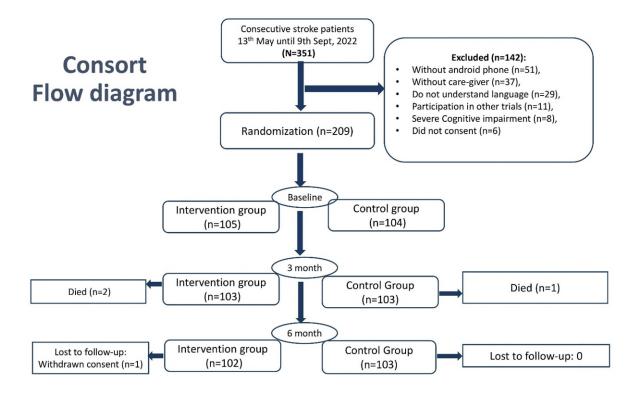
Study report of ISRCTN31718066 titled "Medication adherence and management of risk factors for secondary stroke prevention using smartphone based app".

Participant Flow

Of the 351 stroke survivors screened from May-Sept 2022, 209 were randomized to intervention(n=105) and control(n=104)arm(Figure.1:Consort diagram).

Fig1: Consort diagram



Baseline characteristics

The mean (SD) age of the participants in the intervention group was 60.3(11.5) years and that in the control group was 60.5(10.2) years. The baseline sociodemographic and clinical characteristics were comparable between the intervention and control groups except for tobacco users [20(19%) vs23(22.1%)] and participants with diabetes [58(55.2%)vs69(67%)] which was more in control group (Table 1).

Table 1: Table showing the baseline characteristics of the study participants(N=209)

	Intervention N=105 (n(%))	Control N=104 (n(%))
Age-Mean(SD)*	60.3(11.5)	60.5(10.2)
Gender-Male	80(76.2)	80(76.9)
Education		
Literate	104(99)	103(99)
Illiterate	1(1)	1(1)
Occupation		
Employed	103(81.9)	104(80.7)
Unemployed	17(16.2)	20(19.2)
BMI-Mean(SD)	24.6(5.6)	24.7(3.6)
First ever stroke	87(82.9)	82(78.8)
Type of Stroke		
Ischaemic Stroke	98(93.3)	99(95.2)
Haemorrhagic Stroke	6(5.7)	3(3.8)
Transient ischemic attack	1(0.95)	1(0.96)
Risk factors		
Hypertension	73(69.5%)	75(72.8%)
Diabetes	58(55.2)	69(67.0)

mRS (mean <u>+</u> SD) at recruitment	1.9(1.4)	1.8(1.5)
NIHSS score (median(IQR)) at recruitment	2(0-6)	2(0-7)
Exercise	43(40.9%)	43(41.3%)
Current alcohol users	35(33.3)	35(33.7)
Current tobacco users	2(1.9%)	10(9.6%)
Current smokers	20(19)	23(22.1)
Coronary Artery Disease	24(22.8)	21(10.0)
Atrial fibrillation	4(3.8)	3(2.9)
Hyperlipidaemia	29(27.6)	34(32.7)

Outcome measures

The outcome measures are shown in table 2.

Primary Outcome:-At baseline, mean(SD) medication adherence improved from 2.46(1.76) to 3.61(0.95) in the intervention group and from 2.44(1.78) to 2.88(1.32) in the control group (between group difference, 0.735(95% CI, 0.419-1.050), p<0.001)(Figure 3). After adjusting covariates, being in intervention group(p <0.001), having recurrent stroke(p=0.023) and those who had regular physician follow-up(p=0.040) had significantly better medication adherence.

From baseline to six months, mean(SD) FADS diet score improved from 2.1(1.3) to 4.7(1.3) in the intervention group and from 2.1(1.4) to 4.1(1.5) in the control group (between group difference=0.62(95% CI, 0.21-1.02),p=0.003The intervention group participants were physically more active(89.5% vs 71.2%,p=0.001)at six months.

At six months, mean fasting blood sugar(109.10±28.22 vs 125.5±51.5 mg/dL, p=0.005) and HDL cholesterol (48.60±16.4 Vs 43.87±12.54 mg/dL, p=0.024) were lower in the intervention group. No other risk factors showed any difference between intervention and control group(table2 and supplementary-material Figure:S2-S5). From baseline to 6 months, mean

(SD) mRS improved from 1.9(1.5) to 0.6(1.1) in the intervention group and from 1.8(1.5) to 0.76(1.0) in the control group (between group difference -0.075[95% CI:-0.374 to 0.223] %; p=0.619).

Secondary Outcome:- At six months, recurrent stroke occurred in five participants in control group and three in intervention group. One participant each in the intervention group had MI and TIA. From baseline to 6 months, mean (SD) mRS improved from 1.9(1.5) to 0.6(1.1) in the intervention group and from 1.8(1.5) to 0.76(1.0) in the control group (between group difference -0.075[95% CI:-0.374 to 0.223] %; p=0.619).

Adverse events

At six months, recurrent stroke occurred in five participants in control group and three in intervention group. One participant each in the intervention group had MI and TIA(table 3).

Table 2: Table showing the changes in outcome measures of the study population

		Baseline	3 rd month	6 th month	MD between groups in 6 th month	p-value between groups
		Mean(SD)	Mean (SD)	Mean(SD)	MD	p-value
Primary	Outco	me measures				1
Medicati	on-adh	erence				
	IG	2.46(1.76)	3.60(0.80)	3.61(0.95)	0.735 (0.419-1.05)	<0.001#
MMAS -4	CG	2.44(1.78)	2.83(1.27)	2.88(1.32		
Vascular	Risk fa	ctors	1			1
SBP	IG	151.01(22.95)	137.13(18.6)	134.15(20.83)	-0.266 (-6.02-5.49)	0.927 #
	CG	148.8(25.5)	137.4(21.6)	134.41(20.95)		
DBP	IG	87.25(13.82)	83.53(10.32)	82.09(12.51)	-0.16 (-3.17-2.83)	0.91#
	CG	88.27(12.5)	83.02(10.6)	82.25(8.98)		
HbA1C	IG	7.12(1.76)	6.5(1.17)	6.56(1.29)	-0.53 (-0.9609)	0.018 #
	CG	7.17(1.73)	6.9(1.5)	7.09(1.82)		
FBS	IG	117.37(36.24)	115.9(36.0)	109.10(28.22)	-16.43 (-27.91— 4.94)	0.005 #
	CG	125.53(51.5	117.3(45.8)	125.53(51.57)		
TC	IG	165.80(57.07)	141.1(31.0)	147.55(35.1 1)	0.39 (-8.7-9.49)	0.932#
	CG	160.8(47.55)	145.4(34.8)	147.16(30.47)		

TGL	IG	100.70(41.8)	100.8(41.4)	101.39(43.4)	-9.34 (-22.4-3.71)	0.160 #
	CG	116.7(93.04)	116.4(90.7)	110.73(50.3)		
HDL	IG	49.18(17.78)	48.1(15.8)	48.60(16.49)	4.72 (0.62-8.82)	0.024 #
	CG	96.8(12.6)	42.4(10.5)	43.87(12.54)		
LDL	IG	100.64(48.34)	76.0(25.8)	87.38(60.64)	7.02 (-6.21-20.26)	0.297 #
	CG	94.8(40.7)	79.9(26.0)	80.36(27.76)		
Behavior				147 (12)		_
FADS Score	IG	2.1 (1.3)	4.5 (1.4)	4.7 (1.3)	0.62 (0.21-1.02)	0.003 #
	CG	2.1 (1.4)	4.5 (1.5)	4.1 (1.5)		
Physica	IG	40(38.1%)	74(70.5%)	94(89.5%)	18.3% (7.47% - 28.7%)*	0.001*
activity	CG	38(36.5%)	71(68.3%)	74(71.2%)		
Smokin g, No(%)	IG	20(19)	0	2(1.96%)	0.99% (-3.56%- 5.96%) *	0.752 *
	CG	23(22.1)	1(1)	1(0.97%)		
Smokel	IG	2(1.9)	0	1(0.98)	0.96% (-3.62% - 5.88%)*	0.772 *
ess, No(%)	CG	10(9.6)	1(1)	2(1.94)		
Alcoho l, No(%)	IG	35(33)	4(3.8)	2(1.96)	3.86% (-1.95%- 10.32%*	0.332 *

Table 3: Table showing the adverse events at 6 months among the study population

Vascular events	Intervention Group	Control group	
	(n=105)	(n=104)	
	N(%)	N (%)	
TIA	1(0.95%)	1(0.96%)	
Recurrent Stroke	3(2.85%)	5(4.8%)	
Cardiac events	1(0.95%)	1(0.96%)	
Deaths	2(1.9%)	1(0.96%)	