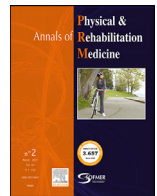




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Original article

Effect of mixed and collective physical activity in chronic stroke rehabilitation: A randomized cross-over trial in low-income settings

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ABSTRACT

Background: The prevalence of physical inactivity after stroke is high and exercise training improves many outcomes. However, access to community training protocols is limited, especially in low-income settings.

Objective: To investigate the feasibility and efficacy of a new intervention: Circuit walking, balance, cycling and strength training (CBCS) on activity of daily living (ADL) limitations, motor performance, and social participation restrictions in people after stroke.

Methods: Forty-six community-dwelling individuals with chronic stroke who were no longer in conventional rehabilitation were randomized into an immediate CBCS group (IG; initially received CBCS training for 12 weeks in phase 1), and a delayed CBCS group (DG) that first participated in sociocultural activities for 12 weeks. In phase 2, participants crossed over so that the DG underwent CBCS and the IG performed sociocultural activities. The primary outcome was ADL limitations measured with the ACTIVLIM-Stroke scale. Secondary outcomes included motor performance (balance: Berg Balance Scale [BBS], global impairment: Stroke Impairment Assessment Set [SIAS] and mobility: 6-minute and 10-metre walk tests [6MWT and 10mWT] and psychosocial health [depression and participation]). Additional outcomes included feasibility (retention, adherence) and safety.

Results: ADL capacity significantly improved pre to post CBCS training (ACTIVLIM-stroke, +3.4 logits, $p < 0.001$; effect size [ES] 0.87), balance (BBS, +21 points, $p < 0.001$; ES 0.9), impairments (SIAS, +11 points, $p < 0.001$; ES 0.9), and mobility (+145 m for 6MWT and +0.37 m/s for 10mWT; $p < 0.001$; ES 0.7 and 0.5 respectively). Similar improvements in psychosocial health occurred in both groups. Adherence and retention rates were 95% and 100%, respectively.

Conclusion: CBCS was feasible, safe and improved functional independence and motor abilities in individuals in the chronic stage of stroke. Participation in CBCS improved depression and social participation similarly to participation in sociocultural activities. The benefits persisted for at least 3 months after intervention completion.

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Introduction

Stroke is the second leading cause of death and the first cause of disability worldwide [1,2]. Disability remains highly prevalent up to 3 years after stroke [3]. More than 60% of affected individuals have long-term balance and lower-limb impairments that interfere with

their ability to complete activities of daily living (ADL) independently [4]. Additionally, the social participation of most stroke survivors remains reduced, even after achieving relatively good recovery from their impairments [5]. Both ADL limitations and participation restrictions reduce wellbeing after stroke, and improvements in ADL and participation depend on several factors including access to rehabilitation [6], socioeconomic context (healthcare coverage and social security) [7], and cultural beliefs [8].

Access to stroke prevention and treatment interventions is particularly challenging in low-resource settings [9], including middle- to low-income countries where stroke tends to affect more young people in comparison with higher-income countries [2]. The highest

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stroke incidence, prevalence, and case fatality rates are seen in sub-Saharan-Africa [2]. Moreover, individuals in the chronic stage of stroke in low-income countries are at a high risk of dropping out of rehabilitation programs, mainly because of socio-economic factors [7–9]. Hence, there is an important unmet need for cost-effective community-based stroke rehabilitation strategies.

Physical inactivity is associated with an increased risk of cardiovascular disease and recurrent stroke [10]. Physical activity is recommended for secondary prevention and rehabilitation [11]. Recreational, group-based community physical activity thus represents an attractive motivational and accessible strategy in stroke rehabilitation. Aerobic or combined (aerobic and resistance) training programs have been shown to improve outcomes in people who are also participating in conventional rehabilitation programmes [12]. It is unclear how effective such training programs would be outside of a clinical environment with expensive equipment (walking robots, cycle-ergometers, treadmills, etc.) and how well multi-modal physical activity plans would be carried out in a group community setting with limited resources. Therefore, we set out to investigate the feasibility and efficacy of an inexpensive multimodal, structured group physical training program (Circuit walking, balance, cycling and strength; CBCS) in a sample of Burundian individuals in the chronic stage after stroke. Specifically, we aimed to assess the effect of CBCS training on impairments, balance, ADL limitations, participation restrictions and depression. We hypothesised that CBCS training would improve impairments, activity limitations and participation restrictions.

Methods

Study design, setting, and ethical considerations

This study was a two-arm, parallel-group, crossover and single-blind randomized controlled trial. It was conducted in a community facility attached to the National Teaching hospital (CHU Roi Khaled) in Burundi. The study protocol was approved by the National Ethics Committee (CNE/25/2019) and registered in the Pan African Clinical Trials Registry (<https://pactr.samrc.ac.za/>; no. PACTR202001714888482).

Participants

Potential participants were identified from hospitals and rehabilitation centres by consulting admission records. Identified persons who were living in the community and who had completed or dropped out of conventional physical therapy at the time of recruitment were invited to enrol. All invited participants were screened to ensure that they met our inclusion criteria: clinical diagnosis of primary or recurring unilateral stroke based on neuroimaging or a clinical neurological examination; chronic stroke stage (≥ 6 months since stroke); ≥ 18 years of age; ability to walk 10 m with or without an assistive device; and moderate disability (modified Rankin scale ≤ 3) [13]. People with a major cognitive impairment (Community Screening Interview for Dementia score ≥ 7) [14], aphasia, or with permanent degenerative damage were excluded. Participants were informed of the study objectives and that the procedures conformed with the Declaration of Helsinki, and provided written consent.

Randomization and allocation

A public health researcher assistant not involved in the study used a computer-generated random allocation sequence to randomize the participants into 1 of 2 groups: immediate CBCS (IG) and delayed CBCS group (DG) using blocks according to age, disability, sex and study variables. The allocation was carried out with opaque, sealed envelopes.

Interventions

The interventions were performed 2 hours/day, 3 times a week for 12 weeks (36 sessions: 72 hours).

Experimental intervention (CBCS)

The experimental group participants were split into 3 subgroups of 6–8 participants with similar within-subgroup disability levels for CBCS training. All participants performed a 15-min warm-up before training and a 15-min cool down with stretching after training. The training consisted of 30 min of circuit walking followed by 30 min of recreational activities intended to improve balance, coordination, and strength, as well as 30 min of cycling at 50–75% of their maximal heart rate (determined by Karvonen's formula [15]). The physical exercises included in CBCS are described in detail in the Supplementary Table. Disability level subgroups were trained concurrently, with each group randomly assigned to a CBCS component, such that while one group was walking, another was cycling, and the third was performing balance, strength, and coordination exercises. Shaping was adapted to each individual. To help increase the duration of targeted motor involvement, encouragement was given through verbal feedback, distance covered was tracked, and level of exertion was followed with heart rate monitors during walking and cycling. Activity intensity was increased as sessions progressed to promote energy expenditure.

Control intervention

While waiting to cross over to CBCS training, participants participated in a sociocultural intervention aimed to improve social interaction through 3 activities that did not involve energy expenditure: board games (Awalé and Checkers), cultural discourse and drama. The board game component was performed in randomly allocated subgroups of 6 to 7 participants. Awalé (a.k.a. awele) is an informal combinatorial board game created in Africa. It is the most widespread of the mancala family of games, a set of African count and capture games in which pebbles, seeds, or shells are distributed in bowls or holes, sometimes dug in the ground. Checkers is an informal combinatorial board game wherein each player captures the opponent's pieces. For each game, participants solely used their non-affected hand and progressed through learning, forming playoff groups, and competing phases. Playoff competitions for each game yielded top-four finalists and then first and second place finishers were determined in a final match. After the board game period of each session, participants reformed groups of 4–6 people for the discourse and drama components. Topics were offered for cultural discourse and drama (topic pools were updated every 2 weeks).

Assessment and outcome measures

Participants were assessed at four timepoints, T1–T4: T1, baseline (at enrolment); T2, at 3 mos. (immediately post-intervention); T3, at 6 mos. (after crossover); and T4, at 9 mos. (3-mo. follow-up). A blind assessor collected participant data according to each of the 3 International Classification of Functioning, Disability and Health (ICF) components, namely impairments, ADL limitations, and participation restrictions. Psychometric questionnaires were administered by face-to-face interview and clinical tests were conducted in the rehabilitation centre.

We used the Community Screening Interview for Dementia (CSI-D) and timed up-and go (TUG) test to evaluate baseline cognitive and mobility abilities. The CSI-D, was developed as a screening instrument for dementia. It consists of 2 components: a cognitive test for non-literate and literate populations and an informant interview regarding performance in everyday living [14]. We administered

only the former. Higher CSI-D scores reflect better cognitive abilities. The TUG test is an objective clinical measure of functional mobility and balance, and thus the risk of falling. It measures the time taken for an individual to rise from a chair, walk 3 meters, turn, walk back and sit down [16].

Primary outcome: ADL limitations

The main endpoint was functional independence in ADL as measured by the ACTIVLIM-Stroke scale, a cross-cultural Rasch-built 20-item self-reported questionnaire instrument that is used to measure ADL limitations in people with stroke and presents good psychometric qualities [17,18]. For each item, the participants rated a particular task on a 3-level scale: impossible (0), difficult (1), or easy (2). Total ACTIVLIM-Stroke raw scores (ranging from 0 “more limited” to 40 “normal”) were subjected to logit and centile metric transformations via an online tool available at www.rehab-scales.org. The relationship between ordinal total score and linear measures (in %) was calibrated as described by Batcho et al. [17]. Higher scores indicate less difficulty with ADL.

Secondary outcomes of motor performance: global impairment, balance, and mobility

We evaluated global impairment with the Stroke Impairment Assessment Set (SIAS), a valid and reliable measure of global stroke impairment [19,20]. It consists of 22 items that evaluate spasticity, aphasia, and motor impairment of the limbs on an ordinal scale. Each item was rated from 0 (severely impaired) to 3 (normal), except the limb motor function items, which were rated from 0 (severely impaired) to 5 (normal). The SIAS total score ranges from 0 (severely impaired) to 76 (normal).

The Berg Balance Scale (BBS), which is valid, reliable, and responsive, was used to assess balance impairment [21,22]. The maximum total score on the BBS is 56 (higher score means better balance). The 95% confidence minimal detectable change (MDC_{95}) is 5 points [22]. A BBS score ≤ 42 is predictive of risk of falling [23].

The 6 min walk test (6MWT) and the 10 m walk test (10mWT) were used to assess mobility. Both are widely used as community walking indicators [23,24]. The 6MWT measures walking endurance based on the distance (recorded in m) walked within 6 min: participants are instructed to walk as fast as possible for 6 min on a 30 m pathway with the option to stop for fatigue at any point. For the 10mWT, participants were instructed to walk at a comfortable pace [24] over a 14 m marked pathway; they were timed over the middle 10 m distance. The fastest of 3 trials was used for the analysis.

Secondary outcomes of psychosocial health: depression and social participation

Depression was examined with the Hospital Anxiety and Depression Scale (HADS). The HADS is a questionnaire divided into an Anxiety and a Depression subscale both containing 7 intermingled items [25]. We considered a score of ≥ 8 on the depression subscale of the HADS to be indicative of the presence of at least mild depressive symptoms: that cut-off has good specificity (0.79) and sensitivity (0.83) [26].

Participation was measured with the Participation Measurement Scale (PM-Scale), a 22-item Rasch-built stroke-specific scale that refers to daily situations encountered by stroke survivors in Africa and has good psychometric qualities [27,28]. Participants were asked to rate their perceived participation in item-specified activities on a 3-level scale: not at all (0); weakly (1); or strongly (2). PM-Scale raw scores were converted into logits and centiles at www.rehab-scales.org. Total PM-Scale raw scores range from 0 to 44; logit transformed scores ranged from -6.56 to 6.51 logits, corresponding to 0 to 100

centiles. Higher raw scores, logits, and centiles indicate greater participation.

Additional outcomes: feasibility and safety

Adherence was determined by session participation rate (attended sessions / total number of sessions $\times 100$). Retention rate was the percentage of participants who completed the final follow-up assessment at T4. Adherence and retention were considered acceptable if the percentages were $\geq 80\%$. The percentage of participants who experienced adverse effects was recorded as a measure of safety.

Statistics

Sample size estimation

Sample size calculation was based on ACTIVLIM-Stroke scale scores derived from earlier studies [18,29]. A mean improvement of 0.45 logits after a walking training intervention [29] and a minimal clinically important difference (MCID) of 2.6 logits [2.63;3.62; 95% confidence interval of mean] [18] have been reported. With $\alpha = 0.05$ and $1-\beta = 0.8$, a minimum sample of 21 and a maximum of 27 per group were required. Considering a dropout rate of around 8%, we needed to include between 44 and 60 participants.

Data analysis

Descriptive statistics were used to summarize group characteristics. Quantitative variables with a normal distribution are reported as means with standard deviations (SDs), while ordinal and non-normally distributed data are reported as medians with interquartile ranges. Independent t-tests and non-parametric tests were used to compare baseline characteristics between the groups. Between-group differences over time were detected with two-way repeated-measures (2×4) analyses of variance (ANOVAs), the findings of which are reported as p values with post-hoc test results. The Benjamin-Hochberg test was used to confirm the Bonferroni post-hoc significance. Because homoscedasticity was sustained, the ANOVAs were conducted without transformation. The effect size (ES) was estimated using the value of the η^2 , rated as small (0.01); medium (0.06) or large (≥ 0.14). Individual changes were analysed using the t-value [30] and the rate of participants with an increase in score greater than the minimal detectable change (MDC) or the MCID was calculated as a proportion of the number of participants in each group (i.e. if in the immediate group, 15 out of 23 participants achieved MCID, the rate would be $15/23 \times 100 = 65\%$). The participants were divided into 4 classes according to their t score significance limits: large improvement ($t \geq 1.96$), improvement ($0 < t < 1.96$), no change ($t = 0$), deterioration ($t < 0$). All analyses were performed in SPSS for Windows® (version 25.0, IBM, Chicago, IL) and the significance was set at $< 5\%$.

Results

Flow of participants and sample characteristics

Fig. 1 shows the flow of participants. Of 336 potential participants who were identified, 103 were screened, and 58 matched the eligibility criteria. Among those, 46 were available to participate, were randomized into the immediate and delayed CBCS training groups and completed the study. The groups did not differ in demographic characteristics, baseline primary outcome values or secondary outcome measures (Table 1).

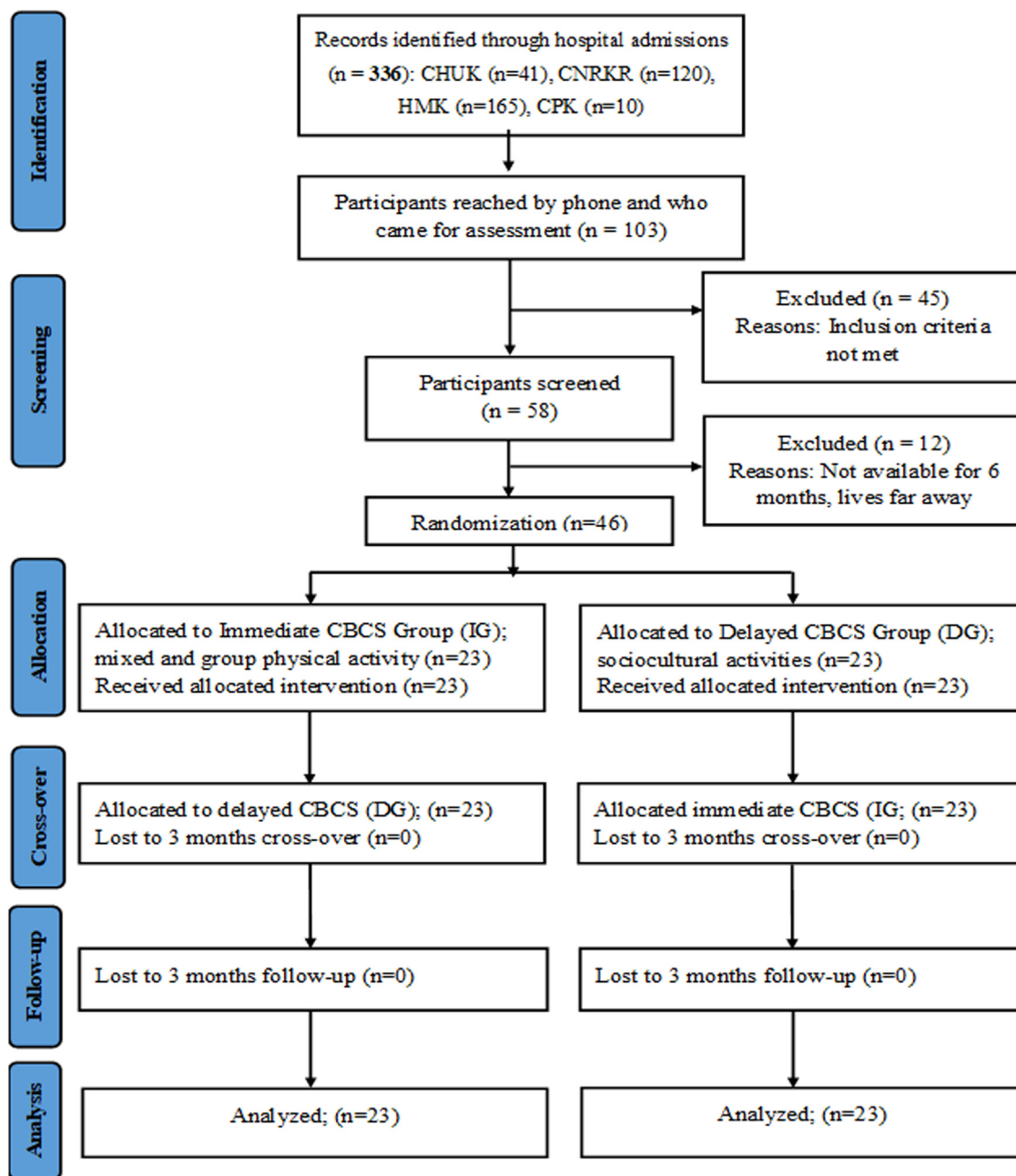


Fig. 1. Consort diagram of eligibility and participant inclusion (CHUK: Centre hospitalier universitaire de Kamenge.; CNRKR: Centre national de reference en Kinésithérapie et readaptation; HMK :Hôpital Militaire de Kamenge; CPK: Centre Professionnel de Kinesitherapie; CBCS: Circuit, balance, cycling and strength).

Primary outcome: overall activity limitations

Group-averaged ADL limitations, represented by ACTIVLIM-Stroke scale scores, assessed at each timepoint are shown relative to the expected response in Fig. 2. The change in functional independence is shown in Fig. 2 and individual change after CBCS training (post-intervention and post-cross-over) is shown in Appendices 1 and 2. At baseline (T1), the immediate (mean 52%, SD 12) and delayed group (55%, SD 12) had similar mean scores. These baseline scores indicate that the participants were able to perform the 7 easiest items easily but were unable to perform the 5 most difficult items.

After the 3 month intervention period, at T2, ACTIVLIM-Stroke scale score improved significantly in the immediate group (87%, SD 19; $p < 0.001$ vs. T1) but not in the delayed group (59%, SD 11; $p = 0.30$). Mean ACTIVLIM-Stroke scale score at T2 of the immediate group was significantly greater than that of the delayed group

($p < 0.001$). This high score in the immediate group indicates that the participants could perform basic tasks and motor skill-dependent ADLs items easily, including “getting up from a chair”, “taking off a t-shirt”, and but could not perform activities that involved substantial walking, such as “walking more than 1 km” and “walking upstairs”.

After the 3 month crossover period, at T3, ADL abilities improved significantly in the delayed group, which completed the CBCS protocol during the crossover period [ACTIVLIM-Stroke measure (88%, SD 20 $p < 0.001$ vs. T2). During the cross over period, no significant improvement occurred in the immediate group, which participated in CBCS in the pre-crossover phase and sociocultural activities during the crossover period [ACTIVLIM-Stroke measure, 92%, SD 20; $p = 0.50$ vs. T2]. At T3, after the crossover period, ACTIVLIM-Stroke scale scores did not differ between groups ($p = 0.30$) and the participants in both groups were able to perform almost all assessment tasks easily.

Table 1
Baseline characteristics of participants (n = 46) in the immediate (IG) and delayed CBCS (DG) groups.

Characteristic	IG n=23	DG n=23	p-value
Mean age (SD), y	50.9 (10.7)	50.1 (11.2)	0.8 [†]
Mean BMI (SD), Kg/m ²	25.57 (5.17)	25.09 (4.35)	0.74 [†]
Median post-stroke duration (Q1; Q3), mo.	24 (11; 37)	21 (9; 32)	0.17 [†]
Sex, N (%)			0.64 ^{††}
Females	5 (22%)	5 (22%)	
Males	18 (78%)	18 (78%)	
Affected side, n (%)			0.12 ^{††}
Right	15 (65%)	10 (44%)	
Left	8 (35%)	13 (56%)	
Type of stroke, n (%)			0.12 ^{††}
Ischemic	11 (48%)	8 (35%)	
Hemorrhagic	11 (48%)	9 (39%)	
Undetermined	1 (4%)	6 (26%)	
Disability; MRS median score (Q1; Q3)	2 (2; 3)	3 (2; 3)	0.33 [‡]
Impairment severity, median scores (Q1; Q3)			
SIAS	30 (23; 33)	29 (26; 31)	0.76 [‡]
HADS	8 (6; 10)	8 (6; 9)	0.6 [‡]
CSI-D	8 (7; 9)	8 (7; 9)	0.8 [‡]
Balance/fall risk, median score (Q1; Q3)			
TUG	15 (11; 35)	15 (9; 28)	0.54 [‡]
BBS	30 (20; 33)	28 (21; 33)	0.72 [‡]
Activity limitations, mean (SD)			
ACTIVLIM-Stroke scale in logits	0.45 (1.64)	0.69 (1.19)	0.5 [‡]
6MWT in m	221 (112.61)	207 (120.57)	0.68 [‡]
10mWT in m/s	0.64 (0.34)	0.7 (0.35)	0.56 [‡]
Participation, PM-Scale in logits, mean (SD)	0.71 (1.19)	0.31 (1.41)	0.3 [‡]

[†] Independent t-test
^{††} Chi-square and Fisher's exact tests
[‡] Mann-Whitney U test
Abbreviations: CBCS: Circuit walking, balance, cycling and strength; 6MWT, 6 Minute Walk Test; 10mWT, 10 metre Walking Test; ACTIVLIM-Stroke, Activity limitation for stroke; BBS, Berg Balance Scale; BMI, Body Mass Index; CSI-D, Cognitive Screening Instrument for Dementia; HADS, Hospital Anxiety and Depression Scale; mo. Months; MRS, Modified Rankin Scale; PM-Scale, Participation Measurement Scale; Q1; Q3, 25th and 75th quartiles; SD, standard deviation; SIAS, Stroke Impairments Assessment Set; TUG, Timed-Up and Go test; y, years.

After the 3 month follow up period, at T4, mean ACTIVLIM-Stroke scale score centiles tended to increase in both groups, though the change from T3 to T4 was not significant: immediate group (98%, SD 24; $p = 0.40$) and delayed group (94%, SD 24; $p = 0.50$). ADL abilities at T4 did not differ between groups ($p = 0.40$) and, on average, the participants in both groups could perform all items.

The results of the two-way ANOVA of ACTIVLIM-Stroke scale scores are detailed in Table 2. Significant session effects were found within each group, with a significant group $\times$ session interaction (pre-post training and interaction effect sizes ES; $\eta^2 = 0.87$ and 0.31 , respectively). ADL performance improved after CBCS training and the improvement was maintained at follow-up. Within-group comparisons of logit scores across assessment time points confirmed that mean performance of the immediate group improved significantly from T1 to T2 (+2.7 logits, ES = 0.33) and T3 (+3.8 logits). The scores of the delayed group only changed significantly from T2 to T3 (+2.99 logits). The overall pre-post training mean change for the sample was 3.4 logits (SD, 1.4), equal to 35 centiles. Large improvements occurred in > 80% of participants, as shown by the t-scores and the fact that changes in scores between T1 and T2 (intervention) and between T2 and T3 (cross over) were above the MCID (Tables 2 and 3). The effects were maintained at follow-up, as indicated by non-significant differences between T3 and T4. In summary, CBCS training improved functional independence by ~41% (Fig. 2) or ~4 logits (mean change from pretraining to follow up).

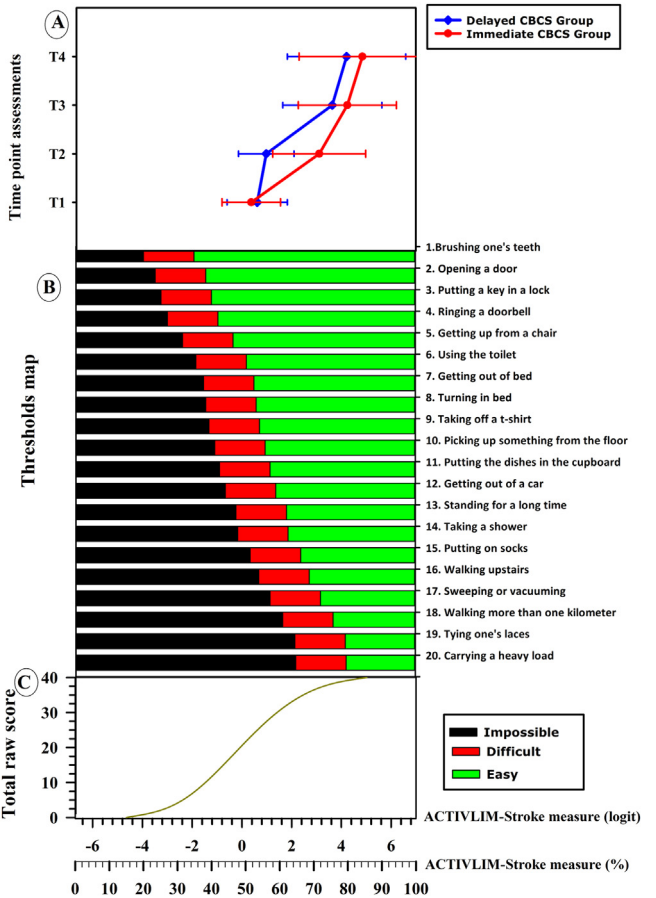


Fig. 2. Activity of daily living limitations at each evaluation time-point (T1, T2, T3, T4) according to ACTIVLIM-Stroke scale scores of functional ability. (A) Mean ACTIVLIM Scores at each time point (error bars represent standard deviation). (B) ACTIVLIM-Stroke scale item-threshold map showing expected responses to each item as a function of the participant's functional ability. (C) Illustration of the relationship between ordinal raw scores and corresponding linear measures in logits and centiles (%).

Secondary outcomes of motor performance

The results of the two-way ANOVA are presented in detail in Table 2 and in Fig. 3.

Global impairment

Regarding global motor impairments assessed with the SIAS (Fig. 3A), the two-way ANOVA revealed a significant effect of session within each group and a group $\times$ session interaction (all $p < 0.001$; pre-post training and interaction ES 0.9 and 0.54). For the immediate group, mean SIAS scores were significantly higher at T2 (+9 points, $p < 0.001$, ES=0.37) and T3 (+11 points) than at T1. For the delayed group, mean SIAS scores were significantly higher at T3, after the crossover phase, than at T1 and T2 (+12 points). By T3, after the crossover phase, there was no longer a significant difference between the groups ($p = 0.80$) because the performance of the delayed group had increased to reach that of the immediate group. A clinically important improvement occurred in over 90% of participants (Table 3). CBCS training effects were maintained at T4 (no difference between T3 and T4 scores in either group).

Balance

The two-way ANOVA demonstrated significant effects of session within each group and a group $\times$ session interaction (all $p < 0.001$; pre-post training and interaction ES 0.9 and 0.76, table 2) on balance

Table 2
Mean (SD) scores for outcomes at each assessment time point for the immediate (IG), and the delayed CBCS (DG) groups.

Outcome	IG n=23				DG n=23				S × G, p(η^2)		Between-group effects, p-value (η^2)	
	T1	T2	T3	T4	T1	T2	T3	T4	T2	T3	T2	T3
ACTIVLIM-Stroke score	0.45 (1.16) <i>p</i> < 0.001; MCID: 20 (87%)	3.16 (1.85) <i>p</i> < 0.001; MCID: 20 (87%)	4.28 (1.95)	4.87 (2.52)	0.69 (1.19) <i>p</i> < 0.001; MCID: 19 (83%)	1.05 (1.1)	3.68 (1.97)	4.24 (2.35)	≤0.001 (0.31)	<0.001 (0.33)	IG>DG	>0.05 (0.02)
SIAS score	28.5 (6.1) <i>p</i> < 0.001	37.2 (6.73) <i>p</i> < 0.001	39.9 (7.66)	41.6 (7.8)	28.3 (4.7) <i>p</i> < 0.001	28.3 (4.9)	40.4 (4.1)	42.7 (6.5)	<0.001 (0.54)	<0.001 (0.37)	IG>DG	0.7 (0.00)
BBS score	27 (9) <i>p</i> < 0.001; MDC: 23 (100%)	47 (7) <i>p</i> < 0.001; MDC: 23 (100%)	49 (7)	51 (7.4)	26 (10) <i>p</i> < 0.001; MDC: 23 (100%)	26 (10)	48 (8)	52 (5)	<0.001 (0.76)	<0.001 (0.62)	IG>DG	0.69 (0.0)
HADS score	7.87 (2.47) <i>p</i> < 0.001	2 (1.16) <i>p</i> < 0.001	0.74 (0.68)	1.7 (2.22)	7.74 (2.47) <i>p</i> < 0.001	7.74 (2.28)	0.91 (1.5)	1.35 (2.16)	0.28 (0.03)	0.21 (0.04)	IG>DG	0.62 (0.01)
6MWT, m	221 (112.6) <i>p</i> < 0.001; MCID: 16 (70%)	346.3 (147.3) <i>p</i> < 0.001; MCID: 16 (70%)	359.1 (161.5)	340.3 (167.9)	207 (120.6) <i>p</i> < 0.001; MCID 20 : (87%)	205.8 (117.5)	359.6 (147.8)	360.8 (144.8)	<0.001 (0.4)	<0.01 (0.22)	IG>DG	0.9 (0.00)
10mWT, m/s	0.64 (0.34) <i>p</i> < 0.001; MCID: 21 (91%)	1.01 (0.51) <i>p</i> < 0.001; MCID: 21 (91%)	1.01 (0.48)	1.04 (0.53)	0.70 (0.35) <i>p</i> < 0.001; MCID: 20 (70%)	0.75 (0.38)	1.07 (0.55)	1.07 (0.50)	<0.001 (0.25)	<0.05 (0.08)	IG>DG	0.7 (0.004)
PM-Scale	0.71 (1.19) <i>p</i> < 0.001; MCID: 21 (91%)	2.57 (1.36) <i>p</i> < 0.001; MCID: 21 (91%)	3.49 (1.18)	5.54 (1.85)	0.31 (1.42) <i>p</i> < 0.001; MCID: 23 (100%)	1.96 (1.57)	3.58 (1.87)	4.93 (2.51)	>0.05 (0.04)	>0.05 (0.00)	IG>DG	>0.05 (0.02)

Note: ACTIVLIM-Stroke and PM-Scale scores are shown in logits. Within-group effects of session T1 – T4 are shown in the group column sets. Between-group effects are shown as p values obtained in post hoc analyses and pre-post training effect size (η^2). MCID: Number (percentage) of participants in each group who achieved the MCID/MDC for each variable after the cross-over period.
Abbreviations: CBCS: Circuit walking, balance, cycling and strength; 6MWT, 6-Minute Walk Test; 10mWT, 10-metre Walk Test; ACTIVLIM-Stroke, Activity limitation stroke scale; BBS, Berg Balance Scale; HADS, Hospital Anxiety and Depression Scale; MCID, Minimal Clinically Important Difference; PM-Scale, Participation Measurement Scale; SIAS, Stroke Impairments Assessment Set; S × G, session × group interaction; T1, baseline; T2, after the intervention period; T3, after the crossover period; and T4, after 3 mo. follow-up period.

measured by the BBS (Fig. 3B). Post-hoc analysis showed that the mean BBS scores of the immediate group improved significantly from T1 to T2, whereas scores for the delayed group improved significantly from T2 to T3. Mean BBS scores were much higher for the immediate (+20 points) than for the delayed group at T2 (*p* < 0.001, ES 0.62). This difference was no longer present after the crossover phase at T3 (*p* = 0.70) because the delayed group's balance performance increased (+21points) to reach that of the immediate group. The improvements in all participants exceeded the MDC and were large (Tables 2 and 3). In both groups, the improvement in balance was maintained (*p* > 0.05 vs. T3) through the follow-up period at T4.

Mobility

As shown in Figs 3C and D, two-way ANOVAs revealed within group session effects and a group × test session interaction for both walking endurance measured with the 6MWT and for walking speed measured with the 10mWT (all *p* < 0.001; pre-post training and interaction ES 0.5 to 0.7 and 0.25 to 0.4 respectively). Post-hoc analysis revealed that the immediate group had a greater mean walking distance (+125 m, ES=0.22) and speed (+0.37 m/s, ES=0.08) at T2 than at T1. For the delayed group, similar respective improvements occurred from T2 to T3 (+152 m distance and +0.37 m/s speed). Multiple comparisons of between-group differences showed that mean 10mWT and 6MWT outcomes were much higher for the immediate than for the delayed group at T2 (*p* < 0.001). This difference no longer existed after the crossover phase at T3 (*p* = 0.70) because the delayed group's distance and speed increased to reach those of the immediate group. More than 70% of participants achieved at least the MCID and large t-score improvements (Tables 2 and 3) for both the 6MWT and 10mWT. For both groups, the effects were maintained at T4 after the follow-up period.

Outcomes of psychosocial health

There were no significant group effects or interactions for depression or participation, assessed with the HADS and PM-Scale respectively. Significant improvements in depression symptoms and participation occurred in both groups over time (*p* < 0.001, Table 2). There were no statistical differences between the mean scores of the 2 groups at each time point (Figs 3F and D). Post-hoc analysis of within-group effects showed that for both groups, depression symptom levels decreased sharply from T1 to T3 (approximately -7 points in each group, ES = 0.9) and participation scores increased gradually from T1 to T4 (total changes: immediate group +4.83 logits; delayed group +4.62 logits, ES = 0.8). The greatest improvements in participation occurred in the immediate group, from T1 to T2 (+1.86 logits) and from T2 to T3 (+0.92 logits) respectively. The changes in the delayed group scores were quite steady over time (+1.65, +1.62, and +1.35 logits).

Additional outcomes of feasibility and safety

No participants dropped out at any stage: the retention rate was 100%. Of the 36 sessions in phase 1, the mean number of sessions completed was 34.8, SD 1.5 and 34.8, SD 1.3 respectively for the immediate and delayed groups. In phase 2, the mean number of sessions completed was 33.3, SD 2.4 and 34.2, SD 1.7 respectively for the immediate and delayed groups. In phase 1, adherence was similar between the two groups (97%). In phase 2, the immediate and delayed group participants attended 93% and 95% of the sessions respectively. Minor adverse effects were reported in 11% of participants during CBCS training, all of which resolved within short periods of time (minutes, hours, or days). Two participants experienced low back pain, 2 reported knee pain after walking, and 1 reported hypotension and dizziness during the second session.

Table 3

Analysis of change at the individual level for all outcomes and for each group (immediate and delayed CBCS groups) reported as the number of participants (percentage) according to the t score significance limits.

Outcomes	Large improvement (t≥1.96)		Improvement (0<t<1.96)		No change (t=0)		Decrease (t<0)	
	T2 vs T1	T3 vs T2	T2 vs T1	T3 vs T2	T2 vs T1	T3 vs T2	T2 vs T1	T3 vs T2
Activlim-Stroke score (logit)								
• Immediate CBCS	23 (100%)	12 (52%)	0	6 (26%)	0	4 (17%)	0	1 (4%)
• Delayed CBCS	11 (48%)	21 (91%)	7(30%)	0	0	2 (9%)	5 (22%)	0
SIAS score								
• Immediate CBCS	21 (91%)	9 (39%)	1 (4%)	10 (43%)	0	2 (9%)	1 (4%)	2 (9%)
• Delayed CBCS	0	23 (100%)	10 (43%)	0	5 (22%)	0	8 (35%)	0
BBS score								
• Immediate CBCS	23 (100%)	1 (4%)	0	17 (74%)	0	4 (17%)	0	1 (4%)
• Delayed CBCS	0	23 (100%)	8 (35%)	0	4 (17%)	0	11 (48%)	0
6MWT, m								
• Immediate CBCS	17 (74%)	2 (9%)	6 (26%)	16 (70%)	0	0	0	5 (22%)
• Delayed CBCS	0	20 (87%)	0	3 (13%)	12 (52%)	0	11 (48%)	0
10mWT, m/s								
• Immediate CBCS	22 (96%)	0	1 (4%)	10 (43%)	0	7 (30%)	0	6 (26%)
• Delayed CBCS	0	21 (91%)	18 (78%)	0	3 (13%)	0	2 (9%)	2 (9%)
PM-Scale score (logit)								
• Immediate CBCS	19 (83%)	15 (65%)	2 (9%)	4 (17%)	1 (4%)	2 (9%)	1 (4%)	2 (9%)
• Delayed CBCS	19 (83%)	19 (83%)	1 (4%)	3 (13%)	2 (9%)	1 (4%)	1 (4%)	0

Note: t values (correspond to effect size), which consider self-relative scores and their associated errors for a person at 2 different time points, were calculated as follows:

$t \text{ value} = \frac{p_i - p_j}{\sqrt{(SE_i^2 + SE_j^2)}}$ where p_i and p_j represent the person's participation level at 2 time points, and SE_i and SE_j are the respective associated standard errors of measurement.

Abbreviations: CBCS: Circuit walking, balance, cycling and strength; 6MWT, 6-Minute Walk Test; 10mWT, 10-metre Walk Test; ACTIVLIM-Stroke, Activity limitation stroke scale; BBS, Berg Balance Scale; CBCS, Circuit walking, Balance, Cycling and Strength training; PM-Scale, Participation Measurement Scale; SIAS, Stroke Impairment Assessment Set. T1, baseline; T2, after the intervention period; T3, after the crossover period.

Discussion

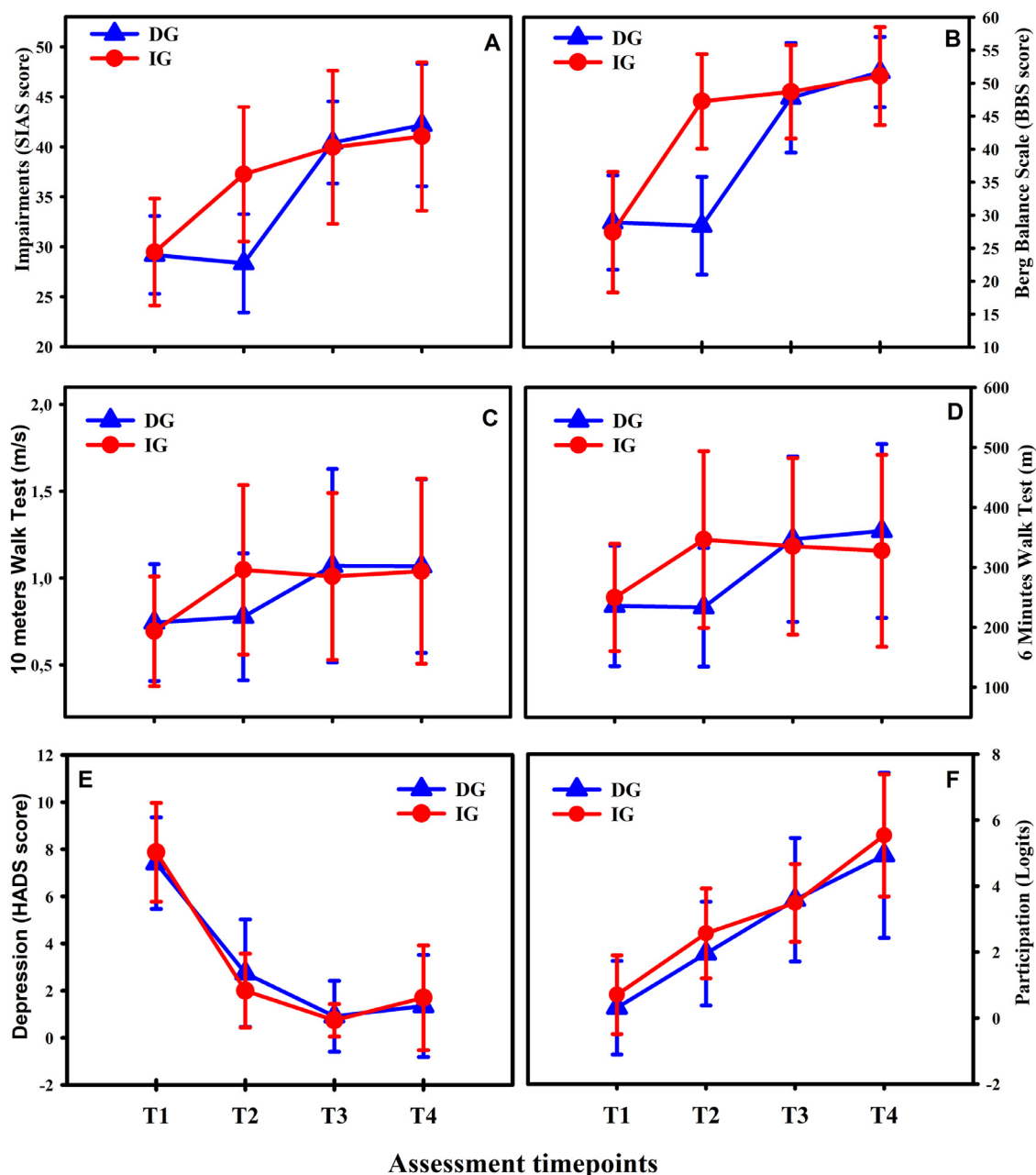
This study demonstrated the safety, feasibility, and efficacy of a CBCS training protocol in individuals with chronic stroke living in a low-resource setting who were not participating in a formal rehabilitation program at the time of study enrolment. Completion of the CBCS training protocol was associated with reductions in ADL limitations together with improvements in motor performance outcomes (global impairment, balance and mobility). Furthermore, depression symptoms reduced and social participation increased in response to both CBCS training and sociocultural activities (the control condition). All improvements were maintained 3 months after the end of the interventions.

Motor performance improvements

Physical activity has well-established benefits on mobility. In their recent systematic review and meta-analysis, Pogrebnoy and Dennett [31] concluded that combined aerobic and resistance training exercise programs improved habitual walking speed (mean difference, 0.07 m/s) and walking endurance (mean difference, 39.2 m). Improvements in mobility (speed and distance) and balance have also been highlighted in other physical activity studies conducted in rehabilitation or laboratory settings [12,32–33]. In a Cochrane review of group-based interventions (circuit classes) in developed countries, English et al. [34] reached similar conclusions noting moderate improvements in walking distance (60–70 m), walking speed (0.15–0.19 m/s), balance, and overall functional independence [34]. The Cochrane review by English et al. included studies conducted in community or hospital settings and participants at all stages of stroke [34]. Although no other studies of group community physical training with which our findings could be compared are available, our results are consistent with those of several community-based studies conducted in developed countries [35–37]. The recent, multicentre “LAST Study” [38] concluded that regular individualized coaching was safe and improved physical activity levels, but it did not improve the maintenance of motor function or mobility outcomes more than

standard care. Other findings [39,40] support the low effectiveness of individualized training programs after hospital discharge, particularly the lack of tailoring of exercises to each individual. In contrast with the context in terms of income with the LAST study, our intervention was supervised, group-based and targeted functional exercises of progressive difficulty adapted to each individual. In addition, our sample was relatively young (mean age 50 vs. 72 years).

Relative to the various aerobic, mixed, and circuit training interventions that have been shown to improve mobility, balance, and functional independence in inpatients and outpatients, the present study demonstrates an apparent advantage of multimodal, structured, and group physical activity for these outcomes. Compared to prior studies, we observed quite robust improvements in ACTIVLIM-Stroke scale scores (>2.4 logits, MCID [18]) and BBS (>5 points, MDC₉₅ [22]), which exceeded the MCID for the 6MWT (71 m [41]) and 10mWT (0.10–0.20 m/s [42]). Large changes occurred in more than 70% of participants. Global impairments, especially lower extremity motor function, were improved in the majority of participants. We attribute the relatively substantial improvements documented here to the intensive and functional aspects of our supervised intervention that enabled continuous motor learning [43], together with the fact that younger people tend to show greater improvements in motor performance than older people [44]. The combination of aerobic and resistance training and the implementation of relatively long (120 min), regular sessions (3 times/week, with ≥ 85% motor involvement, for 12 weeks) and adapted functional exercises with repetition, shaping, and feedback, make this CBCS training program effective as it meets the recommendations for stroke rehabilitation [11]. Furthermore, the activities included playful aspects to help keep the participants engaged. Additionally, the intervention was conducted in groups in a community environment, which may serve to increase participant motivation while promoting mutual support [45] as the participants engage in real-life challenges with clear functional benefits (e.g. crossing a gutter, climbing a slope, etc.). Compared to one-on-one physiotherapy sessions, group-based physical activity programs are more cost effective, requiring little supervision and allowing social integration in real life. The relatively



DG= Delayed CBCS Group
IG= Immediate CBCS Group

Fig. 3. Mean (SD) values for overall and balance impairments: SIAS (A) and the BBS (B) respectively. Mean (SD) values for mobility: 10mWT (C) and 6MWT(D). Mean (SD) values for depression symptoms and social participation restrictions: HADS (E) and the PM-Scale (F). The immediate CBCS (experimental) group and delayed CBCS (sociocultural activities) group data are respectively shown as red and blue lines and errors bars show standard deviations.

young age of our sample (mean age ~50 years) and generally moderate (as opposed to severe) disability levels may have facilitated motor learning and performance [43–45].

Psychosocial health improvements

Our experimental CBCS training intervention and the control sociocultural program improved depression and social participation to similar extents. These findings are not surprising given that social games and social interactions facilitate socialization. Importantly, social support (friendship and social interaction) has been associated with improvement in post-stroke depression symptoms [46] and

high levels of social support have been associated with better participation [47]. Given that physical function has been shown to be an important predictor of community participation in young adults [48], it is clear that that exercise-based interventions (motor relearning program, cognitive-based exercise, community walking training program and home-based combined exercise) are highly effective for improving social participation [49].

Overall, consistent with a Delphi study [50], the functional and playful aspect of the exercises, the motivation linked to the peer-support within the group, feedback, training intensity, the grading of exercises according to capacity and adapted to the individual (or to the group of individuals with similar disabilities) were the main

strategies used to increase adherence and improve outcomes in the chronic phase of the stroke.

Study strengths

We conducted an assessor-blinded, crossover, randomized study of the effectiveness of a CBCS training intervention. We used a socio-cultural program as the control intervention in the crossover design. This study was the first to investigate the effectiveness of a community group and multimodal physical activity program in chronic stroke rehabilitation in a low-resource setting within a sub-Saharan country, namely Burundi. Multiple aspects of post-stroke disability were examined, including ADL limitations, impairments, and participation restrictions and we used socioculturally suitable tools to assess the outcomes. Importantly, our post-intervention follow-up data demonstrated that intervention benefits were maintained on (at least) a mid-term timescale. All participants completed both the intervention and crossover phases of the study (no drop-outs), which lends confidence to the credibility of our statistical analyses.

Study limitations

Because the CBCS training intervention was not compared directly to conventional rehabilitation or to a different physically active intervention, we cannot make conclusions regarding whether CBCS training is superior to conventional rehabilitation programs. Indeed, in low-income settings, many people in the chronic post-stroke stage drop out of rehabilitation or abandon it early due to the high cost of care since the onset of the stroke. Nevertheless, we used a cross-over design to overcome this issue. Future multicentre studies should compare CBCS training with conventional rehabilitation and include long-term follow-up analyses. In addition, we did not specifically assess each impairment, which may affect the overall rationale for functional recovery, but we believe that the main goals of people in the chronic phase of stroke are necessarily functional independence and cardiorespiratory capacity. Finally, we included people with moderate disability and further studies could investigate the effect of this program on people with severe disability.

Conclusion

The results of the present study showed that a community, group and multimodal physical activity program for stroke rehabilitation was safe, feasible, and effective in a low-resource setting. The 12-week CBCS training protocol significantly reduced ADL limitations and global impairments and improved balance and mobility. Additionally, CBCS training improved depression symptoms and participation significantly and similarly to a sociocultural activities program. Importantly, the benefits were maintained 3 months after the interventions ended.

Overall, our study demonstrated the value of combined, group and community-based training for improving impairments, ADL limitations, and social participation in individuals at the chronic stage after a stroke in low-income countries, where its ease of administration and local accessibility may be key to improving adherence and long-term outcomes due to limited geographical and financial access to rehabilitation [7–9]. The CBCS training intervention is cost-effective compared to conventional therapy because it can be delivered in the community in a group format with minimal supervision. An important consideration for people in the chronic stage after a stroke is also the promotion of reintegration into social settings outside of the hospital.

Credit author statement

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Data Availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Félix Nindorera: Conceptualization, Writing – original draft. **Ildephonse Nduwimana:** Conceptualization. **Alexis Sinzakaraye:** Conceptualization. **Eric Havyarimana:** Conceptualization. **Yannick Bleyenheuft:** Conceptualization. **Jean-Louis Thonnard:** Conceptualization, Supervision. **Oyéne Kossi:** Conceptualization, Supervision.

Data sharing

Data (e.g., demographics, clinical characteristics, and detailed participant results) are accessible upon request via e-mail to the corresponding author.

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Disclosures

The author(s) declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:[10.1016/j.rehab.2022.101704](https://doi.org/10.1016/j.rehab.2022.101704).

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