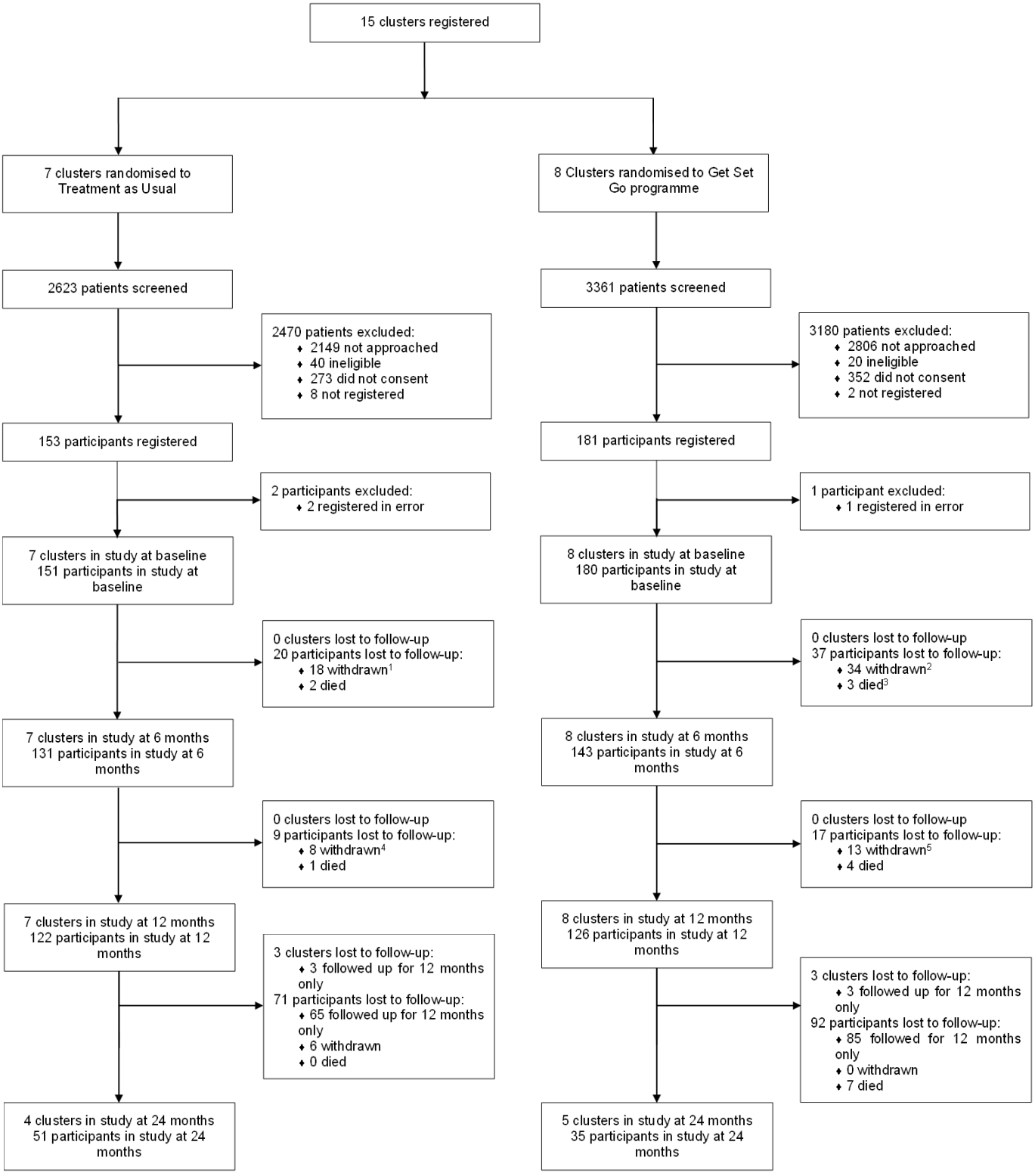
RECREATE Basic Results Summary

Participant flow:

Figure 1: CONSORT diagram illustrating the flow of patients through the RECREATE trial



Baseline characteristics:

	Get Set Go (n=180)	Treatment as usual (n=151)	Overall (n=331)
Age (years) at registration			
Mean (SD)	70.3 (13.68)	68.3 (11.96)	69.3 (12.94)
Median (IQR)	72.7 (61.3, 81.0)	71.5 (59.6, 76.7)	71.8 (60.4, 78.8)
Range	23.5, 98.4	30.0, 92.3	23.5, 98.4
Missing	0	0	0
Gender			
Male	114 (63.3%)	86 (57.0%)	200 (60.4%)
Female	66 (36.7%)	65 (43.0%)	131 (39.6%)
Participant ethnicity			
White - British	170 (94.4%)	129 (85.4%)	299 (90.3%)
White - Irish	1 (0.6%)	0 (0.0%)	1 (0.3%)
Any other White background	2 (1.1%)	9 (6.0%)	11 (3.3%)
Mixed - White and Black Caribbean	0 (0.0%)	3 (2.0%)	3 (0.9%)
Any other mixed background	1 (0.6%)	0 (0.0%)	1 (0.3%)
Asian / Asian British - Indian	1 (0.6%)	1 (0.7%)	2 (0.6%)
Asian / Asian British - Pakistani	0 (0.0%)	1 (0.7%)	1 (0.3%)
Asian / Asian British - Bangladeshi	1 (0.6%)	0 (0.0%)	1 (0.3%)
Black / Black British - Caribbean	1 (0.6%)	1 (0.7%)	2 (0.6%)
Black / Black British - African	0 (0.0%)	4 (2.6%)	4 (1.2%)
Chinese	0 (0.0%)	1 (0.7%)	1 (0.3%)
Any other ethnic group	0 (0.0%)	1 (0.7%)	1 (0.3%)
Not known / prefer not to say	3 (1.7%)	1 (0.7%)	4 (1.2%)
Comorbidities			
Yes	104 (57.8%)	103 (68.2%)	207 (62.5%)
No	76 (42.2%)	48 (31.8%)	124 (37.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of Comorbidities			
Mean (SD)	1.1 (1.17)	1.3 (1.25)	1.2 (1.21)
Median (IQR)	1.0 (0.0, 2.0)	1.0 (0.0, 2.0)	1.0 (0.0, 2.0)
Range	0, 5	0, 6	0, 6
Missing	0	0	0

	Get Set Go (n=180)	Treatment as usual (n=151)	Overall (n=331)
Comorbidity			
Myocardial infarction	12 (6.7%)	8 (5.3%)	20 (6.0%)
Congestive heart failure	20 (11.1%)	4 (2.6%)	24 (7.3%)
Cerebrovascular disease	25 (13.9%)	58 (38.4%)	83 (25.1%)
Peripheral vascular disease	4 (2.2%)	2 (1.3%)	6 (1.8%)
Hemiplegia	6 (3.3%)	18 (11.9%)	24 (7.3%)
Type of stroke			
Cerebral infarction	152 (84.4%)	134 (88.7%)	286 (86.4%)
Primary intracerebral haemorrhage	27 (15.0%)	17 (11.3%)	44 (13.3%)
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Presentation of stroke			
Left hemiparesis	93 (51.7%)	55 (36.4%)	148 (44.7%)
Right hemiparesis	60 (33.3%)	62 (41.1%)	122 (36.9%)
Brain stem	1 (0.6%)	8 (5.3%)	9 (2.7%)
Other	25 (13.9%)	26 (17.2%)	51 (15.4%)
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Functional ambulation category (FAC)			
Mean (SD)	4.5 (1.36)	4.6 (1.26)	4.5 (1.31)
Median (IQR)	5 (3, 6)	5 (4, 6)	5 (4, 6)
Range	1, 6	1, 6	1, 6
Missing	32	0	32
Functional ambulation category (FAC)			
Non-functional ambulator	4 (2.2%)	2 (1.3%)	6 (1.8%)
Ambulator dependent for physical assistance (level II)	7 (3.9%)	3 (2.0%)	10 (3.0%)
Ambulator dependent for physical assistance (level I)	27 (15.0%)	31 (20.5%)	58 (17.5%)
Ambulator dependent for supervision	26 (14.4%)	33 (21.9%)	59 (17.8%)
Ambulator independent, level surfaces only	39 (21.7%)	34 (22.5%)	73 (22.1%)
Ambulator independent	45 (25.0%)	48 (31.8%)	93 (28.1%)
Missing	32 (17.8%)	0 (0.0%)	32 (9.7%)

Primary Outcome Measure:

	Baseline			12 months		
	Get Set Go (n=180)	**Treatment as usual (n=151)**	**Overall (n=331)**	**Get Set Go (n=180)**	**Treatment as usual (n=151)**	**Overall (n=331)**
NEADL total score						
Mean (SD)	56.1 (11.83)	58.9 (10.18)	57.4 (11.17)	43.3 (18.87)	47.4 (17.11)	45.3 (18.09)
Median (IQR)	60.0 (51.0, 66.0)	63.0 (57.0, 66.0)	62.9 (54.0, 66.0)	46.1 (30.0, 60.0)	53.7 (35.0, 62.0)	50.0 (31.0, 61.0)
Range	11.0, 66.0	22.0, 66.0	11.0, 66.0	0.0, 66.0	8.0, 66.0	0.0, 66.0
Missing	5	0	5	85	57	142

The mean difference in the cluster-level adjusted residuals for NEADL score between the two arms at 12 months was -1.7 (95% CI -7.63 to 4.25, p-value 0.530). The difference was not statistically significant.

Adverse Events:

There were eighteen deaths during the study (5.4% of 331 stroke survivors): 15 (8.3%) were in the intervention arm and three (2.0%) in the control arm. None of the deaths in the intervention arm occurred in hospital. Following detailed review, it was determined that the causes of death were unrelated to the intervention. No Related Unexpected Serious Adverse Events (RUSAEs) were reported during the study.