THE LANCET
Global Health

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: SPRINT INDIA trial collaborators. Secondary prevention with a structured semi-interactive stroke prevention package in INDIA (SPRINT INDIA): a multicentre, randomised controlled trial. *Lancet Glob Health* 2023; **11:** e425–35.

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Table 1 shows medication history of the patients between the two groups at baseline

	Intervention (N=2148)	**Control (N=2150)**	**p-value**
Anti-platelets	1580 (73.6)	1587 (73.8)	0.949
Anti-coagulants	241 (11.2)	260 (12.1)	0.387
Lipid lowering medications	1627 (75.7)	1650 (76.7)	0.508
Diabetic medications	774 (36.0)	772 (35.9)	0.922
Antihypertensive medications	1470 (68.4)	1414 (65.8)	0.068

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Table 2 shows baseline demographic characteristics, risk factors and stroke characteristics between the two groups who had completed 1 year follow up

	Intervention (N=1502)	**Control (N=1538)**	**p-value**
Sex			
Male	1075 (71.6)	1130 (73.6)	0.217
Female	427 (28.4)	406 (26.4)	
Age (years)			
Mean±SD	56±12.6	55±12.9	0.558
Highest level of education completed			
No schooling	156 (7.3)	121 (5.6)	0.664
Below high school	1178 (54.8)	1172 (54.5)	
High school and above	794 (37.0)	830 (38.6)	
Region			
Urban	790 (52.6)	830 (54.0)	0.426
Rural	712 (47.4)	706 (46.0)	
Medical history			
Hypertension	1036 (69.0)	1029 (67.0)	0.242
Diabetes Mellitus	619 (41.2)	636 (41.4)	0.913
Previous TIA	48 (3.2)	31 (2.0)	0.041
Coronary artery disease	148 (9.9)	162 (10.5)	0.528
Dyslipidaemia	292 (19.4)	290 (18.9)	0.695
Non valvular atrial fibrillation	31 (2.1)	33 (2.1)	0.871
Valvular heart disease	34 (2.3)	33 (2.1)	0.829
Symptomatic Intracranial Atherosclerosis	35 (2.3)	37 (2.4)	0.887
Symptomatic Extra cranial Atherosclerosis	16 (1.1)	24 (1.6)	0.229
Obesity	105 (7.0)	115 (7.5)	0.598
Others	81 (5.4)	71 (4.6)	0.330
Stroke type			
Ischaemic	1265 (84.2)	1286 (83.7)	0.709
Haemorrhagic	237 (15.8)	250 (16.3)	
NIHSS score			
Mean ± S.D.	4±3.7	4±3.8	0.107
Median (Q1-Q3)	3 (1-5)	3 (1-5)	
<5	1013 (67.4)	999 (65.0)	0.239
5-10	385 (25.6)	429 (27.9)	
11-15	88 (5.9)	83 (5.4)	

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≥15	16 (1.1)	25 (1.6)	
TOAST Classification (n=2551)			
Large Artery Atherosclerosis	135 (10.7)	156 (12.1)	0.297
Cardio Embolism	416 (32.9)	386 (30.0)	
Small Artery Occlusion	35 (2.8)	48 (3.7)	
Others	351 (27.7)	368 (28.6)	
Undetermined	328 (25.9)	328 (25.5)	
OCSP Classification			
Total anterior circulation syndrome	167 (13.2)	171 (13.3)	0.342
Partial anterior circulation syndrome	629 (49.7)	647 (50.3)	
Posterior circulation syndrome	278 (22.0)	304 (23.6)	
Lacunar syndrome	191 (15.1)	164 (12.8)	
Revascularization therapy			
Revascularization therapy given	132 (8.8)	104 (6.8)	0.038
IV tPA initiated	106 (7.1)	87 (5.7)	0.508
Endovascular thrombectomy done	34 (2.3)	26 (1.7)	0.894

TIA= Transient Ischemic Attack, NIHSS= National Institute of Health Stroke Scale, TOAST= Acute Stroke Treatment, OCSP= Oxfordshire Community Stroke Project IV= Intravenous Thrombolysis tPA= Tissue Plasminogen Activator, Q1= First Quartile, Q3= Third Quartile, SD= Standard Deviation

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Table 3 shows median time of event

	Median time (months)	95% Confidence Interval
Intervention	14.7	12..1- 17.3
Control	14.6	13.3-15.9
p-value	0.363	

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Table 4 shows analysis of Serious Adverse Events (SAE)

	Intervention (N=2148)	**Control (N=2150)**	**p-value**
Serious Adverse Events (Overall)	191 (8.9)	172 (8.0)	0.293
Systemic infection	8 (0.4)	6 (0.3)	0.294
Re-hospitalization	75 (3.5)	68 (3.2)	
GI Haemorrhage	3 (0.1)	5 (0.2)	
Death	89 (4.1)	68 (3.2)	
Others	16 (0.7)	25 (1.2)	

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Table 5 shows number of events

	Number of events		Number of patients with one or multiple events				
	Intervention (N=2148)	**Control (N=2150)**	**Intervention (N=2148)**	**Control (N=2150)**	**P value**	**Unadjusted Odds ratio (95% C.I Lower-Upper)**	**Adjusted Odds ratio (95% C.I Lower-Upper)**
Primary Outcome (Overall)	128	113	119 (5.5)	106 (4.9)	0.370	1.13 (0.86-1.48)	1.12 (0.85-1.47)
High Risk transient Ischemic Attack	9	7	5 (0.2)	7 (0.3)	0.694	0.72 (0.23-2.27)	0.73 (0.23-2.31)
Ischemic Stroke	40	42	39 (1.8)	40 (1.9)		0.98 (0.63-1.53)	0.97 (0.62-1.52)
Intracerebral haemorrhage	6	2	5 (0.2)	2 (0.1)		2.52 (0.49-13.0)	2.52 (0.49-13.05)
Acute Coronary Syndrome	11	7	9 (0.4)	7 (0.3)		1.30 (0.48-3.48)	1.27 (0.47-3.43)
Death	66	55	61 (2.8)	50 (2.3)		1.23 (0.84-1.80)	1.22 (0.83-1.78)

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Table 6 shows the secondary outcomes at 6 months

	Month 6				
	Intervention (n=1830)	**Control group (n=1848)**	**P-value**	**Unadjusted Odds ratio (95% C.I Lower-Upper)**	**Adjusted Odds ratio (95% C.I Lower-Upper)**
MRS					
Good Outcome (0-2)	1534 (83.8)	1562 (84.5)	0.562	1.00	1.00
Bad outcome (3-5)	296 (16.2)	286 (15.5)		1.05 (0.88-1.26)	0.90 (0.42-1.89)
SBP	131±14.6	131±15.0	0.781	1.00 (0.99-1.01)	1.00 (0.98-1.01)
DBP	82±9.3	82±8.7	0.911	1.00 (0.99-1.01)	0.99 (0.96-1.02)
BMI	24.9±4.3	24.9±6.6	0.897	1.00 (0.99-1.01)	1.00 (0.99-1.01)
Alcohol intake	78 (4.3)	108 (5.8)	**0.029**	0.72 (0.53-0.97)*	0.744 (0.55-0.99)*
Smoking	72 (3.9)	107 (5.8)	**0.009**	0.67 (0.49-0.91)*	0.69 (0.50-0.94)*
FBS	118.6±40.5	120.4±45.3	0.248	0.99 (0.98-1.00)	1.00 (0.99-1.01)
Lipid Profile					
Cholesterol	151.1±39.0	152.6±40.1	0.333	1.00 (0.99-1.00)	1.00 (0.99-1.01)
Triglyceride	133.8±65.9	136.9±76.3	0.462	1.00 (0.99-1.00)	1.00 (0.99-1.00)
LDL	85.0±32.3	85.4±33.7	0.791	1.00 (0.99-1.01)	0.99 (0.98-1.01)
HDL	46.7±23.1	45.5±17.8	0.146	1.00 (0.99-1.00)	1.00 (0.99-1.01)
Have you missed the medication					
Yes	101 (5.5)	121 (6.5)	0.190	0.83 (0.63-1.09)	0.84 (0.64-1.11)
No	1729 (94.5)	1727 (93.5)		1.00	1.00
If yes reason					
Forgot	27 (26.7)	24 (19.8)	0.336	1.80 (0.82-3.94)	1.86 (0.84-4.13)
Stopped	20 (19.8)	32 (26.4)		1.33 (0.68-2.59)	1.34 (0.69-2.62)
Others	54 (53.5)	65 (53.8)		1.00	1.00
Physical activity met (minutes)	3360 (1330-6880)	3360 (1400-6720)	0.788	1.00 (1.00-1.00)	1.00 (1.00-1.00)

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Table 7 shows baseline demographic characteristics, risk factors and stroke characteristics between the two groups who did not complete 1 year follow up

	Intervention (N=614)	**Control (N=646)**	**p-value**
Sex			
Male	449 (73.1)	468 (72.4)	0.786
Female	165 (26.9)	178 (27.6)	
Age (years)			
Mean±SD	56±12.9	56±12.9	0.541
Highest level of education completed			
No schooling	40 (6.5)	46 (7.1)	0.258
Below high school	359 (58.5)	348 (53.9)	
High school and above	215 (35.0)	252 (39.0)	
Region			
Urban	320 (52.1)	344 (53.3)	0.687
Rural	294 (47.9)	302 (46.7)	
Medical history			
Hypertension	359 (58.5)	421 (65.2)	0.014
Diabetes Mellitus	252 (41.0)	260 (40.2)	0.774
Previous TIA	22 (3.6)	16 (2.5)	0.251
Coronary artery disease	67 (10.9)	74 (11.5)	0.760
Dyslipidaemia	101 (16.4)	86 (13.3)	0.117
Non valvular atrial fibrillation	10 (1.6)	19 (2.9)	0.120
Valvular heart disease	23 (3.7)	27 (4.2)	0.693
Symptomatic Intracranial Atherosclerosis	19 (3.1)	20 (3.1)	0.999
Symptomatic Extra cranial Atherosclerosis	8 (1.3)	13 (2.0)	0.325
Obesity	29 (4.7)	42 (6.5)	0.171
Others	34 (5.5)	31 (4.8)	0.538
Stroke type			
Ischaemic	501 (81.6)	516 (79.9)	0.439
Haemorrhagic	113 (18.4)	130 (20.1)	
NIHSS score			
Mean ± S.D.	7±5.3	7±5.2	0.150
Median (Q1-Q3)	6 (3-10)	5 (3-9)	
<5	245 (39.9)	231 (35.8)	0.313
5-10	246 (40.1)	263 (40.7)	
11-15	85 (13.8)	100 (15.5)	

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≥15	38 (6.2)	52 (8.0)	
TOAST Classification (n=2551)			
Large Artery Atherosclerosis	76 (15.2)	73 (14.1)	0.896
Cardio Embolism	181 (36.1)	191 (37.0)	
Small Artery Occlusion	15 (3.0)	16 (3.1)	
Others	98 (19.6)	111 (21.5)	
Undetermined	131 (26.1)	125 (24.2)	
OCSP Classification			
Total anterior circulation syndrome	65 (13.0)	74 (14.3)	0.600
Partial anterior circulation syndrome	246 (49.1)	267 (51.7)	
Posterior circulation syndrome	109 (21.8)	102 (19.8)	
Lacunar syndrome	81 (16.2)	73 (14.1)	
Revascularization therapy			
Revascularization therapy given	59 (9.6)	53 (8.2)	0.595
IV tPA initiated	52 (8.5)	45 (7.0)	0.508
Endovascular thrombectomy done	14 (2.3)	13 (2.0)	0.678

TIA= Transient Ischemic Attack, NIHSS= National Institute of Health Stroke Scale, TOAST= Acute Stroke Treatment, OCSP= Oxfordshire Community Stroke Project IV= Intravenous Thrombolysis tPA= Tissue Plasminogen Activator, Q1= First Quartile, Q3= Third Quartile, SD= Standard Deviation

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Figure 1 shows intervention material content

Short messaging services	
Improving physical activity	Moving every hour for 2 to 5 min improves circulation in the legs and brain. Try to keep moving throughout the daytime.
Blood pressure control	If your blood pressure is on target today, it may be because of the low salt intake and medications, congratulations and keep it up.
Diabetes control	Medications alone are not enough to lower high blood sugar, daily exercise and low sugar meals are equally important.
Video scripts (excerpts)	
India, Lets Walk ! With Gandhiji	Man standing alone in a garden contemplating whether to exercise today or not. Just then Mahatma Gandhi appears from nowhere in front of him. Mahatma Gandhi: Hello Son, how are you? Man: Bapu it is you! After so many years of independence. Mahatma Gandhi: Son, have you really received your freedom? Man: Yes, I am master of my own will and I can do whatever I wish. Mahatma Gandhi: Okay plesase run for 2 minutes Man tries but huffs and puffs. . . . . . . Man: These restrictions are no less than a Satyagraha. But Bapu who will lead us in this Satyagraha ? Mahatma Gandhi: You have to be the leader of your life. Everybody will have to do it on their own. Only then my vision of a healthy India will be realized and you will receive your freedom in true sense.
Medicines-your friends	A family (including husband, wife, daughter and son-in-law) is rowing a boat together in a beautiful lake. Husband: Today I am very happy. My body is healthy and active. I do not want anything more from my life. But last year, I did not feel the same. A flashback scene of an ambulance and an emergency ward. . . . . . . Son-in-law: We purchase monthly medication one week in advance. Husband: Sometimes I forget to take my medicines but my children have taught me how to set reminders on my phone. Daughter: We just want to tell you that medicines are your friends. Wife: Good friends bring happiness in your life. Husband: In the same way, medicines help in making life happy. All together: Medicines are your friends.

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Figure 2 shows process of intervention and standard of care

Time Line	Structured Semi-interactive Stroke Prevention Package	Control Treatment
Randomization		
Baseline (time 0)	a a a a	a
0-6 weeks	a a a a	a
6 weeks to 6 months	b b b a	a
6 months to 1 year	c b b a	a
1 Year	Measurement of Outcome	

a	Receive daily short messages for first 6 weeks, reminders about medication and motivation
b	Receive twice weekly short messages for first 6months, reminders about medication and motivation
c	Receive once weekly short messages from 6months to 1 year, reminders about medication and motivation
a	Read and perform activities in Work Book completing weekly task for each week for first 6 weeks
b	Monthly revision of the work book concepts From 6 weeks to 1 year
a	Receive stroke prevention videos weekly for the first six weeks
b	Receive stroke prevention videos monthly from 6 weeks to 1 year
a	All patients in both groups will receive antiplatelet/ anticoagulant therapy and risk factor management

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Figure 3 shows recruitment trend from April-2018 to Nov-2021

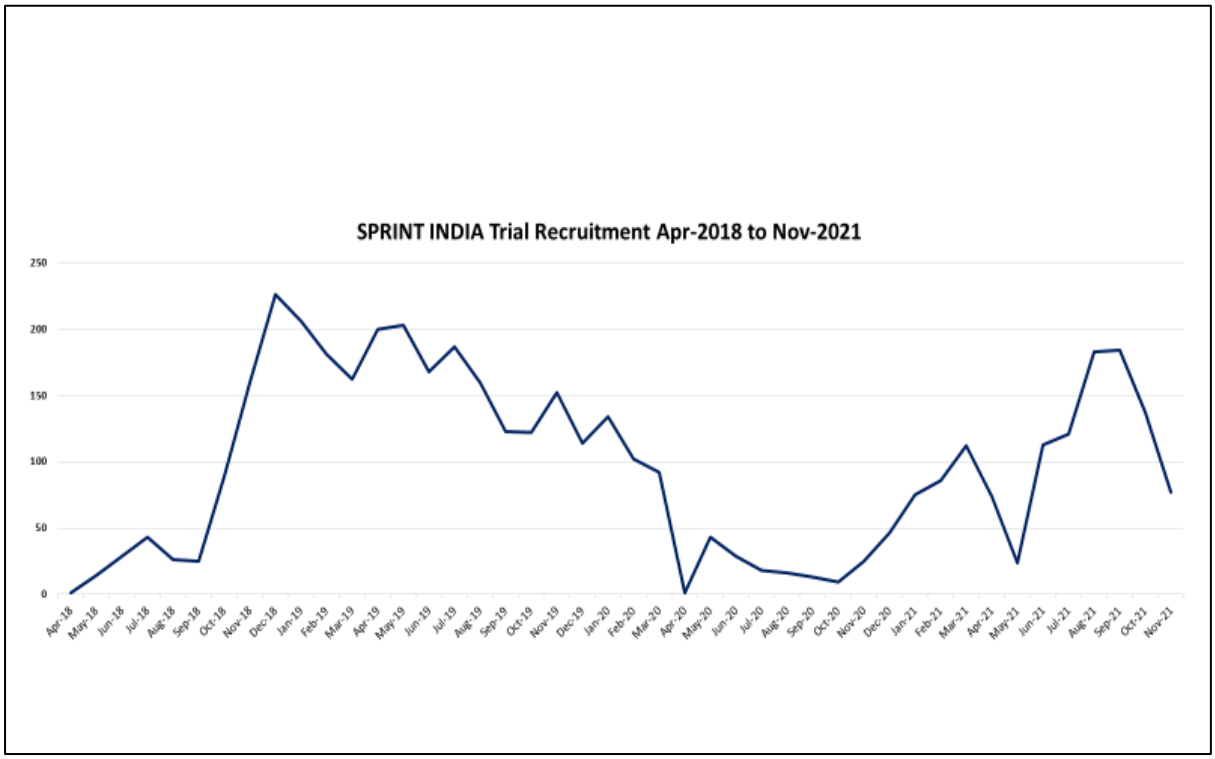

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Figure 4 shows median time to event

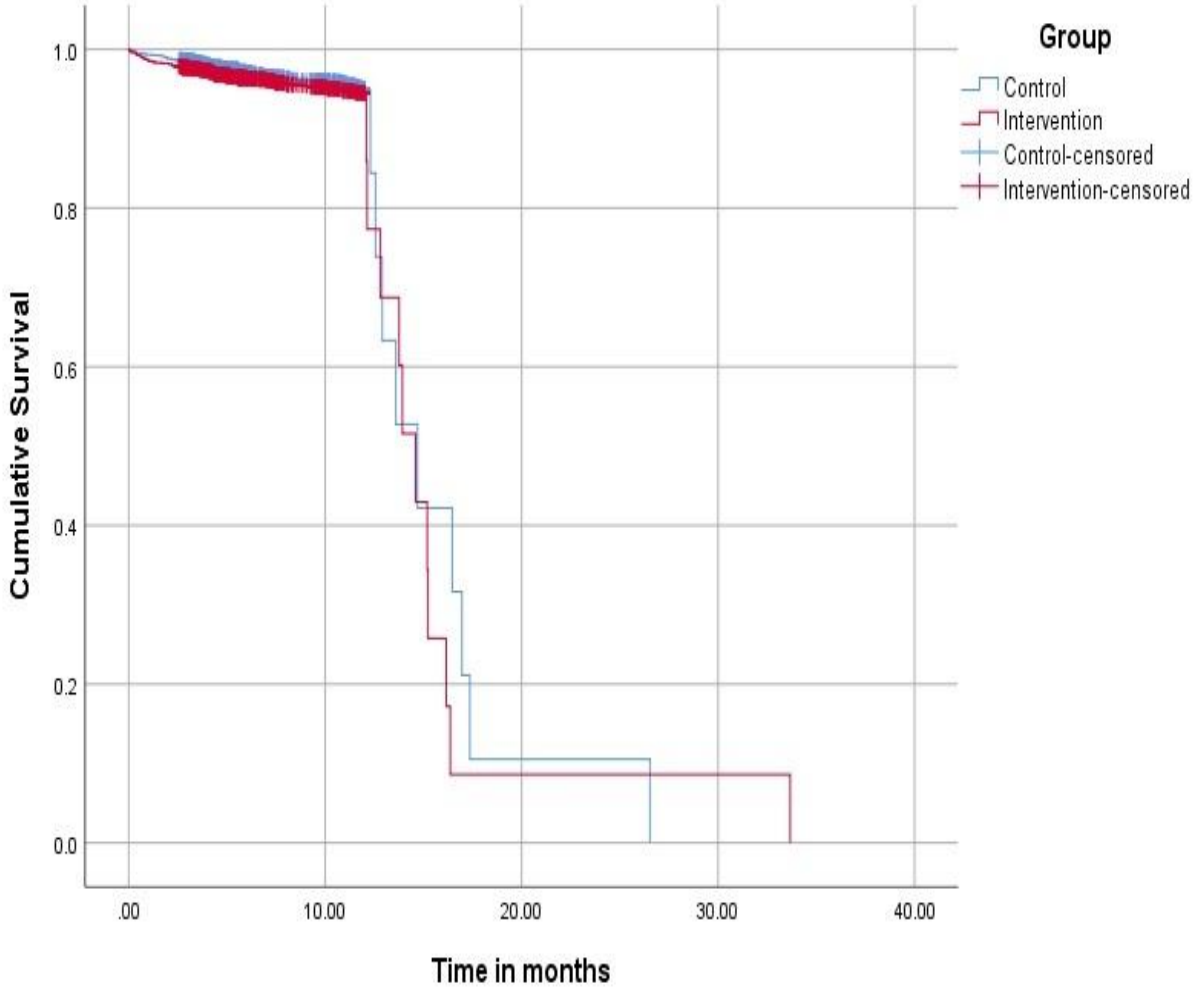

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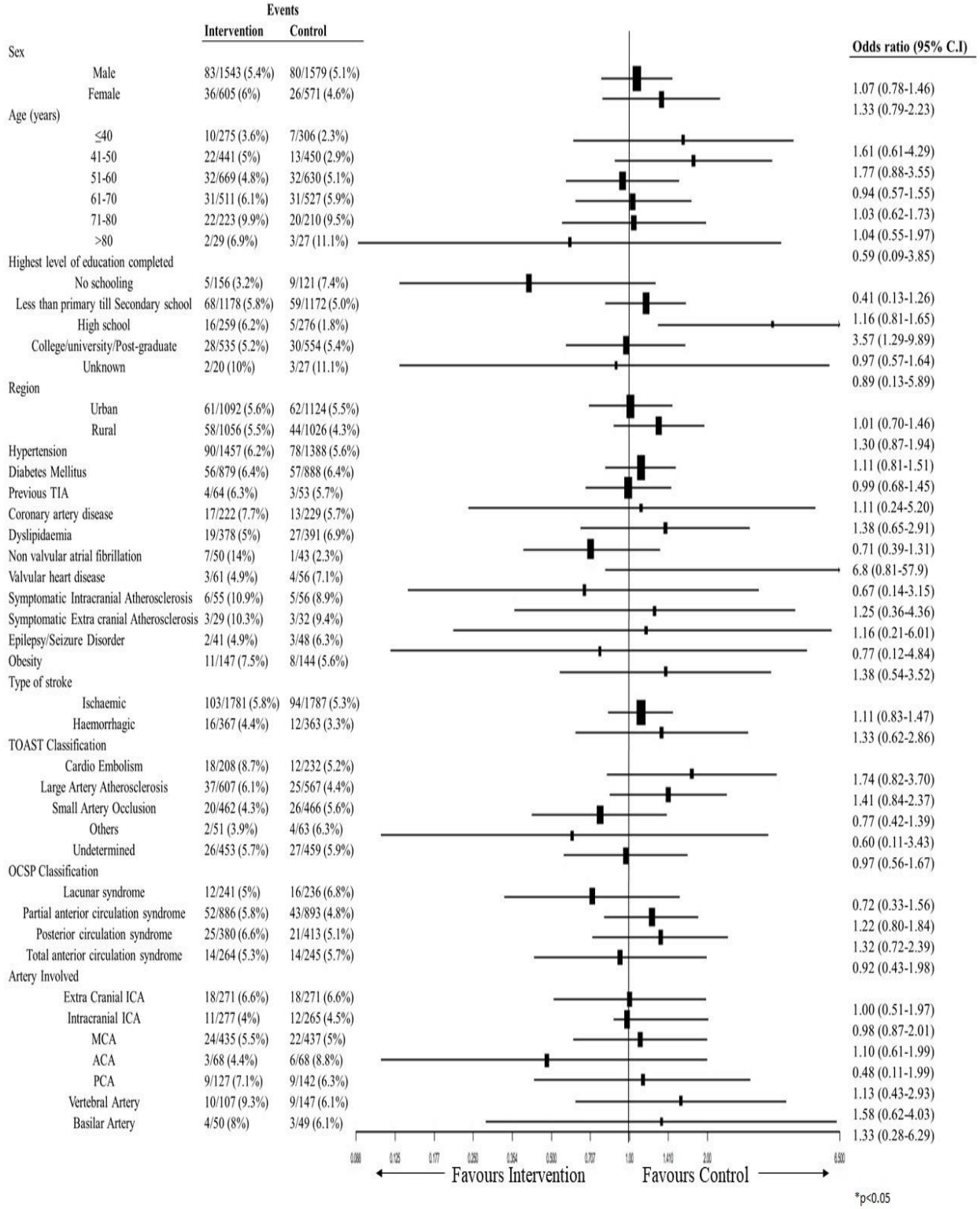
Figure 5 shows forest plot for sub-group analysis



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Medication adherence questionnaire

<table>
<tr><td>Is the patient taking the same medications as at the time of discharge?</td><td><table><tr><td>Yes</td><td>No</td></tr></table></td></tr>
<tr><td>Change in medications compared to discharge</td><td><table><tr><td>Yes</td><td>No</td></tr></table>If Yes, it is<table><tr><td>Medication</td><td>Dosage</td><td>Frequency</td><td>Comments</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Concomitant medications</td><td><table><tr><td>Yes</td><td>No</td></tr></table>If Yes, it is<table><tr><td>Medication</td><td>Dosage</td><td>Frequency</td><td>Comments</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td></tr>
</table>

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Data Sharing

Will individual participant data be available (including data dictionaries)?	Yes
What data in particular will be shared?	All of the individual participant data collected during the trial, after de-identification Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices)
What other documents will be available?	Study protocol, statistical analysis plan, informed consent form, case record form
When will data be available (start and end dates)?	Immediately following publication; no end date
With whom?	Anyone who wishes to access the data for further research in this field after signing an agreement
For what types of analyses?	Metaanalysis and observational studies
By what mechanism will data be made available?	Proposals should be directed to jeyarajpandian@hotmail.com; to gain access, data requestors will need to provide the details for the purpose of the study and analysis