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Functional Electrical Stimulation Improves Lower Limb Function in Patients with Stroke Hemiplegia: A Systematic Analysis

Yanjiao Liu*, Wenying Huang, Yuerong Liu, Shan Lei

College of Physical Education, Jiangxi Normal University, Nanchang, Jiangxi 330022, China

Abstract

Objective: To evaluate the effect of functional electrical stimulation on lower-limb function in stroke patients with hemiplegia. Methods: Through the computer search PubMed, Cochrane, web of science, CNKI, Wanfang, Weipu and other databases for randomized controlled trials of functional electrical stimulation on improving lower-limb function of stroke patients with hemiplegia. After screening literature, quality evaluation and data extraction, meta-analysis was conducted. Results: A total of 13 randomized controlled trials were conducted in 643 patients. The results of meta-analysis showed that the intervention effect of FES group was better than that of routine group in improving lower-limb motor function [MD=4.78,95%CI (3.27,6.29),P<0.001], balance function [MD=8.88,95%CI (5.85,11.92),P<0.001] and activities of daily living [MD=16.74,95%CI (8.48,25.0),P<0.001] of stroke patients with hemiplegia. Conclusion: FES intervention on the lower-limb of stroke hemiplegic patients on the basis of routine rehabilitation is helpful to further improve the lower extremity motor function, balance function and daily life activity ability of the patients.

Keywords

Functional Electrical Stimulation; Stroke; Hemiplegia; Lower-Limb; Meta Analysis.

1. Introduction

Stroke is a common disease of clinical rehabilitation in medicine and neuromedicine and has become the third fatal and first disabling disease in developed countries, while hemiplegia is one of the most common sequelae of stroke[2] and approximately 90% of stroke survivors have[3]. Stroke seriously affects people's cognition, swallowing, language, hemiplegia and other dysfunction[4], and even can lead to muscle weakness, such as well as muscle rigidity and other complications. Functional electrical stimulation was first introduced 60 years ago, and is widely used by[5] in the field of rehabilitation therapy, and is subordinate to neuromuscular electrical stimulation. functional electrical stimulation (FES) refers to the use of a planned low-frequency pulse current to stimulate the muscles and nerves with dysfunction, in order to awaken the deep feeling of paralysis in stroke paraplegic patients and the purpose of to better perform motor function[5], so as to improve functional activity. At present, there is relatively little evaluation and analysis of FES intervention in lower limbs at home and abroad, and the corresponding meta-analysis is temporarily lacking. Therefore, the meta-analysis of a randomized controlled trial of FES intervention in lower limb function in stroke hemiplegia patients, in order to explore the clinical effect of FES on lower limb function in stroke hemiplegia patients.

2. Data and Methods

2.1. Literature Retrieval Strategy

Retrieval was performed in the databases of PubMed, web of science, CNKI, Wanfang, wiper etc. Among them, the Chinese search words include stroke, stroke, functional electrical stimulation,

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lower limbs, randomized controlled experiments, randomized. The English search words include: "stroke, apoplexy, CVA, functional electrical stimulation, lower limb, Lower extremity, random". The retrieval time is the initial construction of each database to January 3,2021, and the languages are only included in Chinese and English. Take PubMed as an example, and the operating procedure details are shown in Table 1.

Table 1. The PubMed retrieval policy

#1	"Stroke"[Mesh]
#2	stroke
#3	Apoplexy
#4	CVA
#5	Functional electrical stimulation
#6	Lower limb
#7	Lower extremity
#8	Random*
#9	#1 OR #2 OR #3 OR #4
#10	#6 OR #7
#11	#5 AND #8 AND #9 AND #10

2.2. Inclusion and Exclusion Standard

2.2.1. Inclusion Standard

(1) Study type: randomized controlled test (randomized controlled trial, RCT). (2) Study subjects:①meets the medical diagnosis criteria of stroke, accompanied by unilateral limb hemiplegia; ②is well aware, has no serious dementia and perceptual disorders, and can be combined with treatment; ③has no complications of serious cardiac and pulmonary insufficiency. (3) Interventions: conventional treatment combined with FES. (4) Control measures: routine treatment. (5) Outding indicators: Fugl-Meyer assessment (FMA), Berg Balance Scale (BBS) and Modified Barthel Index (MBI) scores in the Fugl-Meyer Assessment Scale.

2.2.2. Exclusion Standard

(1) Joint intervention with other therapies; (2) inaccessible original text; (3) repeatedly published articles; (4) missing data or error.

2.3. Data Extraction

The first author searched the literature, manually removed EndnoteX9 and manual questions and abstract, and read the full text. Then 2 researchers were arranged to extract basic information of ①(author, year of publication, baseline), sample size and gender of ②study subjects, ③intervention and control measures, time and cycle of ④intervention, ⑤outcome index, etc. When the data extraction results are inconsistent, consult with a third investigator. If the study data is missing, actively contact the author, and if the acquisition fails, the study is excluded.

ISSN: 2692-7608 DOI: 10.6981/FEM.202201_3(1).0027

2.4. Literature Quality Evaluation

Quality evaluation of the included literature was performed using the risk of bias assessment entry recommended by the Cochrane Manual 5.0.1.From the Cochrane manual, the random sequence included in the literature, the blind generation, allocation of participants and researchers, the blinded outcome assessors, incomplete outcome data, selective reporting results, other bias, "low risk (+)", "high risk (-)", " unclear risk (?) " The evaluation, when the opinion disagrees, will discuss with the third researcher, and then make the judgment after the discussion.

2.5. Statistical Analysis

The obtained data were analyzed by RevMan 5.3, because the FMA score, BBS score and MBI score included in this article were continuous variables and the units of measurement and equity were consistent, the mean difference (MD) was used. When $P<0.1$, $I2>50\%$, the results are heterogeneous, combine random effect models, conduct subgroup analysis, explore the source of heterogeneity, and analyze the factors that may cause heterogeneity; Otherwise, the results have homogeneity, fixed model and descriptive analysis.

3. Result

3.1. Retrieval Results and Basic Information of Included Studies

After screening and exclusion, a total of 446 articles (300 in Chinese and 146 in English) were retrieved. All 446 literatures were imported into EndnoteX9 software, and 76 literatures were deleted systematically. 328 literatures that were obviously inconsistent with each other were removed after the first author read the title and abstract, and the remaining 42 literatures were read in full, and finally 13 literatures were included[5-17] (11 studies in Chinese and 2 studies in English). See Figure 1 for the study screening process The basic information of the 13 articles finally included is shown in Table 2.

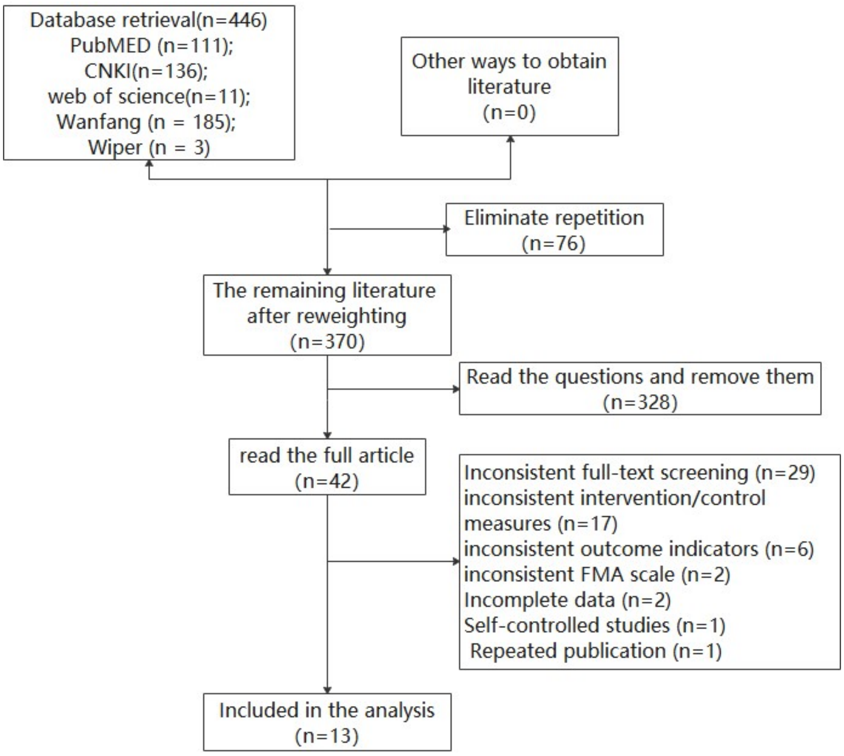

Figure 1. Flow chart of literature screening

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Table 2. Basic information of included studies

Study	Number T/C	sex M/F	Stroke type (Brain infarction / cerebral ischemia)	Intervene study		intervene duration	Intervene period	final result metric
				T(FES)	C(con)			
Liu Dongbo et al.(2020)	13/13	16/9	unspecified	conventional therapy +FES	conventional therapy	1 time / d, 20min / time, 5 times / week	3 weeks	FMA
Zhang Linjian et al.(2019)	20/20	26/14	unspecified	conventional therapy +FES	conventional therapy	1 time / d, 20min / time, 5 times / week	8 weeks	FMA
Hu Qingzhong et al.(2018)	24/24	23/25	23/25	conventional therapy + four channels FES	conventional therapy	1 time / d, 20min / time, 5 times / week	2 weeks	FMA, BBS
Ren Huiming et al.(2018)	20/20	26/14	unspecified	conventional therapy +FES	conventional therapy	1 time / d, 30min / time, 5 times / week	8 weeks	FMA
Dujović SD et al.(2017)	8/8	10/6	13/3	conventional therapy +FES	conventional therapy	30-40min / day	4 weeks	FMA, BBS, MBI
Chu Gaofeng et al.(2017)	76/76	76/76	82/70	conventional therapy +FES	conventional therapy	1 time / d, 20min / time, and 30 sessions were 1 session	3 months	FMA
You Get al. (2014)	19/18	21/16	33/4	conventional therapy +FES	conventional therapy	1 time / d, 30min / time, 5 times / week	3 weeks	FMA, BBS, MBI
Zheng Lijun et al.(2014)	16/16	22/10	20/12	conventional therapy +FES	conventional therapy	1 time / d, 30min / time, 5 times / week	4 weeks	FMA, BBS
You Guoqing et al.(2013)	23/22	28/17	35/10	conventional therapy +FES	conventional therapy	1 time / d, 30min / time, 5 times / week	3 weeks	FMA, BBS
Chen Danfeng et al.(2013)	10/8	13/5	12/6	conventional therapy +FES	conventional therapy +Comfort electricity	1 time / d, 30min / time, 5 times / week	3 weeks	FMA,BBS
Huang Ting et al.(2010)	20/20	33/7	35/5	conventional therapy +FES	conventional therapy	1 time / d, 30min / time, 5 times / week,	3 weeks	FMA, BBS, MBI
You Guoqing (2007)	19/18	21/16	33/4	conventional therapy +FES	conventional therapy	1 time / d, 30min / time, 5 times / week	3 weeks	FMA, BBS
Liu Zhongliang et al.(2004)	56/56	64/48	77/35	early rehabilitative intervention +FES	early rehabilitative intervention	2 times / d, 30min / times, 15d for one course	12.05±5.17 weeks	FMA

3.2. Risk Bias Assessment for the Included Studies

According to the risk bias assessment criteria in the Cochrane manual 5.0.1, risk bias was assessed for 13 included articles, 7 of which described specific random methods, including random number table[6,9,14] , lottery [10] , minimization [5,13,17], etc. Two were hidden by allocation[8,15]; The specific risk bias assessment of the four studies included in the single blind study [5,6,13,17] is shown in figure 2 and figure 3.

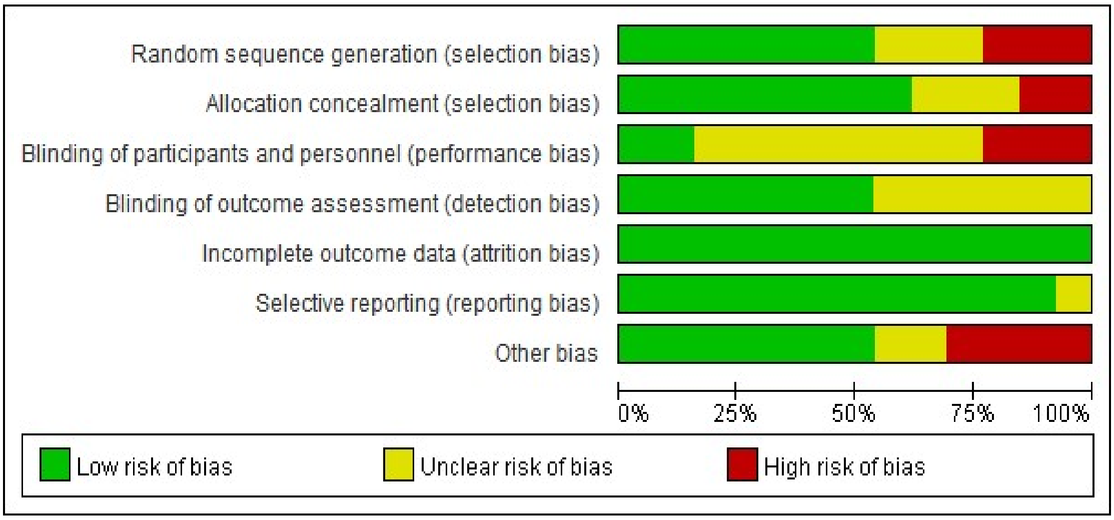

Figure 2. Overall risk bias assessment

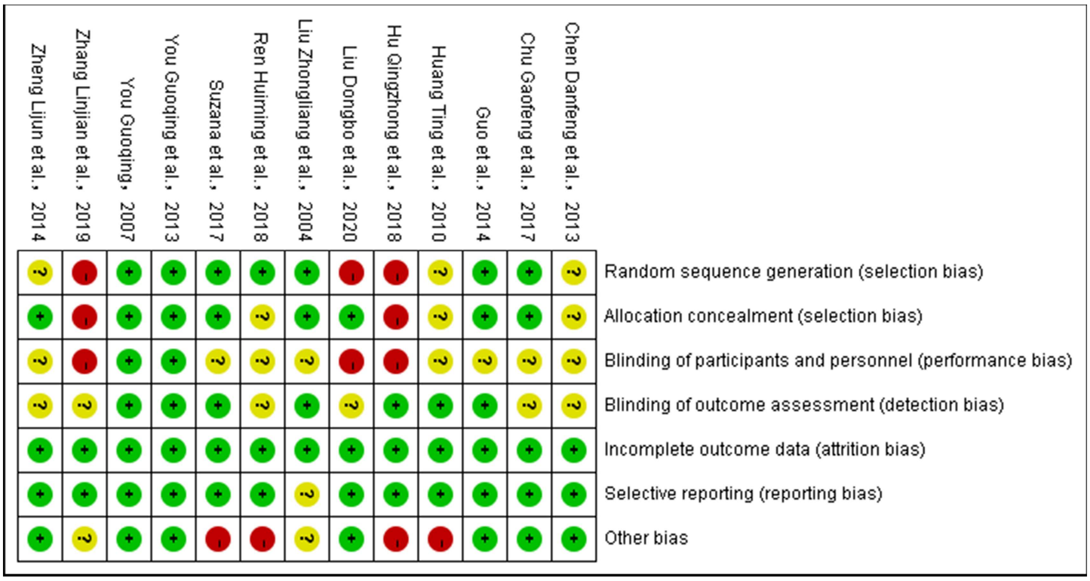

Figure 3. Single risk of bias assessment

3.3. Meta-Analysis Results

3.3.1. FES on Lower Limb Motor Function

The FUGL-Meyer assessment (FMA) is an effective method of measuring motor impairment after stroke, which is achieved through a series of motor tasks to achieve motor coordination. The lower extremity portion of the FMA is designed to assess the lower extremity hip and knee by measuring the reflex flexor tendon and right tendon of the lower extremity or by collaborative mode and volitional movement[6] 13 RCT studies[5-17] all reported FMA lower limb scale scores, and a total of 643 subjects were examined, suggesting heterogeneity in the results (I2=82%, P<0.001), using a random-effect model (Figure 4), the results were [MD=4.78, 95%CI(3.27,6.29), P<0.01], and the combined effect size was on the right side of the ineffective line, suggesting that FES intervention in addition to conventional treatment was more effective than conventional treatment, with a significant difference (P<0.01). Due to the high heterogeneity of the results, subgroup analysis was further performed. They were divided into two groups according to the length of intervention period, namely, intervention period ≤3 weeks and intervention period > 3 weeks. The results showed that there was no heterogeneity between studies with intervention period ≤3 weeks (I2=0,P=0.99). The fixed-effect model was used (Figure 5), and the results were [MD=4.27, 95%CI(3.16,5.38), P < 0.01]. However, there was still heterogeneity among the subgroups with intervention cycles > 3 weeks (I2=92%, P < 0.001). The random-effect model was adopted (Figure 6), and the results were [MD=5.01, 95%CI(2.44, 7.57), P=0.0001], in order to reduce heterogeneity, and sensitivity analysis, after eliminating two references[6,10] found heterogeneity decreased obviously (I2=28%, P=0.24), the result of [MD=6.81, 95%CI(5.95, 7.67), P<0.001], the difference between groups was very significant (Figure 7), suggesting that regardless of whether the FES intervention period was long or short, the effect of the intervention group was better than that of the conventional group, and there was a significant difference.

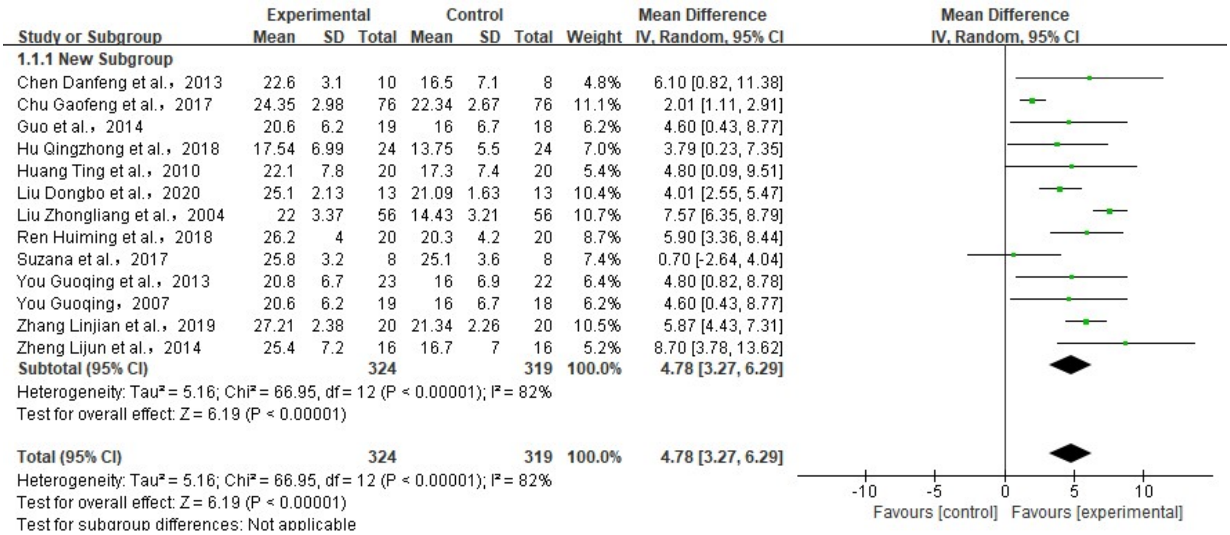

Figure 4. Influence of FES on FMA lower limb score of patients

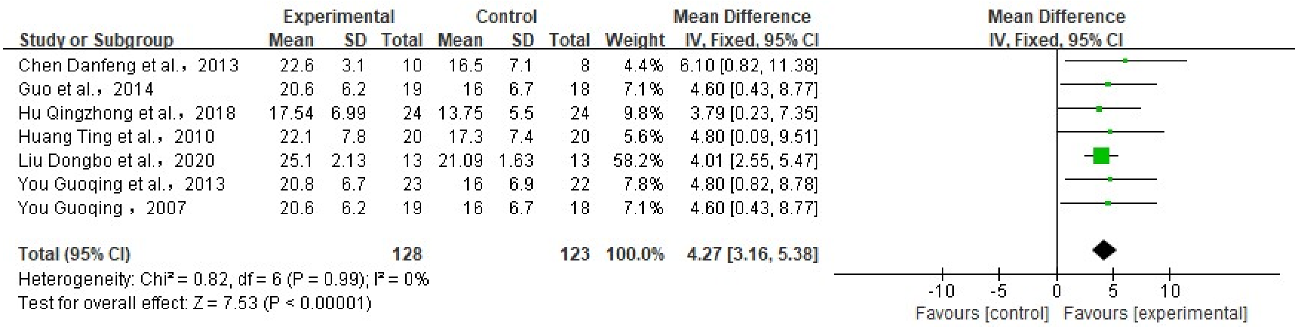

Figure 5. FMA lower extremity score of FES intervention period ≤3 weeks

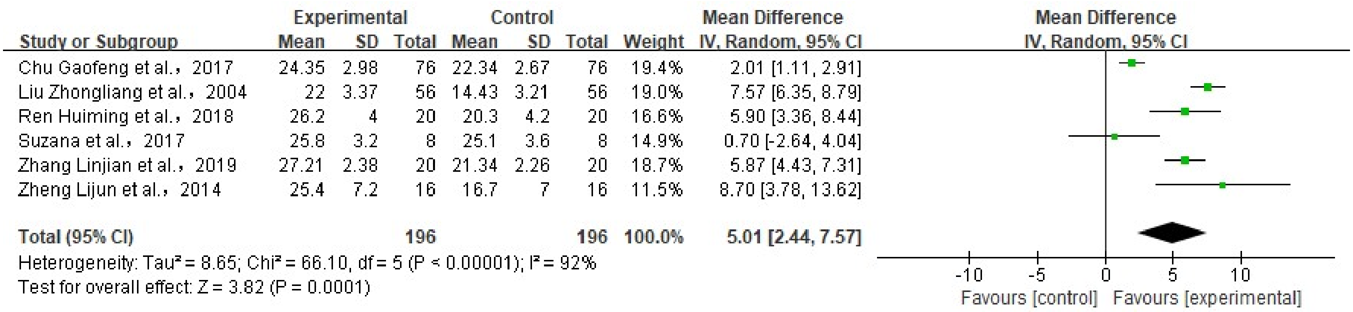

Figure 6. FMA lower extremity score of FES intervention period > 3 weeks

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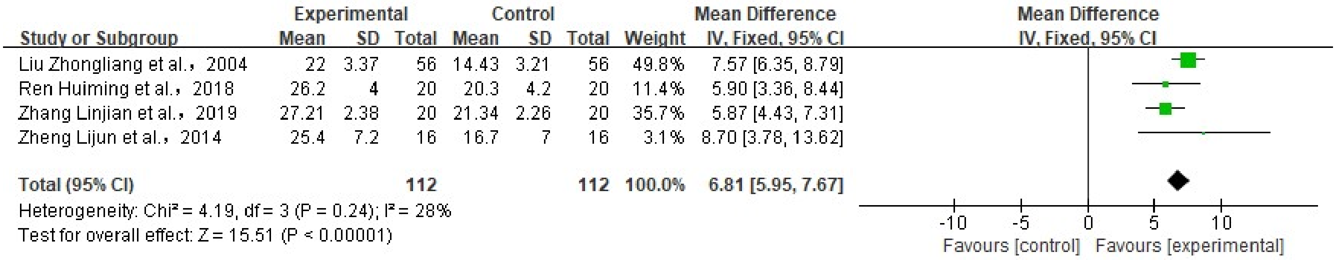

Figure 7. Lower extremity score of FMA with FES intervention period > 3 weeks after sensitivity analysis

3.3.2. Balance Function

Berg Balance Scale (BBS) is one of the scales widely used in clinical practice to measure dynamic and static balance function [6]. Eight articles [5-6,11-13,15-17] reported BBS balance scale, and 273 subjects were studied. The inter-study heterogeneity was 0(I^2=0%, P=0.94), and the fixed-effect model was used (Figure 8). The results were [MD=8.88, 95%CI (5.85, 11.92), P<0.001], suggesting that the FES group was better than the control group, and the difference was significant (P<0.001).

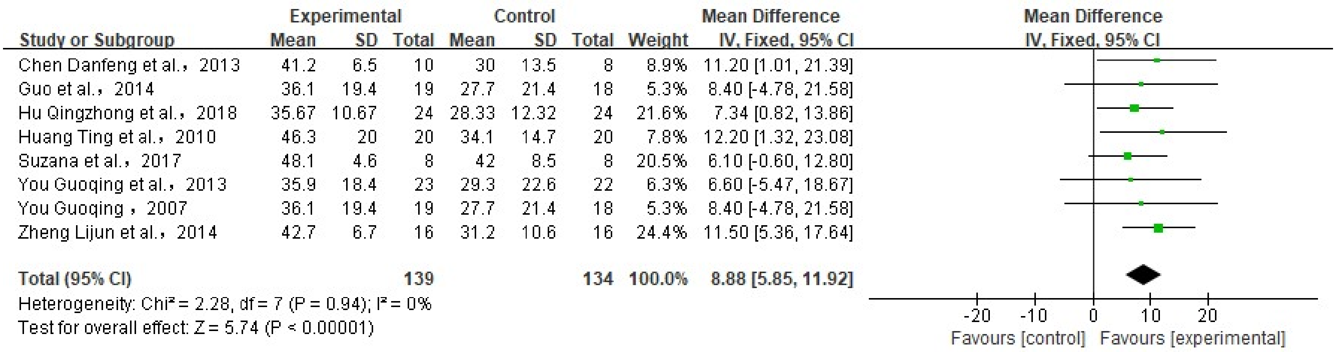

Figure 8. Effect of FES on BBS score of stroke patients with hemiplegia

3.3.3. Ability of Daily Life Activities

Activity of Daily Living Scale (MBI) is mainly used to evaluate activities of daily living and gait behavior [6]. Only 3 articles[5-6,12] reported this scale, a total of 93 cases Set of heterogeneity between (I^2=62%, P=0.07), using random effect model (figure 9), intervention group score is significantly higher than the control group (MD=16.74, 62%CI(8.48, 25.0), P<0.01) sensitivity analysis was performed and heterogeneity was reduced to 0 (I^2=0%) with significant difference (P<0.01), heterogeneity may be derived from the fact that all the subjects in this study were elderly patients.

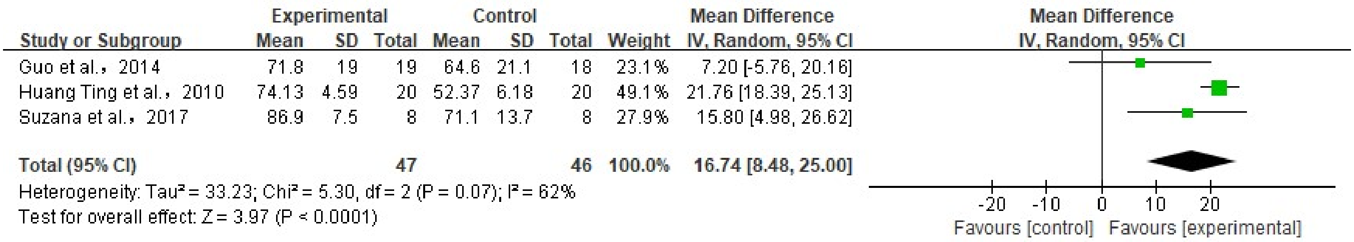

Figure 9. Influence of FES on MBI score of stroke patients with hemiplegia

3.4. Publication Bias

Funnel plot analysis was conducted for the 13 included literatures, as shown in the figure: Although the funnel plot did not show obvious asymmetry on the whole, there was slight

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asymmetry in the middle and lower part, indicating that the included studies had publication bias to a certain extent.

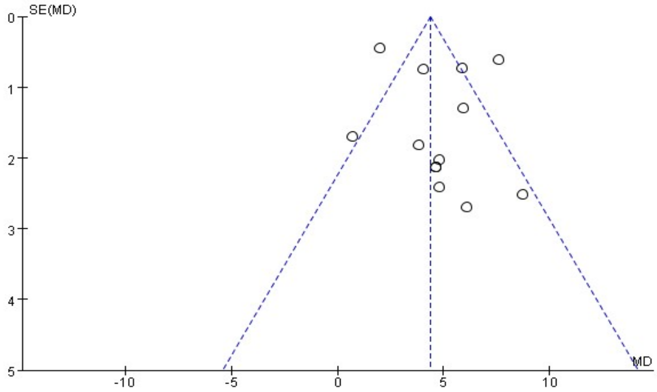

Figure 10. Funnel diagram of FES improving lower limb function in stroke patients with hemiplegia

4. Discussion

A total of 13 RCT studies were included in this paper, involving a total of 643 subjects. Currently, there are mainly FMA partial lower limb Scale Berg Balance Scale in clinical practice Modified Barthel index and 10-meter maximum walking speed test were used to evaluate the lower limb function. Since there were less than 3 studies on 10-meter maximum walking speed in the included studies, this index was not analyzed.

4.1. Effect of Functional Electrical Stimulation on Lower Limb Function of Stroke Patients with Hemiplegia

Stroke is a common cerebrovascular disease in clinic. A large number of studies have confirmed that stroke will cause hemiplegia to a certain extent, cognitive language and other functional disorders, accompanied by muscle atrophy and muscle spasm, seriously affecting the daily life and social interaction of patients Among them, the rehabilitation treatment of lower limb function of stroke patients with hemiplegia is complicated and tricky. The lag and improper rehabilitation treatment will not only lead to the failure of lower limb function recovery on the affected side, but also lead to the occurrence of complications such as soft tissue muscle atrophy and decreased Angle range of motion, which increases patients' pain and increases social and family burden [1] Functional electrical stimulation is a branch of neuromuscular electrical stimulation and a widely used rehabilitation technology that stimulates muscle contraction with electric current to stimulate movement of affected limbs [18] Karniel et al.[19] compared the efficacy of FES and traditional anklefoot orthosis (AFO) in the treatment of foot ptosis after stroke, and found that FES was as effective as or even more effective than traditional AFO treatment. The results of this study showed that on the basis of routine rehabilitation, FES could improve the lower limb motor function of stroke patients in addition, many studies have proved that FES can produce many advantages after the treatment of stroke patients, such as making muscles actively engage in contractile muscle strength to improve muscle coordination Accelerated walking speed and improvement of the overall gait pattern further demonstrate the applicability of FES [6]. However, some studies also reflect the shortcomings of FES, including difficult electrode placement, timing of stimulation and discomfort of skin stimulation, which may affect the role and effect of FES[6,20] The above research results indicate that functional electrical stimulation has both advantages and disadvantages, suggesting that in order to give full play to the effect of FES, the stimulation timing of FES should be defined to

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solve the problems of electrode placement difficulty and skin irritation discomfort, reasonably avoid its disadvantages, and maximize the benefit.

4.2. Mechanism of FES in the Treatment of Lower Limb Function in Stroke Patients with Hemiplegia

The FES treatment system is mainly used to stimulate the affected area of stroke patients with hemiplegia by placing electrodes at a fixed point in a single channel Dual channel or four channels for electrical stimulation output entrance, applied to single or multiple muscle groups, to the induction motor nerve excitement and simulation of autonomous control muscle movement, recovery of patients in order to achieve the correct movement patterns, enhance the patient's cause and frequency of use, promote the reconstruction of the motor function in patients with, restoration of random autonomous movement function[1,5,22-23]. Its mechanism of action may be to set the specific intensity of electrical stimulation according to the specific condition of the patient's disease, and then act on the patient to increase the number of nerve fiber bundles in the ipsolateral region of the patient's disease[10], enhance brain plasticity, awaken and induce the contraction of the muscle lesion, and then promote the repair and improvement of the motor function of lower limbs At present, a large number of experimental and clinical research evidence that brain plasticity in recovery after brain injury plays an important role In addition, the influence of different amount of electricity channel intervention for patients with Zheng there may be differences, on the basis of previous studies using neuroimaging found FES can promote brain plasticity to improve motor function Among them, four-channel FES may be more effective than two-channel FES, possibly because four-channel FES can induce lower limbs to imitate the gait pattern, bring more sensory input to the athletes, and help coordinate muscles to improve the mechanical efficiency of limb movement[2]. Kimberley et al. [24] observed changes in cortical activation through functional magnetic resonance imaging (fMRI) after electrical stimulation of hemiplegic limbs in stroke patients, with significant increase in cerebral cortical signals and significant improvement in limb motor function Kafri et al.[25] showed that neuroplasticity is enhanced when electrical stimulation is combined with autonomic contraction in able-bodied individuals The above studies indicate that FES may control the paralyzed muscle group caused by stroke to resume movement by inducing motor nerve excitation, and enhance sensory input to stimulate the increase of the number of fiber bundles in the lesion nerve area of patients, so as to activate the cerebral cortex and wake up the neural pathway, thus achieving the rehabilitation and treatment of lower limb function.

4.3. Limitations and Recommendations

(1) Only Chinese and English were concerned in literature retrieval; (2) Some of the included literatures had some quality defects. For example, some literatures only mentioned randomness, but did not mention specific randomness methods; (3) Setting of blinding method the duration of FES intervention is also different. It is suggested that researchers pay more attention to setting of blinding method and formulate a unified FES intervention program. Meanwhile, the specific location of electrical pulse and the duration of intervention are standardized to maximize the role of FES.

5. Conclusion

(1) FES induced simulated movement of skeletal muscle by stimulating the diseased muscle groups and nerves of patients, and the improvement effect was very significant regardless of the duration of intervention cycle; (2) FES intervention can improve the balance of lower limbs and the ability of daily living activities, and the effect is significant. Although there are some deficiencies in this study, the results still show the positive significance of FES, which is worthy

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of reference for clinical workers. In view of the limitations of this paper, the results of this study need to be confirmed by better quality RCT studies.

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