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RESEARCH ARTICLE

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Effectiveness of a comprehensive physical activity promotion program on physical activity levels, mobility and quality of life in community-dwelling stroke survivors: a preliminary cluster randomised controlled trial

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ABSTRACT

Purpose: To determine the effectiveness of a comprehensive Physical activity (PA) promotion program on mobility, quality of life, and PA levels among people with stroke living in the community.

Methods: Four community health centres were randomly allocated to the two groups. Participants in the experimental group received a comprehensive PA promotion program over a period of 45 days, whereas control group received an education session. Participants mobility was measured using 6-minute walk test (6MWT) and 10-metre walk test (10MWT), quality of life was measured using Stroke specific quality of life (SSQoL) and PA levels were measured using Physical activity scale for individuals with physical disabilities (PASIPD), Global physical activity questionnaire (GPAQ), and accelerometers. Outcome measures were assessed at baseline, one month and three months post cessation of the intervention.

Results: Mean age of the participants was 58.49 ± 10.01 years ($n = 84$). There was a group–time interaction in 6MWT [F (1, 95) = 29.723, $p < 0.001$, $\eta^2 = 0.266$], fast walking speed [F (2, 125) =19.542, $p < 0.01$, $\eta^2 = 0.192$], quality of life [(F (2, 139)=21.844, $p < 0.001$, $\eta^2 = 0.210$)], PASIPD scores [F (2, 149) =13.548, $p < 0.001$, $\eta^2 = 0.142$], GPAQ total MET mins [F (2, 143) = 13.105, $p < 0.001$, $\eta^2 = 0.138$], and steps/day [F (1, 82) = 5.195, $p = 0.025$, $\eta^2 = 0.060$].

Conclusion: Comprehensive PA promotion program appears to improve mobility, quality of life and PA among community-dwelling people with stroke.

➤ IMPLICATIONS FOR REHABILITATION

- Comprehensive physical activity promotion program incorporating fun and engaging activities such as adaptive sports, context specific activities along with behaviour change techniques can be utilised to enhance physical activity levels of people with stroke.
- Comprehensive physical activity promotion program can be a model of continuum of care for people with stroke living in Low- or Middle-Income Countries where there is limited access to healthcare and leisure centres.
- The findings of the study suggest that a comprehensive physical activity promotion program can be implemented at the community level and allied health professionals can be trained to deliver/monitor this intervention.

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Accelerometers; adults with stroke; exercise; LMIC; step counts

Introduction

The global burden of ischaemic stroke has increased by 37%, whereas the burden of haemorrhagic stroke has increased by 47% in the last two decades [1,2]. Low-to-Middle-Income Countries (LMIC) bear the majority of the global stroke burden [3]. The incidence of recurrent stroke has increased three folds in the last two decades compared to the 1990s [4] and recurrent strokes are associated with higher stroke-related mortality [5]. Physical inactivity is one of the most important modifiable risk factors for stroke and noncommunicable disorders [6,7].

Sedentary lifestyle prevalent post stroke limits the performance of activities of daily living, increases the risk for falls, cardiovascular diseases, and recurrent stroke [8,9]. Regular Physical activity (PA) protects stroke survivors from the recurrent stroke [8], myocardial infarction, atherosclerosis, and peripheral vascular disease [7]. Along with other health benefits, regular participation in PA helps stroke

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survivors in the prevention of detrimental effects of bed rest such as electrolyte imbalance, reduced cardiac output, increased resting heart rate, loss of muscle strength, deep vein thrombosis, and orthostatic hypotension in the acute stage [7]. In addition, PA stimulates the release of Brain derived neurotrophic factor (BDNF) post stroke [10], which has shown to play a critical role in neuroplasticity and functional recovery post stroke [11]. Regular PA has also shown positive effects in management of post stroke fatigue [7–12].

Few studies from High Income Countries (HIC) have framed interventions to improve PA among stroke survivors but found inconsistent results [13–19]. Currently, there is low-quality evidence for interventions promoting PA in stroke globally [20,21] and scarcity of evidence on the same in LMICs. Structured exercise programs aimed at improving PA often fail due to lack of adherence to the program [16,19]. Additionally, PA is a complex, dynamic process that is determined by multiple factors such as the capability of the individual, motivation, and opportunities [22] and driven by reflective and impulsive actions [23] which potentially limit the success of intervention programs targeting single attributes that are responsible for PA participation. We hypothesised that a comprehensive PA promotion program which is based on the theories of behaviour change [22,23], delivered using behaviour change techniques [24] targeting multiple components of PA participation might enhance PA levels among people with stroke. We included context specific activities [25] and adaptive sports [26] into the PA promotion program as adherence to program improves when the activities are enjoyable [27], enagaging, and meaningful [28,29] to the individuals. To influence the motivation for the participation we integrated motivational counselling [30] into the PA promotion program along with the PA exercises in line with the global PA guidelines [7,31]. Therefore, the aim of this cluster randomised controlled trial was to test the effectiveness of a comprehensive PA promotion program on PA levels, mobility, and quality of life (QoL) among people with stroke living in the community.

Materials and methods

Design

We conducted a parallel group assessor-blinded cluster randomised controlled trial in people with chronic stroke. Institutional Ethics Committee approved the study protocol (IEC:47/2018). The study was registered in Clinical Trials Registry-India (CTRI/2019/05/019478). The study was conducted for a period of 16 months from October 2018 to January 2020 in coastal South India.

Participants

We included males or females with stroke with time since stroke of more than 6 months, were aged between 18–75 years, had ability to understand instructions and follow commands, were able to walk independently with or without assistive devices and were living in the community. We excluded adults with stroke if they had unstable cardiac disease, coexisting neurological condition, any other condition contraindicated for aerobic exercises, high risk of falls (Berg Balance Scale scores: 0–20), significant pain in lower limb or trunk (Visual analog scale score ≥ 6) or cognitive or communication impairments.

The sample size was calculated in priori based on the "comparison of means" formula using Easy-R software version 2.5-1. For the self-selected walking speed, considering a 95% confidence interval, 80% power, 5% type I error, standard deviation of 0.19 [32], a clinical significant difference of 0.16 [33], and addition of 20% drop out rate we needed a sample size of 28 in each group. To account for the cluster effect sample size was multiplied by 1.5 thus a total 84 participants were necessary.

Procedure

We used single-stage cluster sampling to recruit the participants. We screened people with stroke who were living in the region of four community-outreach centres of a medical university in the coastal southern part of India. The medical university conducts regular health surveys at these regions and contained medical records of the patients having various health conditions. The medical records of stroke survivors were accessed and used to contact and screen the potential participants. Stroke survivors were contacted through phone call for initial eligibility check, brief description of the study was given and their willingness to participate was inquired. Principal investigator and social worker visited homes of willing participants for screening, provided detailed information about the study and enrolled eligible participants into the study after obtaining written informed consent. Participants were asked to visit nearby community centre for baseline assessments and the participation in the study.

Randomisation

Four community centres were randomly allocated to experimental and control groups. Name of the centres were written in small paper, placed in sealed envelopes and JM randomly picked the envelops. Sequential order of experimental-control-experimental-control was chosen *a priori* for deciding the group allocation. Each centre is located around 6–10 km from each other, which would ensure the prevention of contamination between the groups. All people with stroke living in the region of each centre were screened.

Blinding

Participants were unaware of other groups intervention. But they were not blinded to the study group to which they belonged. An outcome assessor, a physiotherapist, trained in neurorehabilitation, was blinded to the study groups and measured the outcomes for all the participants.

Participant recruitment

Participants were called in a group of six to the community centre. On the first day, participants' baseline demographics were assessed. Participants' walking capacity was assessed using the 6-min walk test (6MWT) and walking speed was assessed using the 10-metre walk test (10MWT). The 6MWT was conducted as per the American Thoracic Society guidelines [34]. For the 10MWT, participants walked 10 metres, walking speed was measured for the intermediate 6 metres to allow for acceleration and deceleration. Both self-selected walking speed and fast walking speed were measured. Participants' PA levels were assessed using the Physical activity scale for individuals with physical disabilities (PASIPD), Global physical activity questionnaire (GPAQ), accelerometers, and QoL was assessed using Stroke specific quality of life (SSQoL). For accelerometry measurement participants were asked to wear the accelerometers for four days [35] during their waking hours from morning to night on their unaffected hip. Participants were also provided with a log to enter the time of wearing and removal of the accelerometer every day. Daily telephone reminders were provided to the participants to wear the device every day. After the preset stop time elapsed, the accelerometer was collected

from the participant and the data were extracted and saved using the Actilife version 6 software. All the accelerometry variables were reset to zero before providing the device to the next group of participants and the reactivation of the device was performed.

Control group (CG) treatment

The CG received one education session on stroke recovery, the importance of PA, education on methods to increase PA, and lifestyle modifications. Following the educational session, there was a discussion to clear the queries of the participants and caregivers. Participants were advised to continue participation in PA at home and caregivers were asked to encourage/assist PA participation.

Experimental group (EG) treatment

The participants in the EG received the intervention in seven sessions over a period of 45 days. In session 1 (day 1), participants and their caregivers were provided with education on stroke recovery, PA, and lifestyle modifications and a session was held to clear any doubts of the participants and their caregivers. In session 2 (days 3–5), clinical psychologist provided individualised counselling using motivational enhancement therapy. Additionally, participants were provided with a validated list of context-specific activities to incorporate in their daily routine (details provided in published article [25]). Participants had to select at least three activities from the list and they were asked to engage in these activities every day for a period of 10–15 min with an intensity of 4–6 in the modified Borg's Rate of Perceived Exertion scale. In session 3 (days 7–9), participants were taught aerobic exercises, strengthening exercises of large muscle groups of the limbs and trunk, balance, coordination, and flexibility exercises [7,31]. The principal investigator and two qualified neurological physiotherapists trained by the principal investigator, a clinical psychologist and a social worker were involved in the intervention delivery. Participants were advised to perform aerobic exercises every day for at least 30 min, strengthening exercises at least two times a week, and balance, coordination, and flexibility exercises at least 3 times a week. In session 4 (days 10–12), as per the balance ability, participants were taught to play group and individual adaptive sports that has been developed and validated earlier (details provided in published article [26]. Rules of the game and scoring were explained, adaptive sports were demonstrated, and a practice session was held. Participants were advised to play adaptive sports at home with their family members. In session 5 (days 22–25), exercises and activities instructed to the participants in the previous sessions were reviewed and exercises were progressed and practiced. Individualised counselling was given again to promote PA and a practice session was held on the adaptive sports. In session 6 (days 27–29), the activity scheduling session was held to promote the PA throughout the day and follow-up was performed on previous sessions to promote motivation. During activity scheduling participants were enquired about their daily schedule. Particular attention was given to the time of the day when participants sit or simply spend lying down continuously for at least 30 min during their waking hours. The participant reported time was cross-checked with the sedentary counts' data of baseline accelerometry assessment. Strategies were developed to target this sedentary behaviour and delivered to the participants during the activity scheduling session. For instance, the majority of the participants reported continuously sitting in the late evening or night for watching television. Such sedentary activities were targeted by asking the participants to get up after every 30 min and walk for at least 1000 steps or 10 min throughout their waking hours. The instructions were included in the activity scheduling sheet for avoiding forgetfulness. *Session 7 (Day 45–47)* was an empowerment session to provide feedback on how participants were progressing, celebrate their progress and to share the observations they have made on their physical and mental health status because of engaging in PA. Participants were encouraged to maintain their PA engagement and adopt it as a lifestyle habit. EG participants were also provided with motivational messages and daily reminders to be active through short messaging services on their phones. The trial was stopped after achieving the pre-specified sample size.

Monitoring

Monitoring of the exercises, and activities taught earlier was performed in the subsequent sessions until the completion of the intervention sessions. To monitor the compliance with the program, participants were provided with the logbooks with the type, intensity, and duration of activity to be recorded every day. Participants were also asked to record adverse events or safety issues that they have encountered during or as a result of participation in the program.

Outcome measures

Outcome assessments were performed after randomisation. The 6MWT, 10MWT, and SSQoL were considered as the primary outcome measures, PASIPD, GPAQ, and Accelerometery measurements were considered as the secondary outcome measures. We assessed all the outcome measures at baseline, one month, and three months after the cessation of the intervention except accelerometry measurements. Accelerometry assessment was performed at baseline and three months post-cessation of the intervention. Mobility was measured using walking capacity and walking speed. Participants' walking capacity was measured with the 6MWT. The 6MWT has excellent test-retest reliability [36] and inter-rater reliability [37]. The 10MWT was used to measure comfortable and fast walking speeds. It has excellent reliability for comfortable and fast speeds [38,39]. SSQoL was used to measure QoL. It has adequate to excellent internal consistency [40], excellent test-retest reliability [41], and inter-rater reliability [40]. We used both subjective and objective outcome measures to assess PA. The PASIPD and GPAQ were used to measure subjective PA levels and accelerometers were used to measure objective free-living PA of the participants. PASIPD is a recall questionnaire that considers the past seven days of PA. PASIPD scores varies from 0.0 MET.hr/day to 199.5 MET.hr/day [42]. PASIPD has been found to be valid and reliable to measure PA in individuals with physical disabilities and has a good test-retest reliability [43]. The GPAQ consists of 16 questions, and it obtains information on PA participation in 3 domains, i.e., activities at work, travel to and from places, and recreational activities. Also, it has a single question on sedentary behaviour. The GPAQ has fair to moderate validity with the accelerometer [44] and has moderate agreement for MVPA mins/day with accelerometer and poor agreement for sedentary behaviour [45].

COVID-19 contingency plans

Due to COVID-19 pandemic and government-imposed lockdowns and restrictions, intervention for some of the EG participants had to be delivered at participants' homes instead of community health centres. Based on the setting of intervention delivery these participants were divided as "centre-based intervention ($n=19$)" and "home based intervention ($n=23$)" groups. The caregivers were asked to participate in the interventions that required group therapy.

Data analysis

IBM SPSS version 28.0 (IBM Corp., Armonk, NY) was used to analyse the data. Baseline characteristics were reported using descriptive statistics. A Pearson chi-squared test was used to analyse the

categorical variables and independent samples *t*-test was used to analyse the continuous variables at baseline. Intention to treat analysis was used to analyse the data. To determine the changes in each dependent variable across baseline (T0), 1 month post cessation of intervention (T1), and 3 months post cessation of intervention (T2), two way repeated-measure analyses of variance (RANOVA) was conducted. The assumption of sphericity was checked using Mauchly's sphericity test; if it wasn't fulfilled, the Greenhouse-Geisser correction was used for interpretation. Repeated-measure analyses of variance (RANOVA) were conducted to within-group (time factor), between-group (group factor), and time-group interaction analysis, with *post hoc* test by Bonferroni test. Effect sizes were calculated using eta squared (ŋ2). Based on the GPAQ scores, participants performing less than 150 min of MVPA per week were categorised as "sedentary", those performing 150 to 300 min of MVPA per week were categorised as "active" and those performing more than 300 min of MVPA per week were categorised as "highly active" underpinned by PA guidelines [31]. The proportion of participants meeting the different PA categories (sedentary, active, and highly active) between EG and CG was analysed using the chi-square test. The wear-time and non-wear time of participants were compared using the independent samples *t*-test. The centre-based intervention group and home-based intervention group were compared using the RANOVA. Bonferroni corrections were applied to reduce the likelihood of type I error when there were multiple statistical comparisons. The level of significance was set at $p \leq 0.05$ for the RANOVA.

Results

Participants

A total of 287 community-dwelling stroke survivors were assessed for eligibility out of which 125 stroke survivors were eligible to participate in the study. Eighty-four stroke survivors were recruited after obtaining their written consent. There was a drop out of one participant from the EG and three participants from the CG due to the reasons provided below at one-month post intervention follow-up. The recruitment rate was 67% and retention rate in the program was 95%. Flow diagram of participant recruitment has been depicted in Figure 1.

The number of male participants (78.57%) was higher than the female participants (21.43%) and most of the participants had an ischaemic stroke (63.1%) compared to haemorrhagic stroke (36.9%). Demographic characteristics of the participants' are presented in Table 1 and additional details on the stroke characteristics are represented in Appendix A.

As shown in Table 2, Comprehensive PA promotion program had a significant effect on mobility outcomes such as 6MWT [F (1, 95) = 29.723, $p < 0.001$, $\eta^2 = 0.266$], Fast walking speed [F (2, 125) =19.542, $p < 0.01$, $\eta^2 = 0.192$], SSQoL scores [(F (2, 139)=21.844, $p < 0.001$, $\eta^2 = 0.210$), PASIPD scores [F (2, 149) =13.548, $p < 0.001$, $\eta^2 = 0.142$]. GPAQ total MET mins [F (2, 143) = 13.105, $p < 0.001$, $\eta^2 = 0.138$], GPAQ sedentary activity [F (2, 133) = 17.397, $p < 0.001$, $\eta^2 = 0.175$].

Post hoc analysis confirmed significant within group improvements in 6MWT in the experimental group from T0 to T1 [MD = 45.13, $p < 0.001$, 95% CI (29.29, 60.77)] and T0 to T2 [MD = 47, $p < 0.001$, 95% CI (29.65, 64.35)]. 6MWT improved significantly at T1 [MD = 52.91, $p = 0.034$, 95% CI (4.06, 101.74)] in the EG compared to the CG. There were significant between group differences in the self-selected walking speed at T1 [MD=-0.15, $p = 0.022$, 95% CI (-0.28, −0.22)] and T2 [MD=-0.14, $p = 0.048$, 95% CI (-0.28, −0.00)]. EG demonstrated significant within group improvements from T0 to T1 [MD = 0.12, $p < 0.001$, 95% CI (0.06, 0.17)], and T0 to T2 [MD = 0.15, $p < 0.001$, 95% CI (0.07, 0.23)] in the fast-walking speed. Also, fast walking speed improved significantly in the EG compared to CG at T1 [MD= − 0.18, $p = 0.045$, 95% CI (-0.36, −0.00)].

In SSQoL, there were significant within group improvements in the EG from T0 to T1 [MD = 20.07, $p < 0.001$, 95% CI (14.23, 25.91)], and T0 to T2 [MD = 19.07, $p < 0.001$, 95% CI (12.12, 26.02)]. Also, SSQoL improved significantly in EG compared to CG at T1 [MD= 32.48, $p < 0.001$, 95% CI (17.20, 47.75)] and T2 [MD= 35.57, $p < 0.001$, 95% CI (20.27, 50.88)].

In PASIPD, there were significant within group differences in the EG from T0 to T1 [MD = 5.10, $p < 0.001$, 95% CI (3.52, 6.68)], and from T1 to T2 [MD= − 2.50, $p < 0.001$, 95% CI (-3.72, −1.29)]. Also, there were significant within group differences in the CG between T1 and T2 [MD= −1.54, $p = 0.008$, 95% CI (-2.76, −0.33)] in PASIPD.

EG demonstrated significant within group differences in GPAQ total scores from T0 to T1 [MD = 1325.71, $p < 0.001$, 95% CI (839.14, 1812.28)], T1 to T2 [MD=-717.62, $p < 0.001$, 95% CI (-1059.27, −375.97)] and T0 to T2 [MD= 608.09, $p = 0.004$, 95% CI (160.20, 1055.99)].

EG demonstrated significant within group differences for the sedentary activity measured using GPAQ from T0 to T1 [MD= −84.29, $p < 0.001$, 95% CI (-115.59, −52.99)], T1 to T2 [MD = 30, $p = 0.001$, 95% CI (9.89, 50.11)] and T0 to T2 [MD= −54.29, $p < 0.001$, 95% CI (-84.90, −23.67)]. Also, there was significant within group difference in the sedentary activity in CG from T1 to T2 [MD= 34.29, $p < 0.001$, 95% CI (14.17, 54.39)].

The proportion of participants achieving different PA categories

A higher proportion of participants achieved active, and highly active status in the EG than in the CG at T1 (χ^2 = 12.55 (2), $p = 0.002$*) and T2 (χ^2 = 9.07 (2), $p = 0.011$*). Comparison of proportions between the groups showed a 55.1% decrease in the number of sedentary participants in the EG compared to a 0.0% decrease in the CG at T2. Additionally, there was a 42.8% increase in the percentage of participants achieving PA level for health benefits (>300 min/week) compared to a 7.1% reduction of the same in the CG at T2 (Appendix B).

Accelerometry variables

Accelerometry measurements were performed at baseline and 3 months post intervention. At baseline, the mean wear time for the EG was 623.14 (199.35) minutes, and that for the CG was 641.90 (251.71) minutes. At the follow up, the mean wear time for the EG was 574.93 (178.19) minutes and that for the CG was 590.19 (313.95) minutes. There was no significant difference between the groups for wear time either at baseline (MD = 18.76, CI −79.87 to 117.40, $p = 0.71$) or follow-up (MD = 15.26, CI −95.99 to 126.51; $p = 0.79$).

Comprehensive PA promotion program had a significant effect on Average kcals/day [F (1, 82) = 8.184, $p = 0.005$, $\eta^2 = 0.091$] and steps/day [F (1, 82) = 5.195, $p = 0.025$, $\eta^2 = 0.060$] as shown in Table 3. Post hoc analysis showed significant within group improvement in the EG for average kcals per day [MD = 65.46, $p < 0.001$, 95% CI (35.02, 95.90)] and steps per day [MD = 966, $p < 0.001$, 95% CI (393.06, 1538.95)] measured using accelerometers.

Subgroup analysis

Comparison of outcomes between the centre-based intervention group and home based intervention group showed no difference

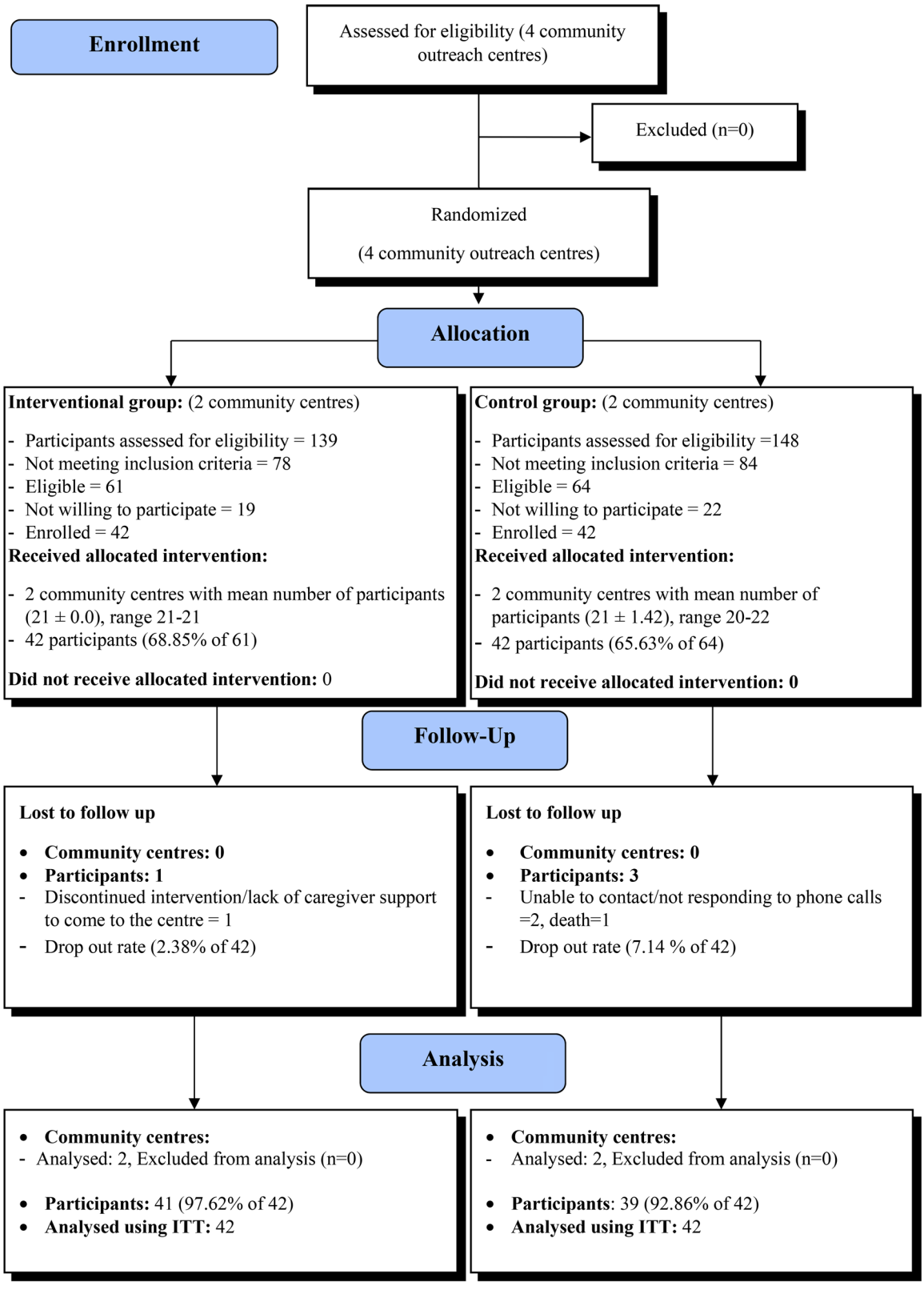

Figure 1. CONSORT flow diagram of participant recruitment.

between the groups for majority of the outcome measures. However, there was a statistically significant time-group interaction effect for PASIPD scores [F (1, 54) = 3.714, $p = 0.047$, $\eta^2 = 0.085$)] and SSQoL scores [F (1, 55)= 11.044, $p < 0.001$, $\eta^2 = 0.216$).

In *post hoc* analysis, there were significant within group differences in PASIPD scores in the centre-based group from T0 to T1 [MD = 3.74, $p = 0.005$, 95% CI (1.19, 6.27)], and T1 to T2 [MD= −3.08, $p < 0.001$, 95% CI (-4.33, −1.84)]. Also, there were significant within group differences in PASIPD in the home-based group from T0 to T1 [MD= 6.23, $p < 0.001$, 95% CI (3.93, 8.53)], T1 to T2 [MD= − 2.03, $p < 0.001$, 95% CI (-3.15, −0.89)], and T0 to T2 [MD= 4.21, $p < 0.001$, 95% CI (2.38, 6.04)]. Also, there was a significant

Table 1. Baseline characteristics of the participants ($n = 84$).

	Experimental ($n = 42$)	Control ($n = 42$)	P
Gender: n (%)			0.183
Male	36 (85.7)	30 (71.4)	
Female	6 (14.3)	12 (28.6)	
Age (*yr*), mean (SD)	57.64 (9.63)	59.3 3 (10.43)	0.443
Height (cm), mean (SD)	160.07 (12.83)	159.72 (8.66)	0.882
Weight (kg), mean (SD)	67.36 (11.64)	60.89 (11.55)	0.120
BMI (kg/m^2), mean (SD)	26.41 (4.44)	23.78 (3.57) *	0.004
Time since stroke (months), mean (SD)	74.40 (60.82)	80.36 (96.93)	0.737
Type of stroke (%)			0.366
Ischaemic	24 (57.1)	29 (69.0)	
Haemorrhagic	18 (42.9)	13 (31.0)	
Side of the lesion (%)			0.190
Left	24 (57.1)	17 (40.5)	
Right	18 (42.9)	25 (59.5)	
Education (*yr*), mean (SD)	8.17 (3.53)	6.60 (4.67)	0.086
Baseline FMA UE total, mean (SD)	91.05 (32.67)	100.50 (23.74)	0.133
Baseline FMA LE total, mean (SD)	69.07 (9.81)	74.86 (10.72)*	0.012
Baseline FMA total, mean (SD)	170.71 (41.49)	185.9 (33.27)	0.068
BBS, mean (SD)	39.69 (6.59)	42.09 (9.06)	0.169
BBS: n (%)			0.187
Medium fall risk (21–40)	20 (42.6)	15 (35.71)	
Low fall risk (41–56)	22 (57.4)	27 (64.28)	
Outcome measures at baseline			
6MWT (m)	172.24 (121.44)	275.13 (112.29)*	<0.001
10MWT – Self-selected walking speed *(m/s)*	0.55 (0.81)	0.68 (0.26)	0.300
10MWT – Fast walking speed *(m/s)*	0.54 (0.41)	0.90 (0.35)*	<0.001
SSQoL	160.05 (34.59)	145.45 (35.09)	0.058
PASIPD	2.64 (4.41)	4.65 (6.27)	0.093
GPAQ Total MET mins/week	1238.57 (2120.77)	1741.43 (1508.39)	0.214
GPAQ Sedentary activity (mins/day)	417.14 (135.76)	364.29 (134.09)	0.076
Average kcals/day	131.61 (125.02)	137.59 (95.03)	0.403
METs/day	1.05 (0.06)	1.05 (0.05)	0.783
Percentage of MVPA/day	1.12 (1.48)	1.05 (1.17)	0.797
Steps/day	3145.56 (2937.37)	3705.83 (2819.05)	0.375

EG – Experimental group; CG – Control group; BMI – Body mass index; FMA – Fugl Meyer sensorimotor assessment scale; BBS – Berg balance scale; 6MWT – 6 min Walk Test; 10MWT – 10 m walk test; GPAQ – Global Physical Activity Questionnaire; MET – metabolic equivalent of tasks; m – metres; m/s – metres per second; MVPA – moderate-vigorous physical activities; PASIPD – Physical activity scale for individuals with physical disabilities; SSQoL – Stroke specific quality of life.
*Significant difference between the groups ($p \le 0.05$).

Table 2. Comparison of mobility and physical activity outcomes between the experimental and control groups at baseline (*T0*), one month post cessation of intervention (*T*1), and three months post cessation of intervention (*T*2).

Outcome	Group	*T*0	*T*1	*T*2		*F*	P	*Eta*
6MWT (m)	EG	172.24 (121.44)	217.37(110.10)*	219.24 (109.33) *	Time	15.688	$p < 0.001$	0.161
	CG	275.13 (112.29)$^+$	270.27 (114.86)$^+$	265.56 (117.18)	Group	7.560	0.007	0.084
					Time x Group	29.723	$p < 0.001$	0.266
10MWT – Self-selected walking speed *(m/s)*	EG	0.55 (0.81)	0.51 (0.33)	0.52 (0.35)	Time	0.220	0.646	0.003
	CG	0.68 (0.26)	0.66 (0.26)$^+$	0.66 (0.29)$^+$	Group	4.061	0.047	0.047
					Time x Group	0.010	0.925	0.000
10MWT – Fast walking speed *(m/s)*	EG	0.54 (0.41)$^+$	0.66 (0.46)*	0.69 (0.49)*	Time	3.225	0.056	0.038
	CG	0.90 (0.35)	0.84 (0.35)$^+$	0.85 (0.39)	Group	7.061	0.009	0.079
					Time x Group	19.542	<0.001	0.192
SSQoL	EG	160.05 (34.59)	180.12 (31.60)*	179.12 (32.28)*	Time	23.177	<0.001	0.220
	CG	145.45 (35.09)	147.64 (38.45)$^+$	143.55 (37.91)$^+$	Group	13.861	<0.001	0.145
					Time x Group	21.844	<0.001	0.210
PASIPD	EG	2.64 (4.41)	7.74 (4.54)*	5.23 (3.45)$^\#$	Time	25.335	<0.001	0.236
	CG	4.65 (6.27)	5.51 (6.46)	3.97 (4.65)$^\#$	Group	0.246	0.621	0.003
					Time x Group	13.548	<0.001	0.142
GPAQ Total MET mins/week	EG	1238.57 (2120.77)	2564.29 (2315.86)*	1846.67 (1417.33)*$^\#$	Time	17.076	<0.001	0.172
	CG	1741.43 (1508.39)	1819.05 (1584.17)	1508.10 (1236.94)	Group	0.303	0.583	0.004
					Time x Group	13.105	<0.001	0.138
GPAQ Sedentary activity (mins/day)	EG	417.14 (135.76)	332.86 (113.38)*	362.86 (114.73)*$^\#$	Time	16.168	<0.001	0.165
	CG	364.29 (134.09)	360.00 (143.95)	394.29 (128.51)$^\#$	Group	0.005	0.943	0.000
					Time x Group	17.397	<0.001	0.175

EG – Experimental group ($n = 42$); CG – Control group ($n = 42$); *T*0 – baseline; *T*1 – 1 month post cessation of intervention; *T*2 – 3 months post cessation of intervention; 6MWT – 6 min Walk Test; 10MWT – 10 m walk test; GPAQ – Global Physical Activity Questionnaire; MET – metabolic equivalent of tasks; m – metres; m/s – metres per second; PASIPD – Physical activity scale for individuals with physical disabilities; SSQoL – Stroke specific quality of life.
*Significant difference when compared with T0 ($p \le 0.05$).
Significant difference when compared with T1 ($p \le 0.05$).
+ Significant difference between the groups ($p \le 0.05$).

Table 3. Comparison of accelerometery outcome variables between the experimental and control groups at baseline (*T0*) and three months post cessation of intervention (*T2*).

Outcome	Group	*T0*	*T2*		*F*	P	*Eta*
Avg kcals/day	EG	131.61 (125.02)	197.07 (159.29)*	Time	10.170	0.002	0.110
	CG	137.59 (95.03)	141.14(101.83)	Group	1.036	0.312	0.012
				Time x Group	8.184	0.005	0.091
METs/day	EG	1.05 (0.06)	1.11 (0.16)*	Time	12.400	<0.001	0.131
	CG	1.05 (0.05)	1.07 (0.08)	Group	1.272	0.263	0.015
				Time x Group	1.912	0.170	0.023
Percentage of MVPA/day	EG	1.12 (1.48)	2.78 (3.92)*	Time	16.546	<0.001	0.168
	CG	1.05 (1.17)	2.19 (3.13)*	Group	0.486	0.488	0.006
				Time x Group	0.551	0.460	0.007
Steps/day	EG	3145.56 (2937.37)	4111.56 (3350.53)*	Time	6.071	0.016	0.069
	CG	3705.83 (2819.05)	3743.43 (3005.96)	Group	0.023	0.879	0.000
				Time x Group	5.195	0.025	0.060

EG – Experimental group ($n = 42$); CG – Control group ($n = 42$); *T0* – baseline, *T2* – 3 months post cessation of intervention; MET – metabolic equivalent of tasks; MVPA – moderate-vigorous physical activities.
*Significant difference when compared with T0 ($p \leq 0.05$).

difference in the PASIPD scores between the groups at T0 [MD= 3.54, $p = 0.008$, 95% CI (0.98, 6.11)].

Centre based group showed significant within group improvements in SSQoL from T0 to T1 [MD = 30.16, $p < 0.001$, 95% CI (23.26, 37.06)], and T0 to T2 [MD = 30.63, $p < 0.001$, 95% CI (21.28, 39.98)]. Also, SSQoL improved significantly in the home-based group from T0 to T1 [MD = 11.74, $p < 0.001$, 95% CI (5.47, 18.01)], and T0 to T2 [MD = 9.52, $p = 0.029$, 95% CI (1.03, 18.02)]. Appendix C represents the outcome variables between the groups at T0, T1 and T2.

No adverse events or safety issues were reported by the participants or their caregivers as a result of the participation in the comprehensive PA promotion program.

Discussion

This study determined the effectiveness of a comprehensive PA promotion program on mobility, QoL, and PA levels in community-dwelling stroke survivors. Results showed significant improvements in the 6-min walk distance, fast walking speed, PASIPD scores, GPAQ scores and quality of life scores in the EG compared to the CG. Objective outcome measures such as average kcals/day, and steps/day improved significantly in the EG from baseline to 3 months post cessation of intervention.

There was a good uptake of the PA program among stroke survivors and no adverse events indicating PA program is feasible among community-dwelling stroke survivors. The observed change in walking capacity (46 metres) was greater than the minimal clinically important difference of 34.4 metres for stroke [46]. Engaging in the context specific activities in the community along with engaging in balance and strengthening exercises would have helped to improve participants' exercise tolerance leading to improved walking capacity [47]. Limited cardiorespiratory fitness and poor walking economy are common problems poststroke [48]. The program delivered in the present study included aerobic, strengthening, and balance exercises [47] which might have helped to reduce the energy cost of walking in the stroke survivors leading to improved walking capacity [48]. Participating in the context specific activities [48] in the natural environment along with the strengthening of the trunk muscles [49–51] could have helped to improve walking speed in our participants. Exercises targeting trunk muscle strength also positively influence walking speed [52]. Trunk muscle strengthening helps to transfer the centre of gravity during the swing phase and provides stable neuromuscular foundation and precise muscular control for locomotion [53]. A recent systematic review has demonstrated that supervised exercises delivered in accordance with the American Stroke Association PA guidelines improve mobility in stroke [54]. Our findings emphasise that performing exercises targeted to improve PA in an unsupervised free-living condition also has the potential to improve mobility after stroke. This finding is significant to the LMICs such as India as most of the chronic stroke population in LMICs either cannot afford or does not have access to supervised exercise facilities [55].

At the end of 3 months, there was a higher improvement in the QoL scores of the EG compared to a slight decrease in the CG. Improved PA in the EG could have led to an improvement in the QoL [56]. PA has been proven to provide both physical and psychological advantages [56]. Physical benefits such as improved motor function and better fitness along with mental benefits [57] such as improved mood and psychological well-being would have facilitated the participants for better social functioning leading to the improved QoL among the participants [58].

PA levels measured using PASIPD, GPAQ, and accelerometers showed higher improvements in PA among EG participants. Higher participation in PA could have been possible due to multifaceted nature of intervention which utilised behaviour change techniques [23], motivational counselling [30], activity scheduling, short bouts of activity to target sedentary behaviour [59], group exercises, context specific activities [23,60,61] and fun and engaging adaptive sports [26,27]. Our comprehensive PA promotion program included the ingredients essential for a successful behaviour change. Successful behaviour change is influenced by capability, opportunity, and motivation [22]. Hence, we aimed to include the activities which are within the abilities of stroke survivors to perform and provide sufficient opportunities for their performance. QoL scores of the centre-based intervention group were significantly higher than the home-based intervention group at 3 months. Greater opportunity for social interaction, responsibility to the team-mates, and social evaluation would have led to improved health outcomes and better quality of life in this group [62].

This is one of the first studies targeting PA promotion in stroke survivors living in LMICs. The present study utilised behaviour change techniques grounded in theory to improve PA levels among stroke survivors. Further, we utilised a combination of subjective and objective measures to assess PA which improves the validity of PA measurements. There are some limitations to the study. First, there were statistically significant differences in the outcome measures at baseline with EG having lower scores than CG. We screened all the participants living in the study region and included all eligible participants until the

sample size was reached which could have led to baseline differences between the groups. Though this methodology would have provided representative data for stroke survivors living in these regions of southern India, the baseline differences could indicate higher room for improvement in the EG compared to the CG, therefore our findings must be interpreted with caution. Second, restriction of participation to individuals with higher balance scores could mean that our results are applicable only to stroke survivors with higher balance ability. Third, all our participants were independent ambulators without walking aids, therefore our findings are applicable only to the population with similar demographics. Fourth, the protocol had to be amended to deliver the intervention at participants' residences instead of community centres as proposed due to restrictions on social gatherings caused by COVID-19.

Conclusion

Comprehensive PA promotion program appears to improve mobility, QoL, and PA levels in community-dwelling people with stroke. This programme can be incorporated into clinical practice among people with stroke living in LMICs where there is limited access to healthcare and fitness/leisure centres. This programme can be incorporated at community level and other allied health professionals can be trained to deliver/monitor this intervention at their first contact with community-dwelling people with stroke. In future, we could consider conducting a robust multicentre trial to test the effectiveness of this program on a wider population and can evaluate the cost effectiveness of this programme.

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Authors' contributions

Pradeepa Nayak was involved in literature search, conceptualisation, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, and writing (original draft). John M Solomon and Senthil D Kumaran were involved in conceptualisation, funding acquisition, supervision, and writing (review and editing). Amreen Mahmood was involved in validation, resources and writing (review and editing). Manikandan Natarajan, and Bhaskaran Unnikrishnan were involved in validation, funding acquisition, and writing (review and editing).

Disclosure statement

The authors report there are no competing interests to declare.

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Appendices

Appendix A. Stroke characteristics of the participants

Group	Experimental ($n=42$)	Control ($n=42$)
Type of stroke (%)		
Ischaemic	24 (57.1)	29 (69.0)
Haemorrhagic	18 (42.9)	13 (31.0)
Side of the lesion (%)		
Left	24 (57.1)	17 (40.5)
Right	18 (42.9)	25 (59.5)
Stroke sub-type (%)		
Large artery	38 (90.5)	34 (81.0)
Lacunar	3 (7.1)	5 (11.9)
Other – (carotid dissection, etc.)	1 (2.4)	3 (7.1)
Stroke location (%)		
Cortical – IC, MCA, frontal	24 (57.2)	22 (52.4)
Subcortical – thalamus, BG	14 (33.3)	16 (38.1)
Midbrain – pons, medulla, cerebellum/brainstem	4 (9.5)	4 (9.5)
Undetermined	0 (0.0)	0 (0.0)
Hand movement at stroke onset (%)		
No	36 (85.7)	29 (69.0)
Yes	6 (14.3)	13 (31.0)
Ability to walk independently at stroke onset (%)		
No	41 (97.6)	28 (66.7)
Yes	1 (2.4)	14 (33.3)
Premorbid walking status (%)		
Independent without walking aid	42 (100.0)	42 (100.0)
Independent with walking aid	0 (0.0)	0 (0.0)
Walks with human assistance (dependent)	0 (0.0)	0 (0.0)
Premorbid living arrangements (%)		
Living alone	1 (2.4)	0 (0.0)
Living with family	41 (97.6)	42 (100.0)
Premorbid living arrangements (%)		
Living at home	42 (100.0)	42 (100.0)
Supported accommodation	0 (0.0)	0 (0.0)
Premorbid Modified Rankin Scale (%)		
0 – No symptoms	42 (100.0)	42 (100.0)
1 – No significant disability despite symptoms	0 (0.0)	0 (0.0)
2 – Slight disability	0 (0.0)	0 (0.0)
3 – Moderate disability	0 (0.0)	0 (0.0)
Present Functional Status (Modified Rankin Scale) (%)		
0 – No symptoms	0 (0.0)	1 (2.4)
1 – No significant disability despite symptoms	7 (16.7)	6 (14.3)
2 – Slight disability	12 (28.6)	19 (45.2)
3 – Moderate disability	17 (40.5)	12 (28.6)
4 – Moderately severe disability	6 (14.3)	4 (9.5)
Currently employed		
No	39 (92.9)	35 (83.3)
Yes	3 (7.1)	7 (16.7)

Appendix B. Comparison of the proportion of participants achieving different PA categories between the groups

Time point	Categories	Experimental (n, %)	Control (n, %)	Pearson's χ^2 (df)	Chi^2 test p value
Baseline	Sedentary	24 (57.1)	12 (28.6)	7.361 (2)	0.025
	Active	5 (11.9)	6 (14.3)		
	Highly active	13 (31.0)	24 (57.1)		
1 month	Sedentary	1 (2.4)	13 (31.0)	12.552 (2)	0.002*
	Active	8 (19.0)	7 (16.7)		
	Highly active	33 (78.6)	22 (52.4)		
3 months	Sedentary	2 (4.8)	12 (28.6)	9.066 (2)	0.011*
	Active	9 (21.4)	9 (21.4)		
	Highly active	31 (73.8)	21 (50.0)		

Sedentary = <150 mins MVPA/week; active = 150–300 mins MVPA/week; highly active > 300 mins/week; $p \leq 0.0166$ is significant after Boneferroni corrections.

Appendix C. Comparison of the outcome measures between Centre-based intervention and home-based intervention groups at baseline (*T0*), one month post cessation of intervention (*T1*), and three months post cessation of intervention (*T2*)

Variable	Group	*T0*	*T1*	*T2*		*F*	P	*Eta*
6MWT (m)	CB	195.21 (152.94)	236.18 (123.73)	235.79 (121.48)	Time	28.619	<0.001	0.417
	HB	153.26 (86.69)	201.83 (97.49)	205.57 (98.84)	Group	1.070	0.307	0.026
					Time x Group	0.365	0.557	0.009
10MWT – Self-selected walking speed *(m/s)*	CB	0.79 (1.16)	0.63 (0.40)	0.65 (0.42)	Time	0.120	0.732	0.003
	HB	0.35 (0.18)	0.40 (0.23)	0.40 (0.22)	Group	8.228	0.007	0.171
					Time x Group	0.587	0.449	0.014
10MWT – Fast walking speed *(m/s)*	CB	0.71 (0.53)	0.85 (0.55)	0.90 (0.61)	Time	27.451	<0.001	0.407
	HB	0.41 (0.21)	0.50 (0.29)	0.52 (0.31)	Group	6.878	0.012	0.147
					Time x Group	1.528	0.226	0.037
SSQoL	CB	153.32 (37.83)	183.47 (30.34)*	183.95 (28.70)*	Time	46.994	<0.001	0.540
	HB	165.61 (31.44)	177.35 (33.02)*	175.13 (35.25)*	Group	0.008	0.929	0.000
					Time x Group	11.044	<0.001	0.216
PASIPD	CB	4.58 (6.01)	8.31 (4.95)*	5.23 (3.66)#	Time	27.705	<0.001	0.409
	HB	1.03 (0.94)+	7.26 (4.23)*	5.24 (3.35)*#	Group	2.325	0.135	0.055
					Time x Group	3.714	0.047	0.085
GPAQ Total MET mins/ week	CB	2262.11 (2820.37)	3688.42 (3042.76)	2549.47 (1842.15)	Time	25.049	<0.001	0.385
	HB	393.04 (470.73)	1635.65 (653.55)	1266.09 (433.82)	Group	11.397	0.002	0.222
					Time x Group	2.258	0.111	0.053
GPAQ Sedentary activity (mins/day)	CB	315.79 (99.68)	246.32 (59.65)	281.05 (80.13)	Time	30.156	<0.001	0.430
	HB	500.87 (100.09)	404.35 (96.10)	430.43 (93.39)	Group	43.181	<0.001	0.519
					Time x Group	1.483	0.235	0.036
Avg kcals/day	CB	137.92(159.58)		175.63 (155.10)	Time	10.956	0.002	0.215
	HB	126.40 (90.73)		214.78 (163.95)	Group	0.117	0.734	0.003
					Time x Group	1.768	0.191	0.042
Steps/day	CB	3366.17(3563.60)		4255.25 (3474.81)	Time	10.863	0.002	0.214
	HB	2963.33 (2369.11)		3992.87 (3318.10)	Group	0.124	0.726	0.003
					Time x Group	0.058	0.811	0.001

CB – Centre based intervention group (n = 19); HB – Home based intervention group (n = 23); T0 – Baseline; T1 – 1 month post cessation of intervention; T2 – 3 months post cessation of intervention; 6MWT – 6 Minute Walk Test; 10MWT – 10 metre walk test; GPAQ – Global Physical Activity Questionnaire; MET – metabolic equivalent of tasks; m – metres; m/s – metres per second; MVPA – moderate-vigorous physical activities; PASIPD – Physical activity scale for individuals with physical disabilities; SSQoL – Stroke specific quality of life.

*Significant difference when compared with T0 ($p \leq 0.05$)

Significant difference when compared with T1 ($p \leq 0.05$)

+ Significant difference between the groups ($p \leq 0.05$)