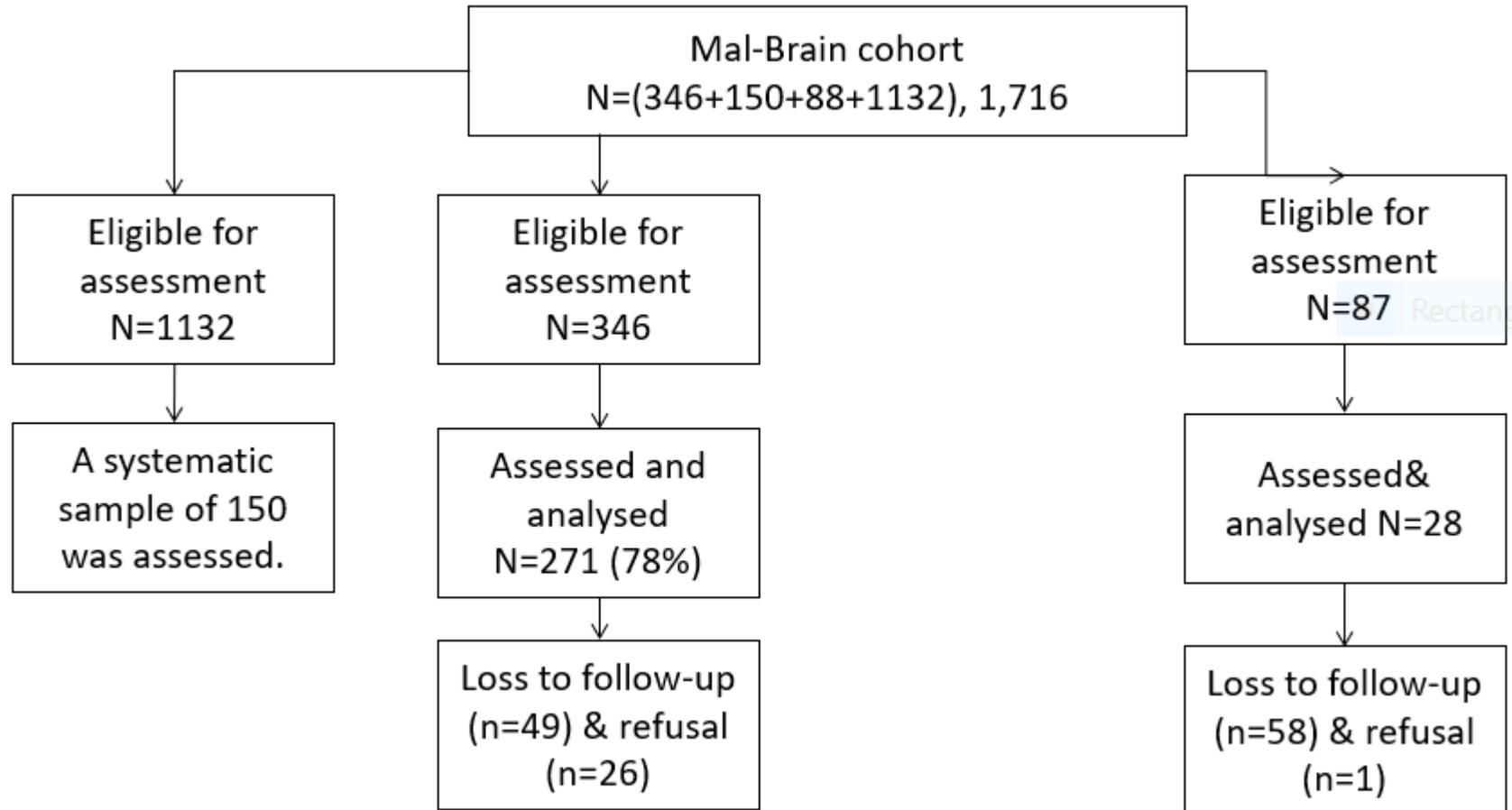


Participant Flow

Total number recruited were 421, of which 221 were from the RTS,S-AS01 vaccine group and 200 from the placebo group.



Baseline Characteristics

Characteristic	Kilifi (N=271)	Siaya (N=150)	Total (421)
Age in years (range)	13.8 (9.9-17.2)	12.8 (9.9-13.5)	13.5 (9.9-17.2)
Male sex	130 (48%)	62 (42%)	192 (46%)
Single marital status	271 (100%)	150 (100%)	421 (100%)
Educational level			
None	1 (0.4%)	1 (1%)	2 (1%)
primary	266 (98%)	149 (99%)	415 (99%)
secondary	4 (2%)	0 (0%)	4 (1%)
Occupation			
Not working	267 (99%)	150 (100%)	417 (99%)
student	3 (1%)	0 (0%)	3 (1%)
Socioeconomic deprivation			
Least	8 (3%)	31 (9%)	39 (21%)
Moderate	81 (30%)	78 (52%)	159 (38%)
Severe	182 (67%)	41 (27%)	223 (53%)

Primary Outcome Measures

Results for seizure disorders and other neurological disorders

	Kilifi and Siaya combined	
	Unadjusted model	Adjusted model
Seizure disorders		
Any seizures	1.09 (0.60-1.05)	1.06 (0.59-1.98)
Acute symptomatic seizures	1.18 (0.53-2.61)	1.15 (0.50-2.66)
Any epilepsy	1.52 (0.57-4.02)	1.15 (0.79-1.67)
Any seizures	1.09 (0.60-1.05)	1.06 (0.59-1.98)
Other neurological conditions		
Motor impairments	0.35 (0.19-0.69)	0.34 (0.24-49)
Visual impairments	FN	FN
Hearing impairments	0.90 (0.61-1.32)	0.93 (0.60-1.46)

Cognitive scores	-0.94 (-1.50, -0.38)	-1.06 (-1.70, -0.42)
Cognitive problems	2.00 (0.89-4.49)	2.05 (0.87-4.83)
Any neurological condition	1.24 (0.62-2.50)	1.22 (0.64-2.33)

Results for mental health problems and other neurodevelopmental disorders

Kilifi and Siaya combined

	Unadjusted model	Adjusted model
Behavioural and emotional problems		
CBCL scores	-1.32 (-1.46; -1.18)	-1.39 (-1.57; -1.20)
CBCL problems	0.64 (0.61-0.67)	0.63 (0.61-0.66)
ADHD problems		
Inattention scores	-48 (-1.34; 0.36)	-0.51 (-1.32-0.28)
Inattention problems	0.61 (0.26-1.43)	0.59 (0.26-1.33)
Impulsivity scores	-0.20 (-0.30; -0.11)	-0.19 (-0.30; -0.08)
Impulsivity problems	FN	FN
ADHD score	-0.21 (-0.06; 0.02)	-0.20 (-0.06; 0.02)
ADHD problems	0.38 (0.08-1.67)	0.36 (0.09-1.42)

Autism spectrum disorder		
Autism Social/reciprocity scores	-0.32 (-1.05; 0.39)	-0.33 (-1.06; 0.39)
Autism language /communication scores	-0.05 (-0.24; 0.13)	-0.04 (-0.22; 0.14)
Autism RRBI scores	0.20 (0.18; 0.23)	0.21 (0.19; 0.23)
Autism scores	-0.14 (-1.00; 0.70)	-0.13 (-0.98; 0.71)
Autism diagnosis	1.31 (0.41-4.14)	1.36 (0.46-4.04)

Secondary Outcome Measures

Overall quality of life		
Poor Quality of life scores	-0.17 (-0.65; 0.29)	-0.18 (-0.55; 0.18)
Poor quality of life	0.89 (0.58-1.38)	0.88 (0.58-1.34)

Adverse Events

There were no adverse events associated with this study.

I intend to publish these findings in the near future.