Medical devices for self-help management: the case of stroke rehabilitation

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***Abstract*— *Introduction: Self-help devices (SHD) have been used as an alternative to conventional treatment for post stroke rehabilitation. This review aims to look for evidence that a stroke survivor may have increased muscle strength with the use of SHD. Methods: This article was conducted according to PRISMA, a statistical tool (state of the art by systematic review) and previously registered in PROSPERO (international prospective registry of systematic reviews) under number CRD42018091424. Studies addressing the use of SHD and its effect on muscle strength in stroke patients were included. The studies were read, selected and their metadata extracted. A Downs & Black scale was used to assess methodological quality. Results: 41 publications were analyzed, of which only three met the proposed inclusion criteria. Two articles showed positive results in strength gain using SHD. One study presented a decrease in the mean reaching forces when compared to the intervention groups (subacute and chronic with assistance to grip) and controls but SHD assisted in performing the activity. Conclusion: Studies using SHD suggest muscle strength improvement in stroke patients*.**

Keywords*— Stroke, self-help devices, strength, systematic review, assistive technology, assistive devices.

I. INTRODUCTION

Stroke is the second main death cause, leading to 11.8% death causes on the planet, and the third leading disability sake in the world[1]. In addition, it generates a high social burden and generates high costs for health systems[2]. This disease is characterized by a cerebrovascular malfunction, ischemic or hemorrhagic, that can result in deficiency of balance and gait, aphasia, dysphagia, intestinal and voiding dysfunction, depression, altered cognition and generalized muscular weakness[3].

The muscle weakness after stroke is a result of affected area neural hypofunction, followed by reducing muscle activity, tissue histochemical changes, and spasticity[4,5]. If it persists, it may progress to function loss and immobility[6]. Recent studies have highlighted the rehabilitation role in improving strength and complications after stroke [7–9]. During rehabilitation some tools can be used to increase treatment such as self-help devices (SHD).

SHD can be defined as any item, piece of equipment, software program or system that is used to increase, maintain or improve the functionality of people with any type of disability[10]. They are part of a growing area of study with multiple applications that promotes greater acceptance by the patient and transforms current health care delivery models [11,12]. Studies suggest the efficacy of SHD in improving upper limb motor function, gait and aphasia, after stroke episode[8,13,14]. Their association with conventional therapy has been the object of study by researchers[15]. However, the effect of SHD on strength in patients with stroke was not elucidated. Provision of home-care, instant feedback and patient entertainment are SHD characteristics that give greater incentive and decrease patient frustration[11,16]. In addition, Bendixen *et al* (2009) demonstrated that the use of SHD can reduce treatment costs by up to 46% when compared to conventional treatment[17].The objective is to review studies that evaluate muscle strength in patients who had had a stroke and underwent SHD.

II. METHODS

This systematic review was performed according to the items established by the PRISMA (Preferred Reporting Items for systematic Reviews) guide[18] of the main items that a systematic review should contain. Previously, a review protocol was drawn up, which included the research strategy, methods and eligibility criteria (inclusion and exclusion). The StArt tool (State of the Art through Systematic Review v.2.3.4.2), developed by the team of the Software Engineering Research Laboratory of UFSCar, was used to conduct the systematic review, and the analysis and selection of the studies were performed by the program. This tool has been used in other reviews[19–21].

Search strategy and eligibility criteria

The descriptors of the MeSH (Medical Subject Headings) were used: "Self-help devices" (which includes the terms Assistive Technology and Assistive Devices), "Stroke" and "Strength". The Boolean operator used was AND and OR and searches were performed from January to March 2018. The electronic databases consulted were: PubMed, Clinical trials, IEEE, Scopus and Web of Science, searching studies that addressed the use of ShD in individuals who had stroke. An unlimited search was performed using the terms: stroke* OR strenght* OR Self-help devices* OR Assistive Technology OR Assistive Devices

Only studies in the English language, which included Self-help devices were included in this review. There was no restriction of design and study period. The PICO strategy (Population, Intervention, Control and Outcomes) was used. The inclusion and exclusion criteria for assessing the eligibility of the studies are described in Table I.

Table I Criteria for eligibility (inclusion and exclusion) of articles for systematic review

Criteriacategory	Inclusion	Exclusion
Population	Men and women, adults and the elderly, after ischemic or hemorrhagic stroke.	Men and women, adults and the elderly, with other diseases associated with stroke.
Intervention	Use of assistive technology as a therapeutic proposal.	Association of conventional therapy (therapeutic exercises, mechanotherapy, etc.) to assistive technology, throughout the intervention period.
Variable	Studies that evaluated muscle strength.	-

The reviewers (P.A.F.M. and N.A.M.V.) independently conducted database searches as well as analyzed the title and summary of articles collected and identified, from the eligibility criteria, the potential studies for this review. The results were compared and, in the event of any disagreement, a consensus was reached. If agreement was reached, they would proceed to the next step, which included reading the full text of the selected articles to certify that they met the eligibility criteria. This step was also performed by the two reviewers separately and, subsequently, consensus was achieved. The studies that did not meet the proposed criteria were excluded with justification. All disagreements were evaluated by a third reviewer (J.C.T.R.).

This study was previously International Prospective Register of Systematic Reviews and Meta-analyzes (PROSPERO) under the number CRD42018091424.

Evaluation of methodological quality and data extraction

The evaluation was performed by two independent authors (P.A.F.M and E.D.S.S.), and a third author (J.C.T.R.) to resolve any disagreement.The articles included in this review had their methodological quality assessed by the Downs & Black instrument[22]. This tool evaluates the delineation of articles from five sub scales: reporting quality, internal validity (bias and confounding), external validity and the ability to detect significant effect of the study (power). This study used the version of 27 yes or no questions, the first 26 being scored a point (1) for yes and zero point (0) for no, except for the fifth question of maximum score two points (2) and the last question item that is scored from zero to five (5) points according to the significant effect of the study.The selected studies had their data extracted: general characteristics (Author, Year and Country), Population, Intervention, Evaluation method, information about SHD used and Results. The metadata were extracted by two independent investigators (P.A.F.M.).

III. RESULTS

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The literature review identified 41 abstracts and after the withdrawal of the duplicate studies, the application of the inclusion and exclusion criteria during the reading of the titles, abstract and later the full text participated in this review 3 studies, two before and after design type and a clinical trial design type in the English language. Figure 1 shows the study flow diagram (PRISMA):

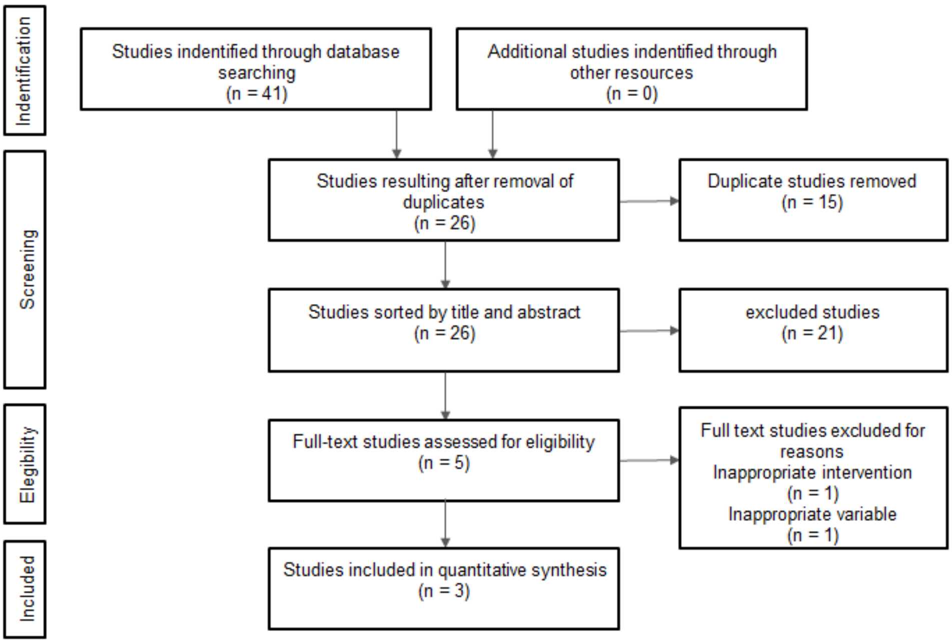

Fig.1: Study flow diagram (PRISMA)

The studies evaluated had low scores for external validity, power and confounding, and median score for bias. All studies had high scores for reporting quality. The evaluation results of the methodological quality of the included studies are shown in table II:

Table II Methodological quality evaluation of the reviewed studies

Author, Year and Country	Population	Intervention	Self-help Devicesemployed	Evaluation method	Results
Lambercy, 2011, Singapore	n = 15 (7 men) Age (mean in years ± standard error of the mean) = 55.5 ± 14.6 Chronicity (mean in days ± standard error of the mean) = 597.5 ± 294.1 Patients lost = 2 (cause: fall and ADHD/depression)	Robot-assisted fingers gripping/extension and pronation/supination exercises in 18 one-hour sessions for 6 weeks associated with conventional therapy (Occupational Therapy) from 6 to 12 weeks.	Haptic Knobis a robotic orthosis with two degrees of freedom for grip training.	Jamar grip dynamometer	Improved hand grip

Thielbar, 2016, USA	n = 23 Age (mean in years ± standard error of the mean) = VAEDA (61 ± 12); sem VAEDA (56 ± 10) Chronicity (mean in months ± standard error of the mean) = VAEDA (95 ± 114); without VAEDA (46 ± 47) Patients lost = 1 (cause: no related)	Task oriented protocol with or without the VAEDA in 18 one-hour sessions for 6 weeks.	VAEDA is a glove driven by voice and electromyography, which performs finger extension and imposes resistance to finger flexion.	Jamar grip dynamometer	Improved hand grip
Ziherl, 2010, Slovenia	n = Sub acute (23); Chronic (10) Age (mean in years ± standard error of the mean) = Sub acute (51,0 ± 13,3); Chronic (45,6 ± 13,0) Patientslost = 0	Robot-assisted take-and-place exercise with the same assistance for 6 minutes of workout per workout session.	Virtual reality game for all groups and the Haptic Master robot with a rotational degree of freedom and two degrees of translational freedom.	Final effector sensor	no improvement in handgrip

Characteristics such as year of publication, country of origin and sample are summarized in table III and the results of the articles in Figure 2:

Table III Data extracted from articles selected for review.

	Reporting (11)	**External Validity (3)**	**Bias (7)**	**Confounding (6)**	**Power (5)**	**Total (32)**
Lambercy	8	0	5	1	0	**14**
Thielbar	8	0	4	3	0	**15**
Ziherl	8	0	3	1	0	**12**

Two studies included [23,24] presented positive effects for muscle strength , one study showed an increase in muscle strength for palmar grip at the end of treatment (Week 6) and both showed an increase in the follow-up period (Week 10 and 12) when compared to the previous intervention period (Week 0). However, there was no statistically significant difference between the periods, p = 0.637[24] and p = 0.307 [23] for grip strength. With reevaluation in the post-treatment follow-up period, there was a decrease in the mean strength compared to the final period of therapy, also without significant statistical differences.

The third study[25] presented a decrease in the mean reaching forces to be arrested when compared to the intervention groups (subacute and chronic with assistance to grip) and controls (control, subacute and chronic without assistance to grip), and the group had negative mean values, which means SHD assists in performing the activity. The study presented a significant difference between the groups without assistance to grip (subacute, chronic and control), with p = 0.004 for subacute and p = 0.003 for chronic.

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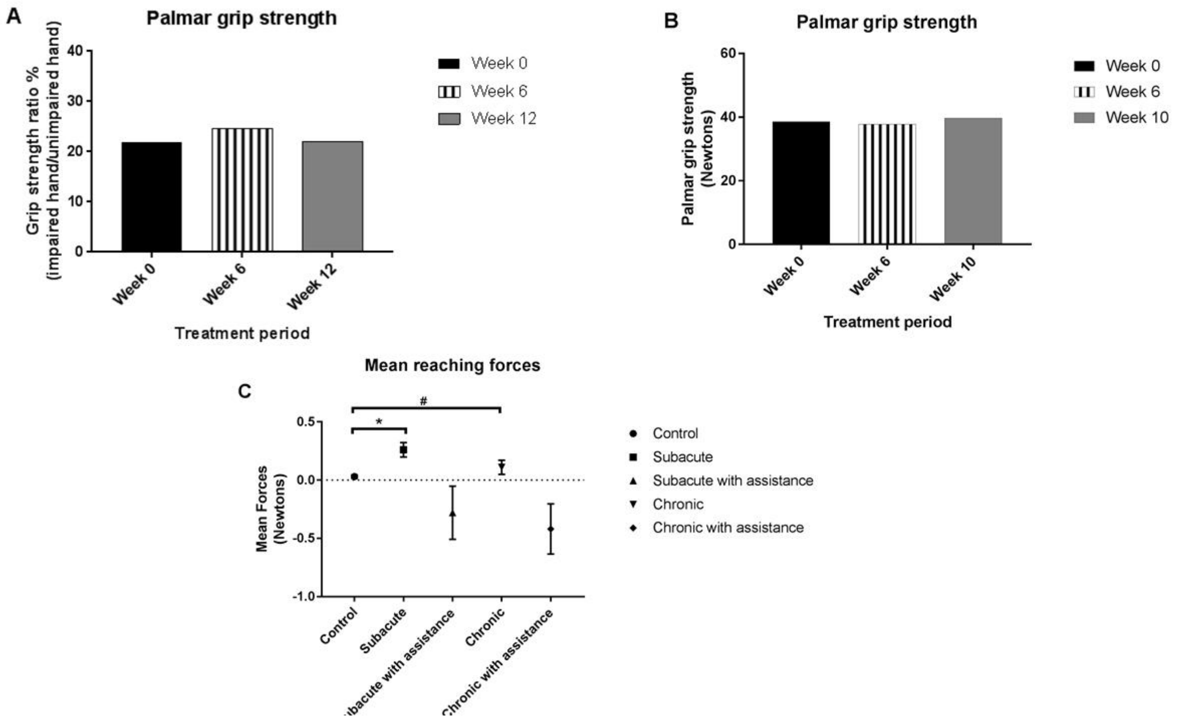

Fig.2 Studies results included to review. A) Analysis of palmar grip strength (%) from results obtained in the Lambercy (2011) study. The force is presented in relative value between the impaired and unimpaired hand. It presents value of p = 0.307 between the periods. B) Analysis of palmar grip strength (N) from the results obtained in the Thielbar (2016) study. It presents a value of p = 0.637 between the periods. C) Analysis of the mean grip strength ± SEM (N) from results obtained in the Ziherl (2010) study. It presents a value of p = 0.004 (*) between the subacute group without assistance and control, p = 0.003 (#) between the chronic group without assistance and control.

IV. DISCUSSION

This study is the first review to evaluate the effect of SHD on muscle strength in stroke survivors. Two revised studies presented a positive effect on improving muscle strength [23,24]. A third study had negative mean grip strength values, although SHD assisted in performing the activity [25]. The results suggest an increase in muscle strength in surviving stroke patients undergoing SHD. Importantly, the study in which there was no increase in muscle strength assumed that the SHD used accommodated the subjects and let the assistants do the movement without making any effort [25]. Regarding the positive effects studies, they present results that demonstrated increased muscle strength in the ten and twelve-week follow-up period compared to the pre-treatment period (week 0), but with no statistically significant difference.

Hand grip strength is indicated as an important variable for cardiovascular disease monitoring. Increasing this variable has been associated with low risk of mortality in cardiovascular disease [26]. Manifestation of palmar grip weakness is a good predictor of functional deficit after stroke [27]. In the revised studies, strength was assessed using dynamometers or sensors widely used in the literature [26,28,29], but there are other ways to assess stroke strength, such as the Wolf test [30] and Stroke. Impact Scale [31]

SHD and the association of conventional motor function rehabilitation have been shown to improve palmar grip strength and beneficial impact on cortical neuronal plasticity [32]. This plasticity is regulated by the expression of proteins such as brain-derived neurotrophic factor (BDNF), calcium-calmodulin-dependent kinase II (CaMKII), glial fibrillar acid protein (GFAP), scaffolding proteins, and post-synaptic membrane receptors that cause adaptation. changes in synapse number, morphology and transmission power [33]. This reveals that increased strength may be explained by factors extrinsic to the muscle. In addition to reaffirming the beneficial effect of SHD in improving the strength of stroke patients.

During the extraction phase, one study was excluded due to the lack of strength as a variable of evaluation. Another excluded work was a case study that combined SHD with conventional therapy throughout the treatment period. In this case study, the subject presented hypertension and end-stage renal disease, predisposing to an inflammatory pattern,

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and a bias that interfered with the structure and production of muscle strength [5,34].

In this study, the Downs & Black scale was used because it presents a wide range of study types to which it can be applied, such as nonrandomized clinical trials, cohort studies, and case studies. There is a great divergence in the literature regarding the assessment of power on the Downs & Black scale. Some researchers suggest the evaluation by the presence of the effect size calculation, α (type I error) and β (type II error), which makes a quantitative evaluation in a qualitative evaluation of the presence of a statistical calculation, underestimating the power proposed by Downs. & Black [35].

In evaluating the quality of the studies, good external validity, confusion and control of mean bias were not presented according to the Downs & Black questionnaire. The lack of control over these variables implies the low reproducibility of these studies, so as not to obtain statistically significant differences and heterogeneity of results. Studies of the randomized clinical trial with strength assessment by blinding evaluators and better methodological quality are needed to evaluate the effect of SHD on muscle strength in stroke patients.

V. LIMITATIONS AND CLINICAL RELEVANCE

We note that some studies may not have been identified for screening because they do not include other databases. Another limitation was the heterogeneity of the studies, which made comparison difficult.

Knowledge of studies evaluating the clinical efficacy of SHD use aimed at increasing post-stroke muscle strength gains has pointed to a new perspective for improving functionality, increasing independence, and contributing to improved post-stroke quality of life stroke.

VI. IMPLICATIONS FOR HEALTH MANAGEMENT PRACTICE

The use of assistive devices assists in the management of post stroke rehabilitation, and this reflects in the functional improvement of the patient as it provides autonomy and independence. In this context, it's applicability includes assessment, patient and caregiver education, treatment and follow-up. The use of these devices in the treatment of post stroke patients is intended to improve functionality as a whole, including not only improved structure and function. Therefore, help-devices contribute to the management of health services and increase the quality of life of patients with stroke.

VII. CONCLUSION

The use of SHD in the stroke can contribute to the increase of muscular strength. However, there is a need for randomized clinical trials with well-defined methodological design to certify the therapeutic effect of SHD on muscle strength in patients with stroke.

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CONFLICTING INTERESTS

The Author(s) declare(s) that there is no conflict of interest.

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