Review Article

Use of the Leap Motion Controller® System in the Rehabilitation of the Upper Limb in Stroke. A Systematic Review

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Objectives: Upper limb impairment is the most common motor impairment in stroke survivors. The use of new technologies in the field of rehabilitation aims to reduce the impact of functional problems. Our objective is to evaluate the effectiveness of using the Leap Motion Controller® virtual reality system in the treatment of upper limb functionality in people with stroke. *Materials and Methods:* PRISMA guidelines were used to carry out the systematic review. The literature search was restricted to articles written in English or Spanish published from 2012 to December 2020 in Pubmed, Web of Science, Scopus, PEDro and Science Direct. Of the 309 search results, 230 unique references were reviewed after duplicates were removed. The Downs and Black and CONSORT scales were applied to evaluate the methodological quality of the included papers and the degree of evidence and level of recommendation were determined through the Oxford Centre for Evidence-Based Medicine. *Results:* Six papers with a total of 144 participants were included in this review, with heterogeneity of the sample, assessment measures, protocols, number of sessions and diversity of games applied. The main results of the studies show favourable data after using the Leap Motion Controller® system in the improvement of upper limb functionality in people with stroke. *Conclusions:* There is a growing trend in the use of the Leap Motion Controller® device as a tool in the treatment of the upper limb in people with stroke. Nevertheless, the limitations encountered suggest the need for future research protocols with greater scientific rigor.

Key Words: Leap Motion Controller®—Neurorehabilitation—Serious games—Stroke—Upper limb—Virtual reality

Introduction

Stroke is considered by the World Health Organisation (WHO) to be a global public health problem that leads to significant disabilities.[1] The number of stroke sufferers is expected to increase as the population ages.[2] A recent European report indicated that between 2015−2035 there will be an overall increase of 34% in the total number of stroke events in the European Union.[3]

Upper limb (UL) impairment is the most common motor impairment in stroke survivors, leading to inability to reach, grasp or manipulate, which directly influences activities of daily living (ADLs).[4] More than 80% of stroke survivors experience acute UL and, for half of them, the disability becomes chronic.[5]

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Received July 10, 2021; revision received October 5, 2021; accepted October 8, 2021.

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1052-3057/$ - see front matter

https://doi.org/10.1016/j.jstrokecerebrovasdis.2021.106174

New technologies, such as virtual reality (VR), are currently positioning themselves as a tool of interest as a complement and/or alternative to rehabilitation in people with stroke in order to address functional problems at the UL level.[6,7]

There are several devices on the market with promising results in the global treatment of motor impairment in UL, although most of these devices do not offer the possibility of working on fine wrist and finger movement, which is necessary to achieve efficient reaching, grasping or manipulation movements.[8]

In this sense, Leap Motion Controller® is a low-cost VR device, recently used in the field of neurorehabilitation, that does not use motion markers, and collects forearm, wrist and hand movements.[9] The collected data is transmitted via USB to the Leap Motion Controller® tracking software. This system analyses images to reconstruct a three-dimensional representation of what the device sees.[10] The result is the generation of a virtual environment in which the subject interacts semi-immersively.

In general, these types of therapies using VR environments are well received by users. The possibility of being able to multitask in the home in a safe and entertaining way, as well as improved adherence to treatment, the availability of real-time feedback and a low economic cost are some of the reasons that explain good acceptance by users.[11] However, the scientific literature lacks evidence to justify its use in stroke survivors.

Due to the high prevalence of stroke, the expected increase in incidence, and the fact that these are chronic processes that will require long-term treatment and care due to the functional disability they entail, it is therefore necessary to establish evidence on whether these recently implemented technologies can provide answers to these key points.

The objective of this review was to evaluate, through a compilation of research studies, the effectiveness of the use of the Leap Motion Controller® VR system in the treatment of UL functionality in people with stroke.

Methods

Criteria for assessment of studies in review

- Design
  The clinical trials and randomised controlled trials (RCTs) included in the study tested the effectiveness of the use of the Leap Motion Controller® system in VR environments as a complementary or non-complementary rehabilitation to other treatments. Single intervention group studies were included, such as a comparison between an intervention group (IG) and a control group (CG).
- Type of participants
  The inclusion criteria for participants in this review were limited to adults with stroke and UL involvement.
- Type of intervention
  The trials performed any type of UL therapeutic technique, based on the use of the Leap Motion Controller® system in VR environments.
- Type of outcome measures
  For the outcome measures, the selected papers evaluated the effect of the Leap Motion Controller® on UL functionality, muscle strength, spasticity, manual dexterity and coordination, participation, satisfaction and usability-related variables.

Search strategy for identification of studies

The search for articles was carried out from November to December 2020. The databases consulted were: Pubmed, PEDro, Web of Science (WoS), Scopus and Science direct. The publication date was set from 2012 (the year in which the first Leap Motion Controller® units were distributed[12]) to the end of 2020. Likewise, only scientific articles published in English and Spanish were included.

The search strategy was based on the following formulas: (1) "Leap Motion" AND stroke; (2) "Leap Motion" AND "cerebrovascular disease"; (3) "Leap Motion" AND " stroke rehabilitation". The results of each search are as below:

1. "Leap Motion" AND stroke. 15 results were found in Pubmed, 1 in PEDro, 67 in WoS, 73 in Scopus and 74 in Science Direct.
2. "Leap Motion" AND "cerebrovascular disease". Only one result found in Science Direct.
3. "Leap Motion" AND “stroke rehabilitation”. In Pubmed we found 9 results, in PEDro 0, in WoS 28, in Scopus 28 and in Science Direct 13.

Review methods

A selection of titles and abstracts of the results found in the databases was performed. We assessed the content of those selected and identified studies that met the inclusion criteria, jointly established by two authors (AAR and IMAD). Subsequently, two authors (AML and ACG) independently read the full texts of the selected articles that met the inclusion criteria and ranked them according to their relevance. In order to improve the quality of the present systematic review, the guidelines of the PRISMA statement[13] were followed.

Risk of bias

Risk of bias is more common in the articles selected for the review. Each article in this systematic review was carefully examined for risk of bias. The following biases were considered and critically analysed: selection bias, performance bias, detection bias, attrition bias and

between-study reporting bias. These details were mentioned in the results section.

Methodological quality assessment

The methodological quality of the selected papers was assessed using the Downs and Black scale[14] and the CONSORT checklist.[15]

In addition, the Oxford scale[16] was applied to all selected articles to determine the levels of evidence and recommendation, rating the level of evidence according to the best design for each clinical scenario.

Results

Description of studies

After searching the different databases, the total number of studies found was 309. A total of 79 were discarded as duplicates, leaving 230 to be analysed. Subsequently, the articles were analysed and 211 were excluded because they did not meet the inclusion criteria for this review. Finally, six articles were included[17-22] after eliminating 13 for not using the device as therapy or if literature was not peer-reviewed (Fig. 1).

The selected papers included a total sample of 144 participants.[17-22] A summary of the characteristics of the included studies[17-22] is presented in Table 1. The main results of each paper are presented according to the following criteria: year of publication (in ascending chronological order), type of study, characteristics of participants, type of intervention, outcome measures used, evaluation and relevant results.

Summary of main results

Functionality. Different tools were used in several articles to quantify the presence of absence of functional improvements: Upper Extremity Fugl-Meyer Assessment (UEFMA),[18,20,22] Action Research Arm Test (ARAT),[20] Wolf Motor Function Test (WMFT),[19] Functional Independence Measure (FIM)[20,21] and The Stroke Upper Limb Capacity Scale (SULCS).[17] With the exception of one article,[18] statistically significant improvements were achieved in all but one of the participants using the Leap Motion Controller® device.

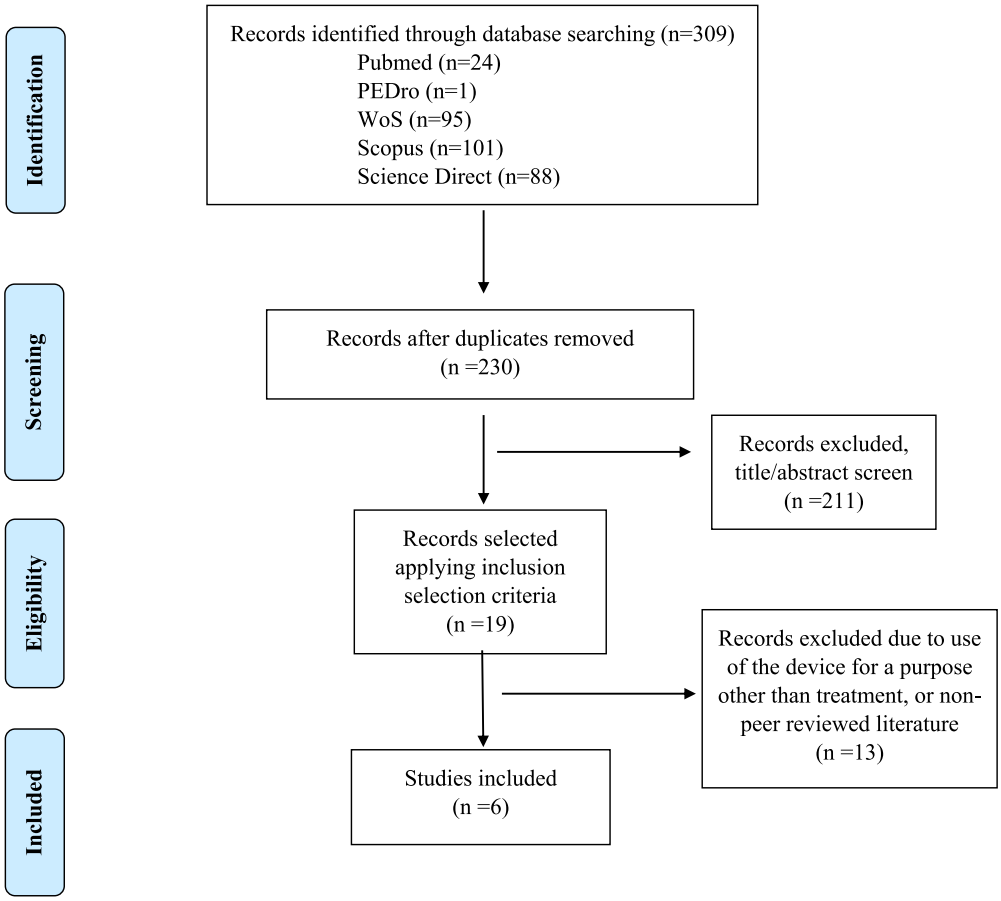


Fig. 1. *Flow chart.*

Table 1. *Summary of results*

Author	Type of study	Injury of the participants	Intervention and duration of treatment	Outcome measures	Evaluation	Main results
Iosa et al. (2015)	CT crossover	Subacute phase stroke Age >65 years. Sex: M and F Ischemic injury Hemiparesis with UL disability. Two groups: IG1: (n=2) IG2: (n=2)	IG1: Conventional therapy (80′day/5 day-week/2 week) (20 sessions) + TTO LMC (30′) (3 day/week/2 week) (6 sessions) Conventional therapy (80′day/5 day-week/2 week)(20 sessions) IG2: Conventional therapy (80′ day/5 day-week/2 week)(20 sessions) Conventional therapy (80′day/5 day-week/2 week) (20 sessions) + TTO LMC (30′) (3 day/week/2 week) (6 sessions)	−PRPS −SULCS −MSA −NHPT −Dynamometer −Abilhand Scale	Pre (T0) and post (T1 and T2) evaluation T1: after the 1st part of the treatment (2 weeks). T2: after the 2nd part of the treatment (4 weeks) The evaluations were conducted on both groups equally. Both groups start from a similar functional state	After the intervention: The participation of the subjects was between excellent and very good. Decreased spasticity in the wrist in one participant, and in two of them in the shoulder during LMC use Significant differences in grip strength between T0 and T2 in 3 of the 4 patients when LMC is added (p=0.006). No significant differences in terms of digital clamping force. Significant differences in hand ability data when LMC is added (p=0.042). No significant difference in manual dexterity (p=0.181), although all participants improved during LMC use.

Table 1 (*Continued*)

Author	Type of study	Injury of the participants	Intervention and duration of treatment	Outcome measures	Evaluation	Main results
Vanbellingen et al. (2017)	CT	Acute phase stroke Age: 24-91 years old. Sex: M and F Affected UL (NHPT > 19; 3 ≤ Medical Research Council scale < 5) IG: (n=8) No CG	IG: 9 sessions (30′) / 3 weeks (3 sessions/week) The LMC protocol includes 5 sets	SUS PRPS NHPT Dynamometer Jamar DextQ-24 UEFMA Questionnaire of satisfaction	Pre-treatment evaluation (T0) Evaluations during treatment (T3, T6) Post-treatment evaluation (T9) Evaluations were conducted equally for all participants.	After the intervention: Positive data regarding the usefulness of the system rated with SUS, as the scores are > 70. Non-significant changes in the level of active participation (p=0.07), although it improved from good to very good. Significant data in (in all measurements and between all measurements): NHPT: Baseline (M = 49.96 s, SD = 26.85) Post-treatment (M = 34.21 s, SD = 7.33). DextQ-24: baseline (M = 41.4, SD = 15.8) Post-treatment (M = 34.6, SD = 16.0). Jamar: baseline (M = 23.5 kg, SD = 8.3) Post-treatment (M = 26.2 kg, SD = 6.6). No significant data in UEFMA (p > 0.05). (M = 57.5, SD = 9.3), (M = 58.5, SD = 6.7). Positive feedback from participants.

(*Continued*)

Table 1 (*Continued*)

Author	Type of study	Injury of the participants	Intervention and duration of treatment	Outcome measures	Evaluation	Main results
Wang et al. (2017)	RCT	Subacute phase stroke Age: 18-75 years old. Sex: M and F Affectation (medium-moderate) in UL Two groups: CG: (n=13) IG: (n=13)	CG: conventional OT 2 sessions per day (45′ each) / 5 days per week/ 4 weeks + Conventional PT 1 session per day (45′) / 5 days per week/ 4 weeks GI: LMC (45') + conventional OT (1 session of each therapy of 45′ each) / 5 days a week/ 4 weeks + conventional PT 1 session per day (45′) / 5 days per week/ 4 weeks The LMC protocol includes 6 sets	WMFT MRI Satisfaction Questionnaire	Pre- and post-treatment evaluation. Evaluations were conducted equally for all participants. Both groups start from a similar functional state.	After the intervention: Significant data in WMFT in both groups ($P < 0.01$). Further increase in the intensity of the sensorimotor system activity in the IG. Positive feedback from participants.

Table 1 (*Continued*)

Author	Type of study	Injury of the participants	Intervention and duration of treatment	Outcome measures	Evaluation	Main results
ÖGÜN et al (2019)	RCT	Ischemic stroke Chronic phase stroke Sex: M and F Mini-Mental State Examination ≥25 MAS <3 UL scale and Brunnstrom's hand ≥ 4 Two groups: CG: (n=32) IG: (n=33)	CG: 45′ conventional therapy + 15′ RV (3 days/weeks / 6 weeks) IG: 60′ RV (3 days/week/6 weeks). The VR protocol includes 4 sets	ARAT FIM EUFMA PASS-BADL PASS-IADL	Pre and post treatment evaluations. Evaluations were conducted equally for all participants. Both groups start from a similar functional state.	After the intervention: Significant increase in UEFMA ($p < 0.001$), ARAT ($p < 0.001$), and FIM ($p < 0.002$), scores in IG. The differences in PASS-BADL ($p = 0.509$) and PASS-IADL ($p = 0.542$) were not significant. The UEFMA, ARAT, FIM and PASS scores increased significantly compared to the baseline in the IG ($p < 0.001$). Significant mean difference comparing pre- and post-treatment scores for ARAT (MCID 5.7), UEFMA (MCID 5.25).
Colombo et al. (2019)	CT	Ischemic and hemorrhagic stroke Acute and Subacute phase stroke Sex: M and F UEFMA FIM BBT MAS Likert Two groups: CG: (n=15) IG: (n=15)	IG and CG: 15′warming up + 20′ therapy Each exercise lasts 1.5′ + 1.5′ rest Total time for each session 12-18′. The VR protocol includes 8 sets. The IG only made between 4 and 6 games.	Forearm Prone Supination (MV; SM; angle) F/E wrist (MV; SM; angle) Grip (MV; SM; grip parameters)	Pre and post treatment evaluations. Evaluations were conducted equally for all participants. Both groups start from a similar functional state	After the intervention: Results between groups: All results were significantly higher in healthy patients. Results between T0 and T1 in the IG: Prono-Supination: moderate to excellent average ICC (0.938-0.580) score on all parameters. F/E wrist: moderate to excellent ICC (0.968-0.670) values, for all parameters except for smoothness of movement.

(*Continued*)

Table 1 (*Continued*)

Author	Type of study	Injury of the participants	Intervention and duration of treatment	Outcome measures	Evaluation	Main results
						Grip: moderate to excellent ICC (0.920-0.485) values, except for the smoothness of movement. Correlation between clinical scales and the 15 measured parameters: During prone-supination: moderate and significant correlation with MV and UEFMA (p=0.012) and FIM (p=0.003) Supination angle moderate negative correlation with BBT (p=0.017) During wrist F/E: moderate correlation between MV and FIM (p=0.017), and between the angle of extension and the UEFMA scale (p=0.033). Grip: moderate to strong correlation with MV and BBT (p=0.005).
Fluet et al. (2019)	CT	Ictus Age: 40-80 years old IC: unilaterally affected stroke Montereal Cognitive Assessment ≥22 No neglect No perceptual problem UEFMA 36-58 No aphasia EC: orthopedic	The VR protocol includes 3 sets. Speed Bump: prone-supination forearm and F/E fingers Urban Aviator: F/E wrist Maze Runner - Reach Movements GEM and GUC: 12 weeks of tto at home with	IMI Adherence UEFMA BBT	Pre and post treatment evaluations. Evaluations were performed equally on all participants except for the increased difficulty. The EMG increased the difficulty by 8-12 levels. The UCG increased the difficulty according to an algorithm.	After the intervention: IMI: Improved intrinsic motivation levels in EMG. Adherence: Both groups have higher levels of adherence than described. UEFMA: statistically significant changes ($P < 0.001$).

Table 1 (*Continued*)

Author	Type of study	Injury of the participants	Intervention and duration of treatment	Outcome measures	Evaluation	Main results
		pathology, another CNS problem Two groups: EMG: (n=5) UCG: (n=6)	online support Min 20'/ day		Both groups do not start from a similar functional state. EMG: average age 58 - 9 years, UEFMA average 44 - 14 (slightly younger and more affectionate) UCG: average age 65 - 15, average UEFMA 51 - 8	EMG: from 0.2 to 0.8; UCG: from 0 to 0.4 BBT: statistically significant changes (P = 0.0485). EMG: from 1 to 6; UCG: from -1 to 4

CT: Clinical trial, RCT: randomized clinical trial, CG: Control Group, IG: Intervention Group, UL: upper limb, LMC: Leap Motion Controller®, VR: Virtual Reality, IC: inclusion criteria, EC: exclusion criteria, CNS: Central Nervous System, F/E: flexo-extension, PT: Physical Therapy, OT: Occupational Therapy, WMFT: Wolf Motor Function Test, UEFMA: Upper Extremity Fugl-Meyer Assessment, MSA: Modified Ashworth scale, SULCS: The Stroke Upper Limb Capacity Scale, BBT: Block and Box Test, NHPT: Nine-Hole Peg Test, DextQ-24: Dexterity Questionnaire 24, PRPS: Pittsburgh Rehabilitation Participation Scale, SUS: System Usability Scale, ARAT: Action Research Arm Test, ICC: Intraclass Correlation Coefficient, PASS-IADL: Performance Assessment of Self-Care Skills—instrumental activities of daily living, PASS-BADL: Performance Assessment of Self-Care Skills—basic activities of daily living, FIM: Functional Independence Measure, MV: mean velocity, SM: smoothness of movement, EMG: enhanced motivation group, UCG: unenhanced control group, IMI: Intrinsic Motivation Inventory.

Strength. Three studies[17,18,21] evaluated the strength of the UL, obtaining statistically significant improvements in all of them. Only one of them[17] differentiated between grip and digital strength, obtaining significant results only in the former.

Spasticity. The Modified Ashworth Scale (MAS) was used in one study,[17] and improvements were observed in participants' spasticity at both the wrist and shoulder.

Bimanual ability: One study measured this variable using the Abilhand Scale, obtaining improvements with respect to the initial assessment.[17]

Dexterity. Improvements in dexterity and coordination were observed in three studies, using the Nine-Hole Peg Test (NHPT),[17,18] the Dexterity Questionnaire 24 (DextQ-24),[18] and the Block and Box Test (BBT),[22] with respect to baseline values.

Performance of daily living tasks. Using the Performance Assessment of Self-care Skills (PASS) observation tool, one study[20] found positive data, compared to the initial assessment.

Participation. The Pittsburgh Rehabilitation Participation Scale (PRPS) was used in two studies,[17,18] with participation scores ranging from very good to excellent in one study,[17] and good to very good in the other.[18]

Satisfaction. Satisfaction surveys are mentioned in three of the six studies, all of which report favourable data on the use of the Leap Motion Controller® in people with stroke.[18,19,22]

Usability. Only one study[18] assessed usability aspects, using the System Usability Scale (SUS), which yielded positive results with scores above 70.

Methodological quality

The Downs and Black scale was used. The following scores were obtained: 20[19,20]; 18[18]; 17[21, 22] and 16[17] in the included studies (Table 2).

In addition, the included papers were also analysed using the CONSORT checklist (Table 3).

The Oxford scale was used to assess both the levels of evidence and recommendation of the clinical trials and RCTs. A level 1b was obtained in two of the studies[19,20] and a level 3b in the remaining studies[17,18,21,22] (Table 4).

Regarding the existence of losses throughout the intervention, only one study[18] described the losses of the participants.

Risk of bias within studies

The results of the bias analysis are presented in Table 5 below.

Discussion

The purpose of this review was to evaluate the effectiveness of the Leap Motion Controller® system as a

Table 2. *Downs and black.*

	Reporting										External validity		Internal Validity (bias)						Internal Validity (confounding)						**Power**	
Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	TOTAL
Iosa et al. (2015)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	U	N	Y	U	N	Y	Y	Y	Y	Y	Y	U	N	N	Y	U	U	16/27
Vanbellingen et al (2017)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	U	U	Y	N	N	Y	Y	Y	Y	Y	Y	Y	N	N	N	Y	U	18/27
Wang et al. (2017)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	U	U	Y	U	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	U	U	20/27
ÖGÜN et al (2019)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	U	U	Y	U	Y	Y	Y	Y	Y	Y	Y	U	Y	U	Y	Y	U	20/27
Colombo et al. (2019)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	U	U	Y	U	N	Y	Y	Y	Y	Y	N	U	N	N	Y	Y	U	17/27
Fluet et al. (2019)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	U	U	Y	N	N	Y	Y	Y	Y	Y	Y	U	Y	N	U	U	U	17/27

Y (yes) = 1 N (no) = 0 U (unable to determine) = 0

therapeutic tool for UL in people with stroke by compiling and critically reading the published literature.

We believe that the search strategy was detailed and identified the most relevant papers.

All selected papers displayed positive aspects of the use of the Leap Motion Controller® as a treatment for people with stroke. However, there are methodological shortcomings that require cautious reading of the results.

The Cochrane review on the use of VR in stroke patients[23] states that most of the studies in this field have small sample sizes (less than 25 participants), limiting the ability to compare results between them. After examining the studies included in this review, three[19-21] included sample sizes above this figure, although in one,[21] the control group consisted of healthy patients. Also, two of the choices were RCTs,[19,20] two trials blinded the assessors[19,21] and one was double-blinded.[20]

Regarding the type of stroke, only one study[21] reported that participants suffered ischaemic or haemorrhagic stroke. Two papers[17,20] specified that participants suffered ischaemic stroke, and the remainder,[18,19,22] did not provide details. Considering that ischaemic strokes account for 80−85% of total strokes, the proportion of studies that differentiated between ischaemic and/or haemorrhagic stroke is comparable to the latest statistics.[24]

In our analysis of the experimental protocols of the included studies, we concluded that the time and dose of treatment were not homogeneous, although the average session time was 30 min and the duration of treatment was between two−six weeks. Follow-up and assessment in all selected studies were limited to a single examination pre- and post-treatment, but none of the studies introduced an assessment after a period of time. Furthermore, the concept emerged that not only the use of the Leap Motion Controller® system in combination with other therapy (physiotherapy and/or occupational therapy) is effective,[17,19] but that its use as the sole form of treatment is also effective.[18,20-22]

In both investigations supplemented with other therapy[17,19], the final treatment amount was the same in all groups. However, in the crossover study,[17] intergroup assessments showed that the increased treatment time allocated to the Leap Motion Controller® intervention helped to provide a significant increase in participants' grip strength and hand dexterity.

It seems that the amount of therapy with use of the Leap Motion Controller® device is not a determining factor in the improvement of functionality of UL, as significant improvements have been obtained with different times. Even so, it is important to emphasise that the article[20] that dedicated the most time to VR (60 min) is one of the two with the highest methodological quality. Among these two articles, the one that uses the most instruments for assessing the functionality of UL, with practically all its data (UEFMA, ARAT, FIM, PASS), was found to be statistically significant.

Table 3. *Checklist consort.*

ITEM (Extension for pilot and feasibility trials)	Iosa et al. (2015)	Vanbellingen et al (2017)	Wang et al. (2017)	Colombo et al. (2019)	Fluet et al. (2019)	ITEM	ÖGÜN et al. (2019)
Title and abstract						Title and abstract	
1a	1	1	NO	1	1	1a	NO
1b	1	1	NO	NO	1	1b	NO
Introduction						Introduction	
2a	1-2	2	2	1-2	1-2	2a	2
2b	1-2	2	2	2	1-2	2b	2
Methods						Methods	
3a	4	2	2	2	2	3a	1,5
3b	NO	NO	NO	NO	NO	3b	NO
4a	3-4	2-3	2-3	2	2	4a	2
4b	NO	NO	2	2	NO	4b	2
4c	4,10	2	2-3	2	NO	5	4
5	4-5	3	4	2-4	3-4	6a	3-4
6a	5-6	4-5	4-5	5-6	3	6b	NO
6b	NO	NO	NO	NO	NO	7a	NO
6c	NO	NO	NO	NO	NO	7b	NO
7a	6	NO	4	2	4-5	8a	2
7b	NO	NO	NO	NO	NO	8b	NO
8a	NO	NO	3	NO	2	9	2
8b	NO	NO	3-4	NO	NO	10	2
9	NO	NO	3-4	NO	NO	11a	2-3
10	NO	NO	3-4	NO	NO	11b	3
11a	NO	NO	3	4	NO	12a	4
11b	NO	NO	4	NO	NO	12b	4
12	6	5	4	4	3	Results	
Results						13a	4
13a	5	NO	3	NO	NO	13b	4
13b	NO	5	3	NO	NO	14a	NO
14a	NO	NO	2	NO	NO	14b	NO
14b	NO	NO	NO	NO	NO	15	5
15	4	5	6	5	NO	16	4-5
16	6-8	5-6	4	5-6	3-5	17a	4
17	6	5	5-6	6	3	17b	NO
18	6	6	5-6	6	NO	18	4-5
19	6	5	6	5	3	19	NO
19a	NO	NO	NO	NO	NO	Discussion	
Discussion						20	7-8
20	9-10	8	7	8-9	5	21	5-7
21	10	8	6-7	9	5	22	5-7
22	8-10	8	6-7	8-9	5	Other Information	
22a	8-10	8	6-7	8-9	5	23	2
Other Information						24	3
23	NO	NO	2	2	NO	25	2
24	4-6	3	2	2-4	2		
25	10	NO	1	NO	6		
26	4,10	8	2,8	2	2		

Data reported in page number.

It is important to highlight that in all the studies analysed, a different VR set was used to perform the interventions. The lack of specific technology for subjects affected by neurological pathology, in this case stroke, makes the creation of validated treatment protocols complex, as mentioned by Viñas and Sobrido[25] in their study.

Bernhardt et al.[26] proposed a timeframe to delimit each of the phases of the rehabilitation process: hyperacute

Table 4. *Oxford scale.*

Article	Level of evidence	Level of recommendation
Iosa et al. (2015)	3b	B
Vanbellingen et al. (2017)	3b	B
Wang et al. (2017)	1b	A
ÖGÜN et al (2019)	1b	A
Colombo et al. (2019)	3b	B
Fluet et al.(2019)	3b	B

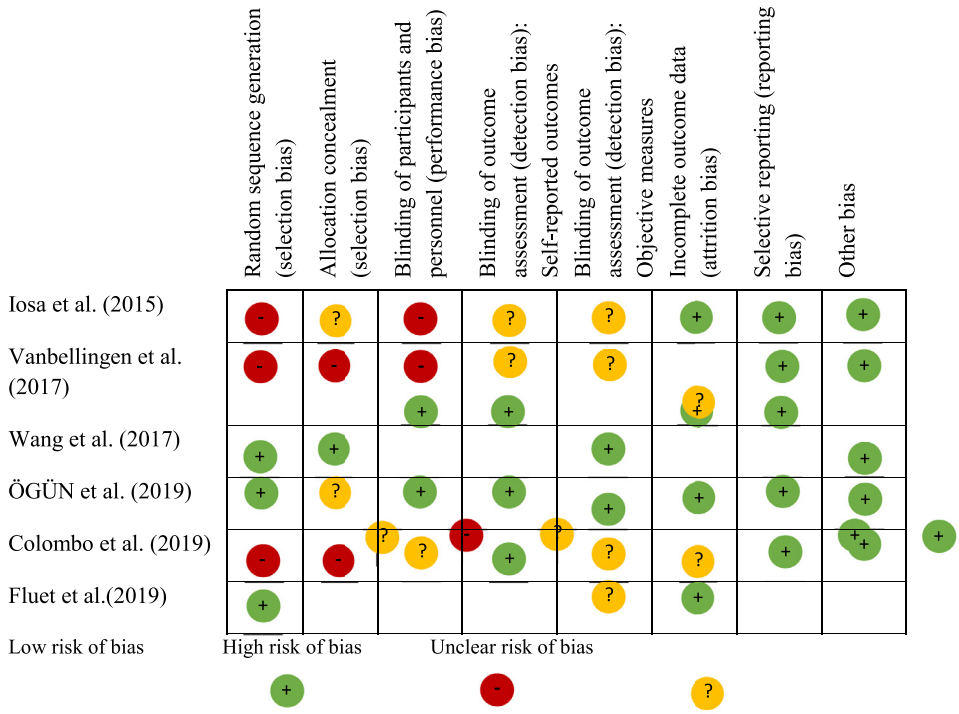
phase (0−24 hours); acute phase (one−seven days); early subacute phase (seven days−three months); late subacute phase (three−six months); chronic phase (after six months). There was no consensus, however, when defining the different stages, although it is known that the less time elapsed in the initiation of treatment after a stroke episode, the greater the potential for recovery.[27,28] The time course of the participants was not always considered, but in those in which it was, most were performed in acute and subacute phases.[17-19,21] Despite this, given the numbers of people with chronic UL damage who have suffered a stroke,[4] it is important to develop trials with chronic subjects, as in the study by Ogün et al.[20]

As a low-cost, easy-to-use device, the Leap Motion Controller® system has been postulated as a tool that can be used as on an outpatient basis for therapeutic purposes. However, only one of the studies conducted the intervention in the participant's own home.[22] Although Vanbellingen et al.[18] conducted the intervention in the clinical setting, some participants in this study valued the use of the Leap Motion Controller® at home, depending on the price, improvements obtained after treatment or the variety of games available, and one participant in particular expressly requested to extend the treatment at home.

Due to the heterogeneity of UL symptomatology in people with stroke, it is complex, but also necessary, to establish common criteria in the functionality of UL that serve as a starting point for creating more effective treatment protocols. In this regard, there is a lack of consensus in this respect, as each study established different criteria for quantifying the initial degree of disability of the participants. Only in one case was no mention made of the level of impairment of UL.[17] In contrast, the most commonly used tools for establishing initial criteria were the BBT,[21] UEFMA,[21] MAS,[20,21] Medical Research Council Scale[18] and Mini-Mental State Examination,[20] although with different inclusion criteria.

Another controversial aspect is the multitude of outcome measures used. Perhaps this concept coincides with

Table 5. *Risk of bias analysis.*



Low risk of bias High risk of bias Unclear risk of bias.

the previous concept. It is difficult to find standardised models to serve as starting points for assessing the functionality of UL, and complex to reach a consensus on how to assess and find the best outcome measure capable of analysing the effect of interventions. Up to five different scales were used to measure functionality (WMFT, UEFMA, SULCS, ARAT, FIM)[17-20,22] and three assessed dexterity (BBT, NHPT, DestQ-24).[17,18,22]

Although the study by Vanbellingen et al.[18] was the sole evaluation that did not report significant results in terms of UL functionality scales, it did obtain positive data in aspects such as strength (improved by 11.3% with respect to baseline), or dexterity (with 31.5% and 16.3% improvement, measured with the NHPT and DextQ-24, respectively).

In stroke patients, a delayed onset of scapular stabiliser muscle activation has been observed, which interferes with UL orientation and stability, even resulting in pain.[29] The incidence rate of shoulder pain is as high as 84%.[30] Considering this figure, it is striking that no study refers to pain.

Webster et al.[31] revealed in their qualitative study that some problems can be experienced during use of the device, such as difficulties in tracking both the patient's hand and the object. Iosa et al.[17] attributed this to the degree of spasticity or when it is necessary for patients to overlap their hands, as the optical sensors may have difficulty correctly capturing the hands.

During the rehabilitation process, the problem of lack of motivation is often common. The use of VR can help to create environments in which more repetitive movements are performed in a playful context, in contrast to traditional rehabilitation; thus increasing motivation, and consequently, adherence to treatment.[32] Most of the selected studies have reflected this important aspect, either with participation scales,[17,18] satisfaction questionnaires and open-ended questions,[18,19,22] or with motivation measurement instruments.[22]

Participation in one of the studies[17] scored from very good to excellent, and in another,[18] although not statistically significant, the result was between good and very good. In most of the studies, there were no losses, but two of them[18,20] reported cases of participants who did not complete the therapy, either due to hospital discharge, lack of motivation or a new stroke episode.[18] Ogün et al.[20] states the main limitation of their research was the drop-out rate in both the control group (22.5%) and experimental group (23%).

Feedback from people with stroke following the use of VR devices is important and necessary, as suggested by the authors of the Cochrane review,[23] who state that these data are of interest to clinicians in order to consider the cost of VR programmes and its benefits to potential users. In this regard, some authors followed these recommendations and reported that some participants found the Leap Motion Controller® therapy more motivating and enjoyable than conventional therapy[19] Others found the experience very good, rating both the treatment and device.[18] Finally, Fluet et al.[22] were the only authors that assessed participants' subjective experiences related to VR device use using the multimodal Intrinsic Motivation Inventory instrument.

In their review, Laver et al.[23] reported little or no side effects after VR use in stroke patients. These data are consistent with the results of all included studies in which no adverse effects such as pain, nausea, fatigue or headache were reported.[17-22]

It is important to consider all the aspects described above in order to focus future research studies.

Limitations

This systematic review has certain limitations that should be noted, mainly due to the significant clinical diversity of the studies included and their methodological limitations. The low number of publications on this topic is noteworthy, indicating the need for studies with adequate methodological quality. Considering that the physiological responses and objectives differ depending whether the patient is in an acute, subacute or chronic phase, the results may not be unified, and therefore conditioned by the rehabilitation phase in which the research is carried out. At the same time, the sample, assessment measures, protocols, number of sessions and diversity of games applied were heterogeneous among the included studies. Finally, this systematic review only selected studies published in Spanish and English.

Conclusion

Research on the effectiveness of the Leap Motion Controller® as a rehabilitation procedure in the treatment of UL in stroke is scarce. However, there is a tendency for it to be valued as a useful tool. The heterogeneous nature of the functional impairment of UL in the disease and, therefore, of its clinical symptomatology, the size of the samples, methodological quality, lack of consensus in the action protocol and recent use of this device are aspects that limit the evidence on the present use of this tool. Future research is needed, with larger samples, long-term assessments and higher methodological qualities, to prove the effectiveness of the Leap Motion Controller® device in improving UL in people with stroke.

Funding

No funds were received for this study.

Competing interests

The authors declare that they have no competing interests.

Declaration of Competing Interest

The authors declare no conflict of interest

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