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Original article

Effectiveness of a self-rehabilitation program to improve upper-extremity function after stroke in developing countries: A randomized controlled trial

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ABSTRACT

Background: About two-thirds of stroke patients present long-term upper-limb impairment and limitations of activity, which constitutes a challenge in rehabilitation. This situation is particularly true in developing countries, where there is a need for inexpensive rehabilitation solutions.
Objective: This study assessed the effectiveness of a self-rehabilitation program including uni- or bi-manual functional exercises for improving upper-limb function after stroke with respect to the context in Benin, West Africa.
Methods: In this single-blind randomized controlled trial, chronic stroke individuals (>6 months post-stroke) performed a supervised home-based self-rehabilitation program for 8 weeks (intervention group); the control group did not receive any treatment. Participants were assessed before treatment (T0), at the end of treatment (T1) and 8 weeks after the end of treatment (T2). The primary outcome was the manual ability of the upper limb, assessed with ABILHAND-Stroke Benin. Secondary outcomes were grip force, motor impairment (Fugl-Meyer Assessment – Upper Extremity), gross manual ability (Box and Block test, Wolf Motor Function test) and quality of life (WHOQOL-26).
Results: We included 28 individuals in the intervention group and 31 in the control group. Adherence to the program was 83%. After 8 weeks of self-rehabilitation, individuals in the intervention group showed significantly improved manual ability and grip force as compared with the control group ($P < 0.001$), with effect size 0.75 and 0.24, respectively. In the intervention group, the difference in average scores was 10% between T0 and T1 and between T0 and T2. Subscores of physical and psychological quality of life were also significantly improved in the intervention group. The other variables remained unchanged.
Conclusions: A self-rehabilitation program was effective in improving manual ability, grip force and quality of life in individuals with stroke in Benin. More studies are needed to confirm these results in different contexts.

1. Introduction

About 80% of individuals with stroke present upper-limb impairment during the acute phase following a stroke, which persists in 55% to 75% of these individuals 6 months after stroke [1] and affects their independence in many activities of daily living [2]. Hence, upper-limb rehabilitation has been considered an important issue in post-stroke management, leading to the development of new therapeutic approaches and technologies [3].

Among other programs, self-rehabilitation management is a low-cost therapy that has been found useful in improving upper-limb functional recovery [4,5]. Such programs are based on self-administered homework exercises, supplementing or substituting conventional rehabilitation, and can be implemented in developed

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and developing countries. The interest of these programs is two-fold. On one hand, because the duration and intensity of rehabilitation programs remain largely insufficient in developed and developing countries, this approach seems promising to supplement conventional rehabilitation [5,6]. On the other, given that the emergence of new and expensive technologies is restricted to developed countries, owing to the limited economic resources of health care systems in developing countries [7], neurological rehabilitation would benefit considerably from such innovative, effective and inexpensive therapies in developing countries.

A feasibility study of a self-rehabilitation program aiming to improve upper-limb activities after stroke in Benin highlighted the good adherence of participants and showed some upper-limb functional improvement [8]. Given these encouraging results, the present single-blind randomized controlled study was designed to assess the effectiveness of a self-rehabilitation program to improve performance in upper-limb activities assessed by the ABILHAND-Stroke Benin in individuals with chronic stroke [9].

2. Methods

This single-blind randomized controlled study was approved by the ethics committee of the Centre national hospitalier et universitaire – Hubert Koutoukou Maga (CNHU – HKM), in Cotonou, Benin. Individuals agreed to participate after giving their written informed consent. This report follows the CONSORT, CONSORT Pro and SPIRIT Pro checklists [9–11]. This trial has not been declared in any international database because at the time of the trial, research in Benin was not recognized by international databases.

2.1. Participants

Participants were recruited at the CNHU-HKM. To participate in the study, individuals had to be:

- at least 18 years old;
- with hemiparetic single stroke at least 6 months before inclusion in the study;
- with no hospitalization during the 4 weeks before the study;
- living in or around the city of Cotonou, and;
- with a Fugl-Meyer Assessment – Upper Extremity (FMA-UE) score 9 to 57 [12].

Patients were excluded if they had:

- visual hemineglect (Bells test score $< 26/35$) [13];
- another pathology or a long-term complication of stroke that may be responsible for limiting manual ability (severe spasticity, fixed contracture, shoulder pain, etc.);
- cognitive disorders (Mini-Mental State Examination score ≤ 20) [14], and;
- an inability to understand and follow instructions given by the investigators.

Participants meeting the following criteria were randomized to the intervention and control groups (1:1). Randomization was stratified according to upper-extremity impairment (level 1: FMA-UE score 9 to 27; level 2: FMA-UE score 28 to 57) and to participation or not in routine rehabilitation treatment before and during the study period. Someone external to the research team performed randomization with use of a computer-generated random number.

The number of patients to be included was calculated taking into account the primary outcome (ABILHAND-Stroke Benin score [15]). Because the minimum detectable change was 1.1% [16], considering 10% dropout and 80% power, we needed to recruit a total of at least 56 patients.

2.2. Protocol

All participants were evaluated by the same assessor who was trained in the use of the assessment scales. The assessor was blinded to the group to which the participant was assigned. Participants were sensitized not to tell the assessor the treatment they received. Each evaluation lasted about 1 hr. Participants were evaluated 3 times. Evaluations were conducted within 1 to 7 days before the beginning of treatment (T0), after the 8 weeks of treatment (T1) and 16 weeks after the beginning of treatment (T2).

2.3. Assessment scales

2.3.1. Primary outcome

The ABILHAND-Stroke Benin [15] (called ABILHAND hereafter) is a 16-item patient-reported questionnaire evaluating bimanual activities in everyday life. Each item presents 3 categories of response: impossible, difficult and easy. The scale has been validated and calibrated with the Rasch model for the Beninese stroke population. In the present study, the total patient score was expressed as a percentage.

2.3.2. Secondary outcome

The FMA-UE [12] consists of 33 items evaluating the proximal and distal motor function of the upper limb. Each item is rated from 0 to 3. The maximum score is 66. The computerized adaptive version of the FMA-UE was used. The scale is reliable [17] and well validated for both acute [18] and chronic stroke individuals [19].

The Box and Block test (BBT) evaluates unilateral gross manual ability [20]. It consists of carrying one by one, within 60 s, the maximum number of blocks from one box to an adjacent box of equal size. The BBT is validated in stroke individuals with moderate upper-limb impairment. It is reliable and sensitive to change [21,22]. Reference values have been published for the Beninese population [23].

The grip force of the paretic hand was measured with the Jamar dynamometer [24]. The mean of 3 consecutive measures is considered. This test has been found reliable and valid in stroke individuals [25].

The Wolf Motor Function test (WMFT) [26] includes 15 tasks of increasing complexity. The first 6 tasks assess the upper-limb motor impairment. The following 9 tasks include more elaborate movements with object manipulations. This test is simple but takes 20 to 30 min to complete. It is sensitive to change, reproducible within and between observers, and is validated in stroke individuals with moderate impairment [27]. The quality of execution of each task is rated on a scale of functional capacity from 0 to 5. The maximum score is 75.

WHOQOL-26 is a generic and multidimensional patient-reported questionnaire assessing quality of life developed by the WHO and validated in several countries, including African countries [28]. The scale includes 26 items evaluating 4 areas of quality of life: physical health, psychological health, social relations and environment [29]. Each item is rated from 1 to 5. The score is calculated for each domain. In this article, we present the scores for physical health and psychological health with transformation on a scale from 0 to 20 [29].

2.4. Study design

2.4.1. Intervention group

Participants of the intervention group attended an explanation session, including a demonstration of the exercises to be carried

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out. At the end of this session, a self-rehabilitation equipment kit was given to each participant. This kit included the material required for performing the exercises, a daily notebook, and the self-rehabilitation protocol, with pictures describing all exercises. Participants had to perform the self-rehabilitation exercises at home, 2 h a day, 6 days a week for 8 weeks. A physiotherapist of the research team visited each participant once a week and reached them by phone once a week to check the completion of exercises, adapt them if necessary and motivate the participant to pursue them.

The upper-limb self-rehabilitation protocol included 21 exercises divided into 3 parts and is similar to that used in the preliminary study [8]: self-mobilization exercises (15 min), unimanual exercises oriented toward a functional task (60 min), and bimanual exercises (45 min). The participant could spread out the different exercise groups during the day. The precise list of exercises was attributed as a function of the manual ability.

2.4.2. Control group

Participants in the control group had no study-related treatment. They were called once a week by a physiotherapist of the research team to determine any change in health status.

3. Statistics

Data were analyzed with SigmaStat 3.5 (WPC ubed GmbH, Munich, Germany). We used descriptive analysis (mean [SD], median [range]) for general data (age, sex, type of stroke, duration of stroke, affected side). The equivalence of the 2 groups at baseline was checked (T0). We used Student t test when the continuous data complied with rules of homoscedasticity or Mann-Whitney test for categorical data. Data were analyzed according to per-protocol (presented in the "Results" section) and intent-to-treat methodologies (see Appendix tables). Missing data were not considered for statistical analysis. We evaluated the treatment effect over time by two-way (group and time) repeated-measures Anova when the data complied with homoscedasticity rules. The presence of an interaction between group and time was examined. When the difference was significant, a multiple comparison test involved Bonferroni correction. For ordinal data, we used Mann-Whitney test to assess the group effect at each time and Friedman Anova to assess the time effect. Tests were considered significant at $P < 0.05$. The effect size was computed following the method of Morris for repeated measures [30].

4. Results

We included 59 individuals with stroke, 31 in the control group and 28 in the intervention group. The flow of participants in the study is in Fig. 1. The demographic and clinical characteristics of both groups are shown in Table 1. The groups did not differ in characteristics at baseline. Overall, 83% of the participants completed the study (72% in the intervention group). No participant reported any adverse event. All participants continued their physiotherapy sessions at the same frequency, if they had some sessions before the study. No participant started physiotherapy sessions during the study.

Results for both groups are summarized in Fig. 2 and Tables 2 and 3.

4.1. Primary outcome: manual ability

The analysis of the ABILHAND scores revealed a significant interaction between group and time ($P < 0.001$). Participants of the intervention group improved their manual ability by 20% on average between T0 and T1 ($P < 0.001$) (Table 2). They maintained these results between T1 and T2 without additional improvements ($P = 1.0$). The difference in average scores was 20% between T1 or T2 versus T0, with a medium effect size of 0.75. In the control group, manual ability scores did not significantly differ at T0, T1 and T2 (Fig. 2).

4.2. Secondary outcomes

The intent-to-treat analysis of grip force (Jamar dynamometer) revealed a significant interaction between groups and time ($P = 0.008$) (Appendix Table 2). Participants of the intervention group improved their muscle strength by 20% on average between T0 and T1 ($P < 0.001$), with a small effect size, 0.24. They maintained these results between T1 and T2 ($P = 1.0$). However, gross manual ability (BBT) did not show any interaction effect (Table 2). The median scores for FMA-UE and WMFT did not significantly differ between the groups at T0 ($P = 0.59$ and 0.62), T1 ($P = 0.80$ and 0.22) or T2 ($P = 0.77$ and 0.22) (Table 3). However, although the FMA score increased with time in both groups, the WMFT score improved in the intervention group only from T0 to T1 and from T0 to T2 but remained stable in the control group (Table 3).

The physical health subscores of the WHOQOL-26 revealed an interaction between group and time ($P < 0.001$) (Table 2), showing an improvement in the intervention group at T1 and T2 versus T0 ($P < 0.001$). The average scores were similar at T1 and T2 ($P = 0.16$). The average difference was 2.5 points between T1 and T0, with a large effect size of 0.95, and 2.0 points between T2 and T0. Multiple comparisons showed that in the control group, scores were not significantly different at T0, T1, and T2.

The psychological health subscores of WHOQOL-26 also revealed a significant interaction ($P < 0.001$) (Table 2), with an improvement at T1 and T2 in the intervention group only ($P < 0.001$) versus T0. The average difference was 3.3 points between T1 and T0, with a large effect size of 1.28, and 2.6 points between T2 and T0. In the control group, scores were not significantly different at T0, T1, and T2.

Results of the intent-to-treat analysis are presented in Appendix tables and figure. These results were similar to the per-protocol analysis, except the effect on grip force was non-significant in the per-protocol analysis.

5. Discussion

The present study shows the effectiveness of a supervised self-rehabilitation program to improve muscle strength, upper-limb activity and quality of life among chronic stroke individuals in Benin.

6. Safety and adherence

Overall, 72% of the intervention group followed the entire program and completed the study (83% for both groups). This adherence is similar to that of a preliminary study performed in Benin with the same kind of program among individuals with chronic stroke [8]. The adherence to self-rehabilitation programs can be influenced by several factors including fatigue, motivation, pain [31] and cognitive impairment. In the present study, no participant complained about such factors, and dropout was related to factors not involved in the self-rehabilitation program itself (relocation to another city, hospitalization for other illnesses, etc.). In the Harris et al. study [5], 91% of patients completed the study and, among the 9 who had left, only one withdrew for a reason possibly related to the self-rehabilitation program (complex regional pain syndrome). In the Barzel et al. study [32], 94% of

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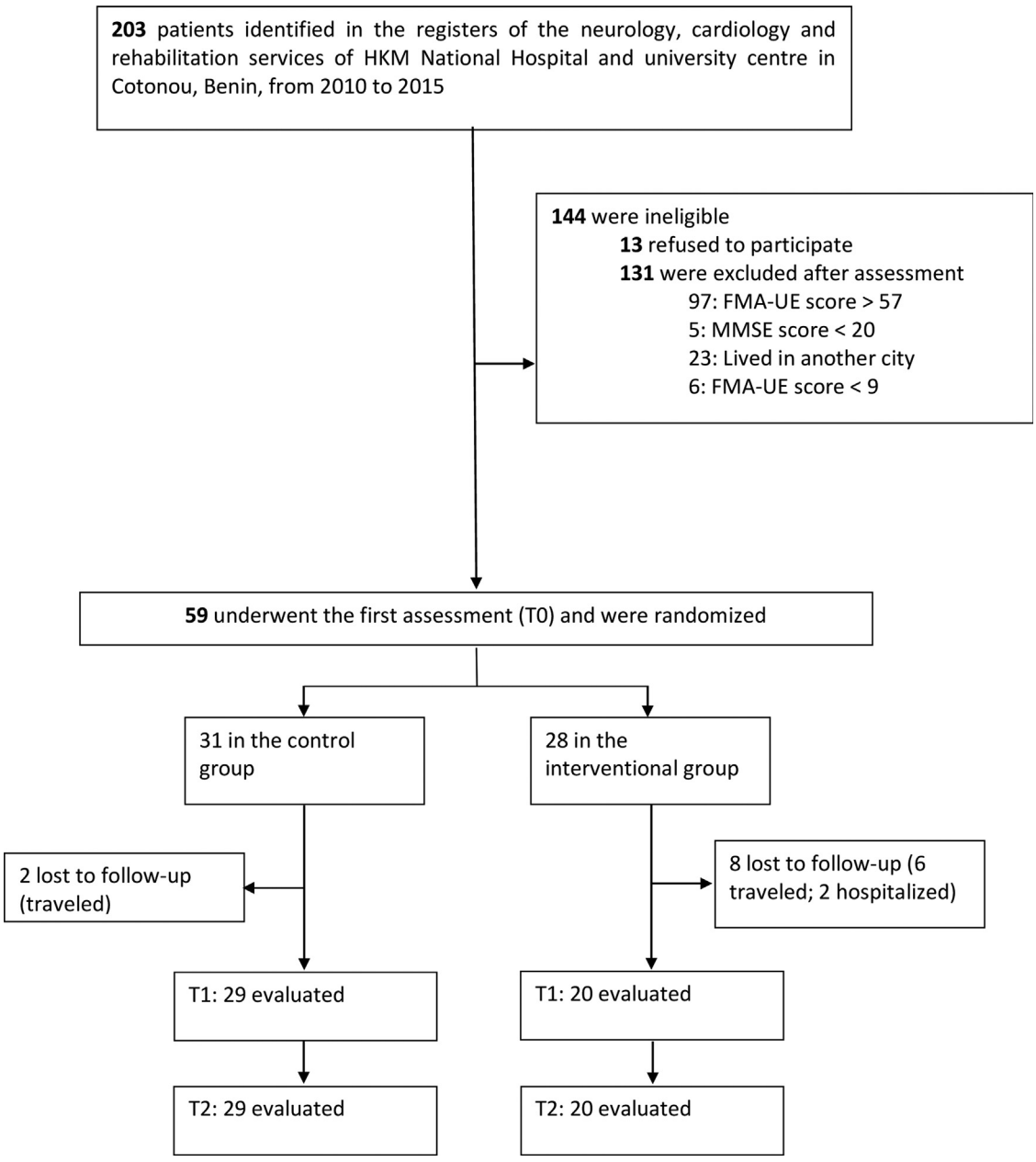

Fig. 1. Patient inclusion flow chart. FMA-UE: Fugl-Meyer Assessment – Upper Extremity; MMSE: Mini-Mental State Examination.

patients completed the study at 6 months, and the reasons for dropout were also unrelated to the study.

7. Effectiveness of self-rehabilitation

At the end of the self-rehabilitation program, the intervention group had significantly better manual ability than the control group (Fig. 2). This difference, about 20%, was maintained 8 weeks after the end of the self-rehabilitation program (Fig. 2). The minimum detectable change of ABILHAND has been set at 1.1% [16]. The Jamar dynamometer (grip strength) scores also improved significantly, by about 20%, in the intervention group. Likewise, the WMFT score improved in the intervention group, even if the difference between the intervention and control groups did not reach statistical significance. Similar results were observed by Harris et al. in individuals with acute stroke [5]. In that study, individuals in the intervention group followed a self-rehabilitation program in addition to conventional therapy. Individuals in the intervention group presented a significant improvement in manual ability, rated with the Chedoke Arm and Hand Activity Inventory-9 as compared with the control group. For individuals with subacute stroke, several studies [33–35] showed the feasibility of home-based exercise programs for the upper limb. Simpson et al. [33] investigated the feasibility of a phone-monitored home-based exercise program (H-GRASP) for the upper limb after stroke in 6 individuals with subacute stroke and showed some improvements in manual ability. Bernocchi et al. [34] implemented home-based rehabilitation and monitoring during 3 months in 26 stroke individuals (15 subacutes and 11 chronics). Participants performed a mean (SD) of 33 (12) sessions of exercise at home. Both stroke groups improved in terms of balance, motor control, gait endurance and fine manual ability. Turton et al. [35] showed the effectiveness of the Reach-to-Grasp program on improving upper-limb function in 47 individuals with subacute stroke, in a

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Table 1
Sociodemographic and clinical characteristics of patients in interventional and control groups at baseline (T0).

	Intervention group ($n = 28$)	Control group ($n = 31$)	*P*-value
Sex, male/female, *n*	13/15	8/23	
Age	51.8 (8.4)	55.1 (8.8)	0.1
Stroke, *n*			
Ischemic	5	8	
Haemorrhagic	6	6	
Not specified	16	17	
Affected side, *n*			
Dominant	10	16	
Non-dominant	18	15	
Delay since stroke (month)	41.9 (68.7)	46.6 (57.8)	0.8
BBT (number of blocks)	16 (14.2)	16 (14.6)	0.7
Gripping force (kg)	12.6 (8.3)	14.3 (7.7)	0.6
FMA-UE	35.5 [24–47]	38 [19.5–52]	0.6
ABILHAND, *n* (%)	47 (17)	46 (11)	0.9
WMFT (functional capacity)	45 [26–51.5]	47 [25.5–59]	0.6
WHOQOL-26			
Physical health	11.3 (2.3)	11.9 (2.9)	0.3
Psychological state	13.6 (2.6)	13.7 (2.7)	0.7

Data are mean (SD) or median [Q1–Q3] unless indicated. BBT: Box and Block test; FMA-UE: Fugl-Meyer Assessment – Upper Extremity; WFMT: Wolf Motor Function test; WHOQOL-26: World Health Organization Quality of Life 26.

pilot randomised controlled trial. For individuals with chronic stroke, Benvenuti et al. [36] and Barzel et al. [32] found similar effectiveness for telerehabilitation and home-based self-rehabilitation, respectively.

To our knowledge, the effectiveness of upper-limb self-rehabilitation programs has never been studied in developing countries. However, Nketia-Kyere et al. showed that about 76% of 207 individuals presented significant economic barriers to accessing physiotherapy services in Ghana [37].

8. Improvement of upper-limb performance

The present study shows an improvement in the activity domain of the International Classification of Functioning, Disability and Health (ICF, 2001) [38], as assessed by the ABILHAND and WMFT. However, the WMFT score did not reach a significant difference between groups, but it improved significantly in the intervention group (Table 3). The WMFT evaluate upper-limb functionality by various unimanual activities. The WMFT assesses the highest level of functionality the individual can reach, namely capacity according to the ICF [38]. However, self-reporting questionnaires such as ABILHAND assess self-perceived difficulty in daily bimanual activities, namely performance [38]. Both scales assess 2 different aspects of activities. Self-rehabilitation programs seem to improve performance more than capacity. Similar results were noted by Barzel et al. [32], who used constraint-induced movement therapy as intervention treatment. Two evaluation tools have been used: the Motor Activity Log – Quality of Movement, a self-reported questionnaire assessing performance, and the WMFT. A significant difference has been observed for the Motor Activity Log – Quality of Movement only.

In our study, the self-rehabilitation program improved grip force by 20%. Because the average post-stroke delay was 44 months and the exercises were designed to improve patients' manual ability in everyday life, we were not expecting such an improvement. In this context, the improvement in grip force shows that participants recovered some muscle strength, which could have been lost because of lack of paretic hand exercise such a long time after stroke, a phenomenon known as a "learned non-use" [39]. However, motor impairment assessed by the FMA-UE did not differ between the groups.

9. Bimanual and unimanual exercises

The self-rehabilitation program we proposed included task-oriented unimanual (60 min) and bimanual exercises (45 min). Task-oriented unimanual exercises of the affected upper limb constitute a common approach in neurological rehabilitation, such as constraint-induced therapy. In bimanual exercises, increasing paretic upper limb function is supposed to be facilitated by doing simultaneous healthy upper-limb movements, via neural pathways connecting both sides of the central nervous system. Recent randomized control trials did not show any difference in efficiency between the 2 approaches on body functions and structures or

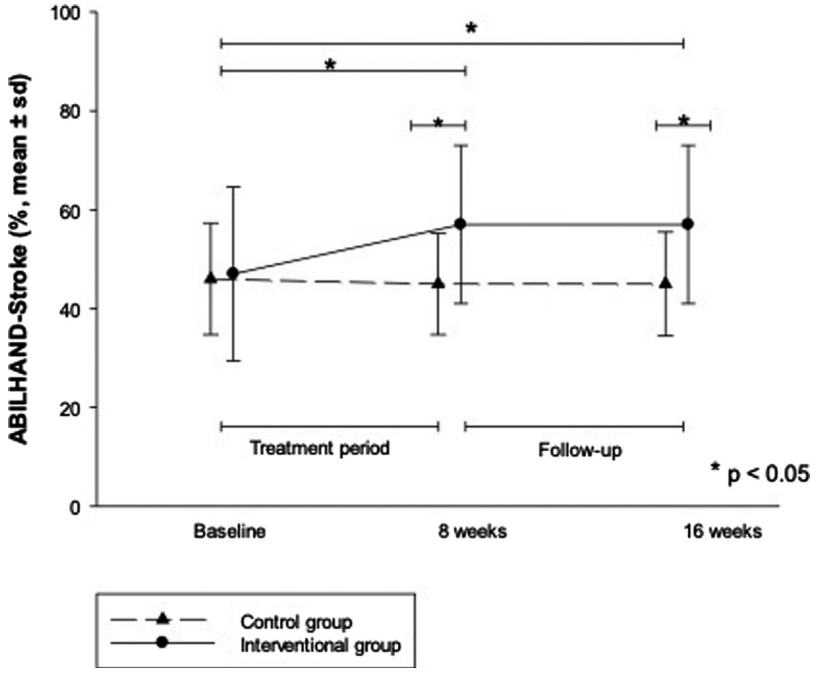

Fig. 2. Per-protocol analysis of mean manual ability scores (ABILHAND) for the control and intervention groups at evaluation times. Data are mean (SD).

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Table 2
Per-protocol analysis of group by time interaction (two-way repeated-measures Anova).

	T0	T1	T2	Interaction *P*-value	Time effect *P*-value			Group effect *P*-value		
					T0-T1	T0-T2	T1-T2	T0	T1	T2
ABILHAND-Stroke (%)										
CG	47 (11)	45 (10)	45 (10)	<0.001	0.79	1.00	1.00	0.991	<0.001	<0.001
IG	47 (18)	57 (14)	57 (14)		<0.001	<0.001	1.00			
BBT										
CG	16 (14.6)	18 (15.6)	20 (15.8)	0.1						
IG	15 (13.9)	19 (12.5)	22 (13.1)							
Grip force (kg)										
CG	13.9 (7.6)	15.0 (7.5)	15.2 (7.6)	0.1						
IG	12.7 (8.2)	15.7 (7.2)	15.5 (6.5)							
WHOQOL-26 (physical health)										
CG	11.9 (2.8)	11.9 (2.6)	11.7 (2.6)	<0.001	<0.001	<0.001	0.020	0.284	0.002	0.019
IG	11.2 (2.4)	13.8 (1.9)	13.2 (1.8)							
WHOQOL-26 (psychological state)										
CG	13.7 (2.6)	13.6 (2.1)	13.8 (2.4)	<0.001	<0.001	<0.001	0.055	0.666	<0.001	<0.001
IG	13.4 (2.4)	16.9 (1.6)	16.1 (1.8)							

Data are mean (SD). T0: pretreatment evaluation; T1: evaluation at the end of treatment; T2: evaluation 2 months after treatment; CG: control group; IG: intervention group; BBT: Box and Block test; WHOQOL-26: World Health Organization Quality of Life 26.

Table 3
Per-protocol analysis of group by time interaction (Friedman Anova and Mann-Whitney test).

	T0	T1	T2	Time effect	T0–T1	T0–T2	T1-T2
FMA-UE							
CG	41 [21–52]	44 [26–53]	45 [26–52]	<0.001	0.025	<0.001	0.412
IG	34.5 [24–47]	42.5 [35.5–48]	42.5 [36–48]	<0.001	0.030	0.003	0.743
P (group effect)	0.59	0.80	0.77				
WMFT							
CG	47 [26–59]	41 [28–57]	42 [27–56]	0.286			
IG	43 [27–53]	53 [41–60]	52.5 [41–60]	<0.001	<0.001	0.006	0.412
P (group effect)	0.62	0.22	0.21				

Data are median [Q1–Q3]. T0: pretreatment evaluation; T1: evaluation at the end of treatment; T2: evaluation 2 months after treatment; CG: control group; IG: intervention group; FMA-UE: Fugl-Meyer Assessment – Upper Extremity; WFMT: Wolf Motor Function test.

activities (WHO, 2001) [38] and if they are dose-matched [40–42]. Even the neural coupling between both hands does not seem higher after bimanual than unimanual intervention [42].

10. Self-rehabilitation and quality of life

At the end of the 8 weeks of self-rehabilitation, the intervention group showed significantly improved quality of life in physical and psychological health. The literature data are inconclusive. Indeed, although self-rehabilitation programs likely improve quality of life in psychological health [4,43], previous studies assessing upper-limb self-rehabilitation programs did not show any effect on quality of life parameters [5,32–36].

11. Limitations

The absence of treatment in the control group could be considered a limitation of this study. However, the study took into consideration the context of individuals with stroke in Benin. Although this choice precludes any conclusion on the superiority of self-rehabilitation over other therapies, it demonstrates that a self-rehabilitation program is an effective alternative in developing countries, where conventional rehabilitation cannot be implemented for economic reasons. In the future, the program should be compared to conventional therapy and its effectiveness assessed in the acute phase of stroke. The second limitation is a dropout rate slightly greater in the intervention than control group. Of note, no adverse event was reported by participants throughout the study and thus, dropout does not seem to be a side effect of the intervention. A third limitation is that we did not have any feedback on the actual performance of participants.

12. Conclusions

This upper-limb self-rehabilitation program was effective in improving muscle strength, manual ability and quality of life in individuals with chronic stroke in Benin; motor impairment and manual dexterity remained unchanged. Future studies are needed to confirm these results on objective and patient-reported outcomes.

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Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version at: https://doi.org/10.1016/j.rehab.2020.03.017.

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