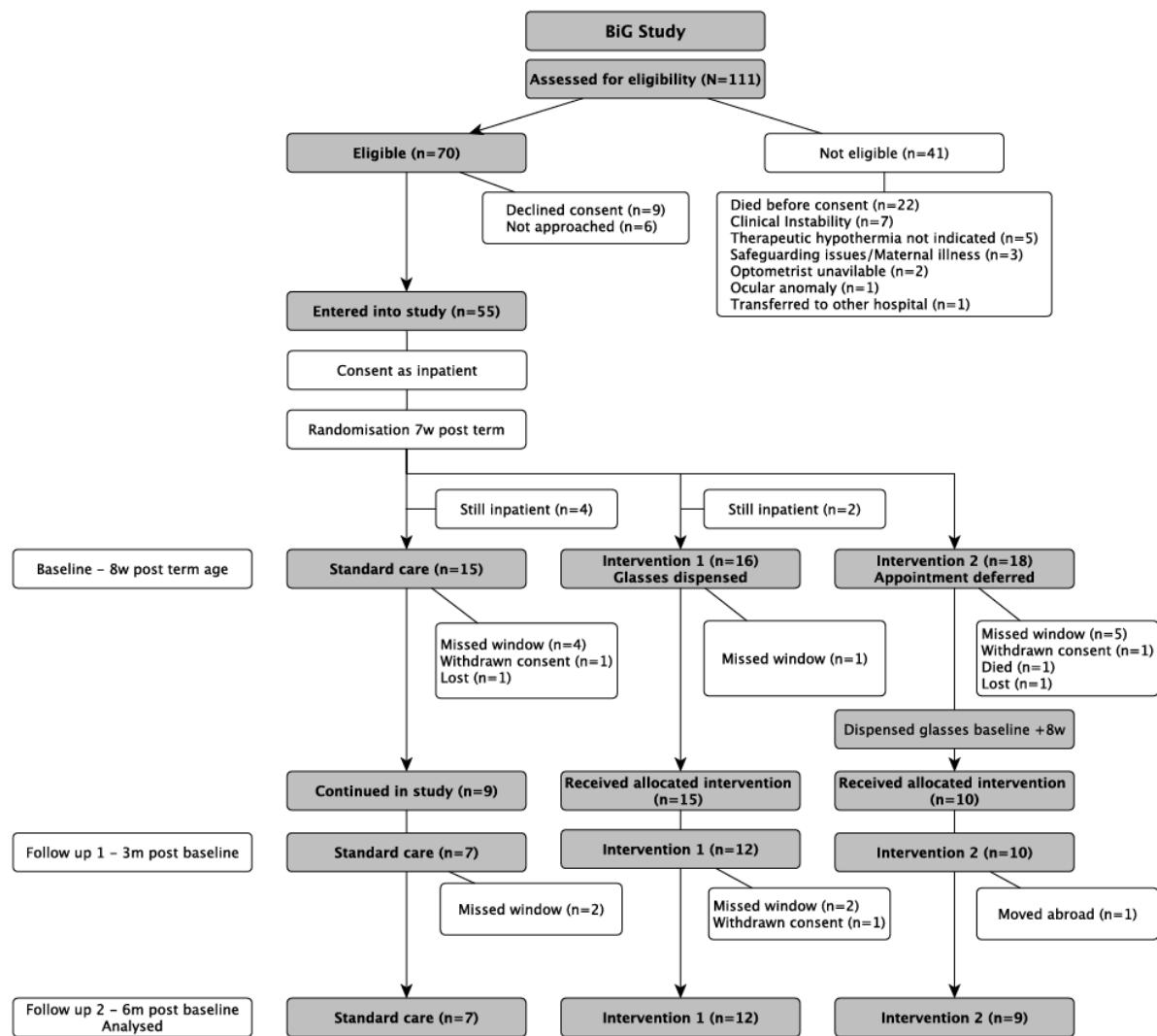# RESULTS

Participant Flow

Figure 1 – Consort diagram for BiG Feasibility Study

Baseline Characteristics

	Preterm group			HIE group		
	Standard Care	**Intervention 1**	**intervention 2**	**Standard Care**	**Intervention 1**	**intervention 2**
Male sex	11/17 (65%)	11/17 (65%)	7/15 (47%)	2/2 (100%)	0/1 (0%)	2/3 (67%)
Gestational age, mean (SD)	26 (2.0)	26 (1.9)	27 (1.6)	38.5 (0.7)	41 (-)	38.7 (2.1)
Birthweight (g), median (IQR)	795 (560-1170)	799 (575-1386)	890 (452-1290)	3520 (3290 –-)	3387 (---)	2852 (2800 –-)

Ethnicity
  White
  Black
  Asian
  Mixed/other
	3
	4
	4
	6
		5
		2
		3
		7
			5
			2
			5
			3
				1
				1
				0
				0
					0
					1
					0
					0
						1
						1
						0
						1

Plurality
  Singleton
  Twin
  Triplet
	10
	4
	3
		6
		11
		0
			9
			3
			3
				2
				0
				0
					1
					0
					0
						3
						0
						0

Bronchopulmonary dysplasia (BPD)[1]	8/17 (47%)	10/17 (59%)	5/15 (33%)			
Necrotising enterocolitis	3/17 (18%)	3/17 (18%)	1/15 (7%)			
Sepsis (n episodes)	3/17 (18%)	6/17 (35%)	4/15 (27%)			
Intraventricular haemorrhage	1/17 (6%)	2/17 (12%)	3/15 (20%)			
Periventricular leucomalacia	4/17 (24%)	8/17 (47%)	3/15 (20%)			
ROP[2]	1/17 (6%)	3/17 (18%)	0/15 (0%)			
Therapeutic Hypothermia (days)				3.5	3	3 3
Seizures				0/2 (0%)	0/1 (0%)	1/3 (33%)
Abnormal MRI scan				2/2 (100%)	0/1 (0%)	2/3 (67%)

[1] Supplemental oxygen at 36 weeks postmenstrual age; [2] Retinopathy of prematurity requiring treatment

Table 1: Demographics, clinical outcomes and comorbidities by study arm

Outcome Measures

	Baseline			Visit 2 Assessment (12-week follow-up)			Final assessment (24-week follow-up)		
	Standard care	Intervention 1	Intervention 2	Standard care	Intervention 1	Intervention 2	Standard care	Intervention 1	Intervention 2
Uncorrected logMAR visual acuity Mean (SD)	1.48 (0.31) n=9	1.45 (0.33) n=14	1.09 (0.25) n=10	0.91 (0.15) n=7	1.08 (0.35) n=9	0.88 (0.15) n=10	0.96 (0.21) n=7	0.88 (0.45) n=10	0.76 (0.39) n=5
Corrected logMAR visual acuity Mean (SD)	-	-	-	-	0.89 (0.28) n=11	0.70 (0.17) n=7	-	0.79 (0.38) n=10	0.74 (0.34) n=8
Refractive error * (dioptres, D), Mean (SD)	+1.94 (2.07) n=9	+2.15 (1.43) n=10	+1.55 (1.29) n=10	+1.11 (1.44) n=7	+2.07 (1.25) n=7	+0.38 (3.14) n=10	+0.75 (1.21) n=7	+1.39 (1.61) n=7	-0.17 (3.60) n=9
δ Refractive Error (D) Mean [95% CI]	-	-	-	0.68, [-0.79, 2.15] n=7	0.00 [-0.82, 0.82] n=7	1.18 [-0.45, 2.80] n=10	1.04, [−0.16, 2.23] n=7	0.43, [−0.62, 1.48] n=7	1.81, [−0.40, 4.02] n=9
Uncorrected accommodative response (D) Mean (SD)	-0.25 (1.75) n=8	-0.42 (1.59) n=12	0.20 (1.51) n=10	0.04 (1.16) n=7	0.17 (1.30) n=12	1.00 (1.03) n=9	0.43 (0.59) n=7	-0.15 (0.98) n=10	0.03 (0.79) n=9

δDifference in means; baseline visit minus final visit i.e. myopic shift, *mean spherical equivalent right eye

Table 2: Summary of uncorrected and corrected visual acuity, refractive error, and accommodative lag (+)/lead (-) across study arms, comparing baseline to final visit measurements in the right eye.

	Baseline			Final assessment		
	Standard care	**Intervention 1**	**Intervention 2**	**Standard care**	**Intervention 1**	**Intervention 2**
	n=9	n=15	n=10	n=7 age 8m[2]	n=11 age 8m[2]	n=9 age 10m[2]
Corneal Reflections	3 (33%)	6 (40%)	8 (80%)	7 (100%)	8 (73%)	8 (89%)
Diffuse light reaction (RHS)	3 (38%)[1]	4 (29%)[1]	7 (78%)[1]	6 (100%)[1]	7 (88%)[1]	8 (100%)[1]
Lateral tracking (RHS)	6 (67%)	10 (71%)[1]	9 (90%)	7 (100%)	10 (100%)[1]	9 (100%)
Saccadic/smooth tracking (RHS)	6 (100%)[1]	10 (100%)[1]	9 (100%)[1]	7 (100%)	10 (100%)[1]	9 (100%)
Peripheral refixation (RHS)	5 (56%)	6 (43%)[1]	9 (90%)	7 (100%)	9 (90%)[1]	9 (100%)
Sustained Visual attention (RHS)	1 (14%)[1]	2 (15%)[1]	3 (38%)[1]	5 (71%)	6 (67%)[1]	9 (100%)
Distance visual attention is broken	2 (29%)[1]	5 (39%)[1]	3 (38%)[1]	6 (86%)	7 (78%)[1]	9 (100%)
Pupillary response to light	8 (100%)[1]	12 (100%)[1]	10 (100%)[1]	7 (100%)	11 (100%)	9 (100%)
Object permanence (partially covered)	-	-	-	5 (71%)	8 (89%)[1]	7 (78%)
Object permanence (fully covered)	-	-	-	2 (29%)	5 (56%)[1]	4 (44%)
Batting and reaching	1 (11%)	0	4 (40%)	7 (100%)	10 (100%)[1]	9 (100%)
Follows fallen toy	-	-	1 (14%)[1]	6 (86%)	9 (90%)[1]	9 (100%)
Defensive blink	5 (56%)	9 (64%)[1]	10 (100%)	7 (100%)	10 (100%)[1]	9 (100%)
Convergence	8 (89%)	8 (53%)	10 (100%)	7 (100.0%)	10 (100%)[1]	9 (100%)

[1] Not all infants completed this task; [2] Age corrected for preterm birth where appropriate (i.e post term age)

Table 3: Pass rates for ABCDEFV items assessed binocularly.

Adverse Events
There were no adverse events associated with this study.