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# Electrical Stimulation for Quadriceps Strengthening in Patients with Spinal Cord Injury

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# Electrical Stimulation for Quadriceps Strengthening in Patients with Spinal Cord Injury

## Disciplines

Physical Therapy

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## **Electrical Stimulation for Quadriceps Strengthening in Patients with Spinal Cord Injury**

**Clinical Scenario:** I am working in a skilled nursing facility and am working with a 29 year-old female who was in a motor vehicle accident about 6 months ago resulting in paraplegia with neurologically induced weakness of her quadriceps. Her spinal cord injury is incomplete at level T12, and she is slowly regaining sensation and motor control in her lower extremities. This weakness is interfering with her function, making transfers and gait difficult. Her quadriceps strength is 2/5 bilaterally with manual muscle testing. She is currently able to transfer sit→stand and ambulate >100 feet using a front-wheeled walker with stand-by-assistance; however, she occasionally experiences knee buckling, which could lead to injury. She struggles standing from a low surface and is unable to climb stairs. Since she is unable to fully activate her quadriceps, I am wondering if using electrical stimulation could augment her strength training.

**Introduction:** For the purpose of my clinical question, I want to know what the research says about the effect of electrical stimulation on strength in patients with spinal cord injuries. Muscle strengthening using electrical stimulation recruits muscle units in the opposite order than voluntary contractions, thus recruiting the biggest muscle units first (1,2). My thought is that by recruiting bigger muscles units through electrical stimulation, stronger contractions can be elicited than by voluntary muscle activation alone, and bigger strength gains will be attained. After performing an exhaustive literature search, I did not find much research looking specifically at this intervention with this population. There is recent evidence that has found electrical stimulation to be effective at strengthening the quadriceps in healthy individuals (3,4). There has also been some research looking at the use of this intervention in patients post-stroke, which appears to be beneficial (5,6). Some research has also found electrical stimulation to help retard disuse atrophy in quadriceps post surgery (7,8). My hope is to review the literature to find the best evidence that focuses on this specific intervention with patients with spinal cord injuries.

### **My Clinical Question:**

Is electrical stimulation effective for strengthening of the quadriceps in patients with spinal cord injuries?

### **My PICO:**

**Population:** patients with a spinal cord injury, ages 20-40, with some voluntary control of their quadriceps (MMT at least 2/5)

**Intervention:** electrical stimulation superimposed onto voluntary muscle contractions

**Comparison:** voluntary muscle contractions

**Outcome:** muscle strength using dynamometer (Nm)

**Overall Clinical Bottom Line:** Based on the results of the outcomes from Harvey et al. and Rabischong et al. the effectiveness of electrical stimulation for strengthening of the quadriceps in patients with spinal cord injuries is uncertain. Harvey et al found that electrical stimulation combined with progressive resistance training increased voluntary muscle strength by an average of 12 Nm with a 95% confidence interval of -17.03 to 41.03 in the experimental group. The control group, which received no treatment, experienced an average decrease in strength by 4 Nm with a confidence interval of -29.31 to 37.31. These statistics show that there is uncertainty of the true change in both groups, thus no conclusion can be drawn from these results. This study had no major threats to internal or external validity, but did have a small sample size and subjects were slightly different than the population of interest. Rabischong et al. found that electrical stimulation increased quadriceps evoked muscular output to 42.21 Nm (11.73) in the treatment group, while the control group, which received no treatment, only reached a muscular output of 25.78 (11.15). No pre-test data was provided so the change in each group is unknown, however, the authors did report that the experimental group's change was significant, although no MCID was stated. The MCID stated in the article by Harvey et al. for strength was 8 Nm, so if in fact the experimental group met this MCID, the change would be clinically significant. There also appears to be a clinically significant difference between the groups post-treatment, with a mean difference of 16.43 and a 95% confidence interval of 6.77- 26.09 and a large effect size of 1.44 with a 95% confidence interval of 0.55- 2.34. Using the MCID stated by the previous article of 8 Nm, the mean difference meets this, however the low end of the confidence interval does not. Despite these statistics, there are major threats to this study's internal and external validity, including a lack of randomization, blinding, reliable and valid outcome measures, small sample size, and a lack of reporting pertinent data. Due to these major threats, the results are unreliable and cannot be extrapolated to a larger population. More research is needed to determine the effectiveness of electrical stimulation on quadriceps strengthening in patients with spinal cord injuries, specifically comparing electrical stimulation plus voluntary muscle contractions with voluntary muscle contractions alone.

**Search Terms:** electrical stimulation, muscle strength, quadriceps, spinal cord injury, paraplegic, paraplegia, rehabilitation

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#### **Rationale for Chosen Articles:**

I searched in multiple databases on Pacific University's website including Medline-Ovid, Medline-Pubmed, CINAHL, and PEDro using the search terms mentioned above. I found some literature review papers, which I read and looked through the references to find more articles. I

browsed all of the references sections of the articles I found that pertained to my clinical question. After sifting through everything my comprehensive search came up with, I narrowed it down to these three articles. I tried to pick articles that matched my PICO the closest, while also being of high quality, as determined by the PEDro scale. When comparing PICOs, I struggled to find any article comparing the exact interventions I was looking for, so I chose the closest ones that would still be beneficial in my clinical scenario.

(1) Harvey LA, Fornusek C, Bowden JL, et al. Electrical stimulation plus progressive resistance training for leg strength in spinal cord injury: a randomized controlled trial. *Spinal Cord* 2010; 570-575.

PEDro Score: 7/10

P: 20 people with spinal cord injuries, male & female, ages 28-49

I: electrical stimulation superimposed on progressive resistance training

C: no intervention

O: voluntary quadriceps strength (Nm)

(2) Rabischong E, Ohanna F. Effects of functional electrical stimulation (FES) on evoked muscular output in paraplegic quadriceps muscle. *Paraplegia* 1992; 467-473.

PEDro score: 3/10

P: 25 people with paraplegia, 10 healthy people, male & female, mean age 26

I: electrical stimulation

C: no treatment

O: muscle torque (Nm)

(3) Belanger M, Stein RB, Wheeler GD, et al. Electrical stimulation: can it increase muscle strength and reverse osteopenia in spinal cord injured individuals? *Arch Phys Med Rehabil* 2000; 1090-1098.

PEDro score: 3/10

P: 14 people with spinal cord injuries, 14 healthy people, male & female, ages 23-41

I: electrical stimulation to quadriceps without resistance

C: electrical stimulation to quadriceps with resistance

O: muscle torque (Nm)

Table 1. Comparison of PEDro Scores

	Harvey et al.	Rabischong et al.	Belanger et al.
Random	1		
Concealed Allocation	1		
Baseline Comparability			1
Blind Subjects			
Blind Therapists			
Blind Assessors	1		
Adequate Follow-up	1	1	1

Intention-to-Treat	1		
Between Group	1	1	1
Point Estimates & Variability	1	1	
Total Score	7	3	3

When comparing these three articles, I looked at similarity of PICO's and quality. All of these articles used similar subjects to my patient, as they all had SCI and were in the age range. They all used electrical stimulation as an intervention and muscle strength as an outcome measure. The only difference between these studies PICO's and mine was the comparison. None of them compared the exact interventions I was looking for, but they were the closest I could find and I thought they would at least show the effectiveness of electrical stimulation to increase muscle strength of the quadriceps. When comparing the PEDro scores that I came up with, displayed in the table above, the article by Harvey et al. is of the highest quality. The other two articles are of lower quality, lacking randomization and blinding. The article by Rabischong et al. included the availability of point estimates and variability, which is important when analyzing the data for comparison.

Based on the above comparisons, I have chosen to write this critically appraised paper on the articles by Harvey et al. and Rabischong et al.

**Article 1 of 2:** Harvey LA, Fornusek C, Bowden JL, et al. Electrical stimulation plus progressive resistance training for leg strength in spinal cord injury: a randomized controlled trial. *Spinal Cord* 2010; 570-575.

**Clinical Bottom Line:** Based on the results of this study, there is insufficient evidence to suggest that for patients with a complete or incomplete spinal cord injury, an intervention of electrical stimulation combined with progressive resistance training results in better strengthening of the quadriceps when compared to no intervention. The experimental group experienced a mean increase of voluntary quadriceps strength, as measured by the Biodex Isokinetic System, of 12 Nm with a 95% confidence interval of -17.03 to 41.03. This leaves uncertainty to the true difference after treatment. The control group experienced a mean decrease in strength of 4 Nm with a confidence interval of -29.31 to 37.31. Again, there is uncertainty to the true change due to this large confidence interval that crosses zero. This study had no major threats to internal validity, but did have a small sample size, and the participants were slightly different than the population of interest, which limits the ability to generalize the results to my patient. Additional research is needed to answer the question of whether electrical stimulation can effectively strengthen quadriceps in patients with spinal cord injuries.

**Article PICO**

**Population:** 20 people (14 males, 6 females) with complete/incomplete SCI (mean age 39)

**Intervention:** electrical stimulation to quadriceps superimposed on progressive resistance training

**Comparison:** no intervention

**Outcome:** voluntary quadriceps strength (Nm), endurance, performance & satisfaction items on the Canadian Occupational Performance Measure (COPM)

**Blinding:** Neither subjects nor therapists were blinded in this study; however, the assessors were blinded. I don't feel that the blinding of subjects or therapists would have made a difference in the outcomes of the study because people either performed strength training or they did not and muscles will respond accordingly, no matter what. The important part is that the assessors were blinded because they are the ones that could have potentially biased the results.

**Controls:** The control group received no intervention.

**Randomization:** Participants in this study were randomized into two groups using a computer. This randomization was also concealed. Despite this randomization process, the subjects' level of impairment was not similar at baseline. The experimental group had more neurological involvement than the control group, although quadriceps strength measurements showed little differences per author report. The authors did not report if the groups were statistically significantly different at the start at the study. Subjects were otherwise similar at baseline.

**Study:** This study was a randomized controlled trial. Subjects were split into two groups, ten in the control group and ten in the experimental group. To be included in this study, subjects had to have either complete or incomplete spinal cord injuries of at least six months. They had to have at least 90 degrees of passive knee flexion, a muscle strength grade of 3/5 or 4/5, and responsive to electrical stimulation. Subjects were excluded if they had a recent trauma to the lower extremity, were unable to comply, or were already involved in a resistive training or electrical stimulation program. The experimental group received electrical stimulation superimposed on progressive resistance training 3 times per week for 8 weeks. The target muscle group was the quadriceps of one leg. Treatment was given at the subject's home with the subject seated, and their leg strapped to a device specially made for this study. It consisted of a wheel with weights suspended off of it, which is where the resistance was added, and a counterbalance of offset the weight of the lower leg and lever arm. The electrical stimulation was given by a STIWELL med4 portable neurostimulator, with the parameters of 50 Hz frequency, 300  $\mu$ s pulse width, 50% duty cycle of 12 seconds on:off, and up to 100mA intensity (determined by subject tolerance). 7 x 13 cm electrodes were placed on the quadriceps where the best contractions were elicited. Subjects performed 12 sets of 10 repetitions separated by 2-3 minute rests. The first 6 sets were with both electrical stimulation and voluntary muscle contractions, while the last 6 sets consisted of just electrical stimulation. Resistance was added so that in every set, only 10 repetitions could be performed before the muscles were fatigued. The control group did not receive any interventions.

**Outcome measures:** The only outcome measure relevant to my clinical question is voluntary quadriceps strength. All subjects were assessed prior to group assignment, and then again at the end of the 8 weeks, using a Biodex Isokinetic System. The reliability of this device was not stated, and the authors failed to report any intra- or inter-rater reliability of this assessment; however, the reliability and validity of this device is widely accepted and has been documented in another study (9). The authors stated that 8 Nm would be used as the minimal clinically importance difference (MCID), which was determined by taking 15% of the average baseline strength measures, and referenced by two other studies (10,11).

**Study Losses:** There were no study losses. All subjects completed the follow-up and were analyzed in the groups to which they were randomized.

**Summary of Internal Validity:** This study has good internal validity. There was randomization of subjects, concealed allocation, and blinding of assessors. The outcome measure used was reliable and valid, and subjects were pretty similar at baseline. No subjects were lost and all calculations were performed with the intention to treat principles. The only threats to internal validity are the lack of subject and therapist blinding, which are minor threats and do not compromise the results of this study.

**Evidence:** To determine the effects of electrical stimulation on quadriceps strength, measurements of strength taken before and after the 8-week treatment will be analyzed. This data is displayed in the table below. All calculations were performed by the authors. No raw data was provided.

Table 1: Mean quadriceps strength measurements (Nm) with standard deviations taken pre and post treatment in control group and experimental group, along with mean differences and 95% CI.

	<b>Pre-Test</b>	<b>Post-Test</b>	<b>Mean Difference</b>	<b>95% Confidence Interval</b>
<b>Control</b>	56 (41)	52 (28)	-4	-29.31 to 37.31
<b>Experimental</b>	46 (28)	58 (33)	12	-17.03 to 41.03

The table above shows that the experimental group improved their voluntary quadriceps strength by an average of 12 Nm, while the control group experienced an average decline of 4 Nm over the 8-week period. Standard deviations are large, which means there was much variability in the measurements between subjects, and there appears to be a considerable difference in strength between groups at the pre-test measurements, although no significance was mentioned. Assuming subjects were not similar at baseline, groups were analyzed for the mean difference between pre and post-treatment measurements to find out if there truly was a change in strength. The control group's mean difference was -4 Nm with a 95% confidence interval of -29.31 to 37.31. Since the confidence interval is extremely large and crosses zero, we are uncertain if there is a difference in this group or whether or not the difference was an increase or decrease in strength.



The experimental group's mean difference was 12 Nm with a 95% confidence interval of -17.03 to 41.03. Although the mean difference meets the MCID of 8 Nm, the confidence interval is extremely large and crosses zero. This means we cannot be sure that there was a difference after treatment, and it is possible that some subjects experienced a decrease in strength.

### **Applicability of study results:**

Benefits vs. Costs: The experimental group, which received combined treatment of electrical stimulation and progressive resistance training, achieved better strength in the quadriceps than the control group, and the costs of the treatment is relatively low. The treatment used in this study lasted approximately 1 hour, 3 times a week, for 8 weeks. There were no adverse effects reported and subjects who underwent treatment perceived the treatment to be effective. The cost of the device used to administer the treatment was not mentioned and was developed by the authors for this study; however, typical resistance training equipment and electrical stimulation units can be found in most physical therapy clinics/rehab departments, so the costs would be low to carry out this treatment.

Feasibility of Treatment: This treatment is feasible, and could easily be applied in the clinical setting. The treatment procedures were described well enough to be reproduced, although the device used in this study would have to be replaced with typical resistance training equipment, which most rehabilitation departments have readily available. Most rehab departments also have an electrical stimulation unit. If patients are receiving skilled physical therapy services, either in a skilled nursing facility or in an inpatient rehab facility, insurance companies would likely cover the number and duration of PT sessions required. If patients are in one of these settings, then a home exercise program would not be necessary. If patients are only receiving outpatient PT, then a home treatment program would be required and adherence may be lower. No pain was reported with treatment.

Summary of External Validity: The sample size is very small, which is a threat to external validity, and slightly limits our ability to generalize results. Subjects used were similar to those seen in the clinical setting, although they were selected by convenience. Subjects were not allowed to participate in any other strengthening outside this study, so the results should be a true effect of the treatments provided. Because the control group received no intervention, a comparison can be drawn between no treatment and resistance training plus electrical stimulation. This does make it hard to determine the respective contribution that electrical stimulation had on the strength gains. If there was another group that just received progressive resistance training, that would allow us to assess the effectiveness of electrical stimulation on strength training. There were no significant threats to internal validity which compromise our ability to generalize the results to a larger population, but the accuracy of statistical calculations is unknown. The participants in this study are slightly different than my patient, as they had higher quadriceps strength at baseline and they all had their spinal cord injuries longer than my patient. These differences do limit the ability to extrapolate the results of this treatment to my patient.

**Article 2 of 2:** Rabischong E, Ohanna F. Effects of functional electrical stimulation (FES) on evoked muscular output in paraplegic quadriceps muscle. *Paraplegia* 1992; 467-473.

**Clinical Bottom Line:** Based on the results of this study, there is insufficient evidence to suggest that for patients with paraplegia, an intervention of electrical stimulation results in strengthening of the quadriceps when compared to no intervention. Electrically evoked muscle torque, as measured by a force transducer, increased to 42.21 Nm (11.73) in the treatment group. Authors reported this as a significant increase in strength, although no pre-test data was provided and no MCID was stated. There appears to be a clinically significant difference between the groups post-treatment, with a mean difference of 16.43 and a 95% confidence interval of 6.77- 26.09 and a large effect size of 1.44 with a 95% confidence interval of 0.55- 2.34. Using the MCID stated by the previous article of 8 Nm, the mean difference meets this, however the low end of the confidence interval does not. Despite these statistics, there are major threats to this study's internal and external validity, including no randomization, no blinding, lack of reliable and valid outcome measure, small sample size, and a lack of reporting pertinent data. Due to these major threats, the results are unreliable and cannot be extrapolated to a larger population. Additional research is needed with good internal and external validity comparing electrical stimulation to traditional strengthening in order to determine if this is an effective intervention for patients with spinal cord injuries.

#### **Article PICO**

**Population:** 25 people with paraplegia (22 male, 3 female), 10 healthy people, mean age 26

**Intervention:** electrical stimulation to quadriceps

**Comparison:** no treatment (subjects with paraplegia and healthy subjects)

**Outcome:** muscle torque (Nm)

**Blinding:** There was no blinding of subjects, therapists, or assessors in this study. Not blinding subjects or therapists is not a major threat to the study; however, not blinding the assessors is a significant threat because this could lead to biased measurements, which affect the overall outcome of the study.

**Controls:** This study technically had two control groups, one group of subjects with paraplegia, and one group with healthy subjects. Both groups received no intervention. This allows the results to accurately show the effectiveness of electrical stimulation on muscle strength.

**Randomization:** This study did not mention the randomization of subjects. Subjects with paraplegia appear to be similar at baseline, although no initial strength measurements were reported so it is difficult to say if they had similar strength at baseline.

**Study:** This was a controlled study design with three different groups, two serving as controls. Group 1 consisted of 15 subjects with paraplegia (12 male, 3 female) and did not receive any

intervention. Group 2 consisted of 10 subjects with paraplegia (all male) and received functional electrical stimulation twice daily for 2 months. Group 3 consisted of 10 healthy subjects (6 male, 4 female) and received no intervention. Inclusion criteria for subjects with paraplegia was complete lesions between T2 and T10 acquired no more than 6 years previous, and presence of quadriceps reflex. Average time since injury was 6-12 months. Subjects were excluded if they had severe spasticity or spasms. The electrical stimulation was given using a 2-channel current regulated generator (Stipro, Selectron) with the parameters of 20 Hz frequency, 0.3 ms pulse width, and intensity up to 100 mA. Two electrodes (50 x 50 mm) were placed on the anterior portion of the thigh, where the best muscle performance was found. One electrode was placed just above the patella, and the other on the vastus lateralis, 25 cm superior and lateral.

Outcome measures: The only outcome measure relevant to my clinical question is quadriceps muscle torque. This measurement was taken before and after the 2 months of treatment, using a force transducer designed by the authors of the study. They reported the sensitivity was 0.1 mV/mm. No other reliability or validity of this device was mentioned in this study, nor could be found elsewhere, although it appears to have face validity. No MCID was reported or could be found in the literature.

Study Losses: No study losses were reported. No intention-to-treat analysis was mentioned. All subjects appear to have been analyzed in the groups to which they were assigned.

**Summary of Internal Validity:** This study has poor internal validity. There was no randomization, no blinding, and a lack of a reliable and valid outcome measure for torque measurements. Subjects' similarity at baseline is hard to determine due to the lack of information provided by the authors. These are all major threats to internal validity and thus compromise the results of the study.

**Evidence:** Muscle torque measurements taken at a knee angle of 60° in groups 1 and 2 will be analyzed for comparison. This angle was chosen because the greatest torques were found at this angle in the paraplegic population. No pre-test data is provided so the below table displays only the post-test data.

Table 2: Average evoked muscle torque (Nm) and standard deviations for quadriceps muscles with knee angle at 60° in group 1 and 2 post treatment.

	<b>Torque (SD)</b>
<b>Group 1 (control)</b>	25.78 (11.15)
<b>Group 2 (experimental)</b>	42.21 (11.73)

Table 2, above, shows the post-test results for muscle torque in groups 1 and 2. These measurements were taken with the knee at a 60° angle, which is where the largest torques were

found. Group 1 reached an electrically evoked torque of 25.78 Nm (+/- 11.15) after 2 months of no intervention. Group 2 reached an electrically evoked torque of 42.21 (+/- 11.73) after 2 months of functional electrical stimulation treatment. No pre-test data was provided, but authors did report that there was a significant increase in muscle torque of group 2 after treatment with a P-value of < 0.0006, meaning that this increase was likely due to the intervention and not chance.

Table 3: Mean difference and effect size for evoked quadriceps muscle torque post treatment between groups 1 and 2.

		<b>95% Confidence Interval</b>
<b>Mean Difference</b>	16.43	6.77- 26.09
<b>Effect Size</b>	1.44	0.55- 2.34

The above table displays the mean difference and effect size between groups 1 and 2 post treatment, as well as the 95% confidence intervals (CI). The mean difference between the two groups is 16.43 with a 95% confidence interval of 6.77 to 26.09. The authors consider this a significant difference, even though no MCID was stated. This CI is large, meaning that the true difference could be anywhere between these numbers, thus there is some uncertainty as to where the true difference lies. This appears to be a clinically significant difference. The effect size is 1.44 with a 95% confidence interval of 0.55 to 2.34. This effect size is considered large, and the entire interval falls into the large range so this means the treatment is likely to have increased muscle torque. It should be noted that no mean changes were reported, or could be extracted from the data, so those could not be analyzed for a between-group comparison.

**Applicability of study results:**

Benefits vs. Costs: The electrical stimulation treatment used in this study was performed twice a day for a half hour over a two-month period. The authors did not state whether this was done at home or in the clinic, so it is unclear if a therapist was present during treatments. Most physical therapy clinics/rehab departments have electrical stimulation units available so there would likely be no equipment costs to carry out this treatment. If the patient wanted to purchase a portable unit the costs would be approximately \$400, which may or may not be covered by insurance. No adverse events were reported in this study so this treatment appears to be safe and painless. Due to poor statistical data, the benefits of this treatment are unclear.

Feasibility of Treatment: This treatment is feasible, and could easily be applied in the clinical setting. Even though the intervention procedures were not explained in detail, the parameters used for the electrical stimulation were given as well as a treatment time, which make it possible to reproduce this treatment in the clinic. The equipment requirements are likely to be available in physical therapy settings and administering this treatment should be within the therapist’s expertise. In an inpatient rehab setting, the number and duration of physical therapy sessions

would likely be covered by insurance. Of course a portable unit could be issued to the patient, and after proper training, the patient could administer all treatments on his/her own. This treatment was not reported to be painful, but it would possibly require adherence to a home program.

Summary of External Validity: This study has major threats to the internal validity, including a lack of randomization, blinding, and valid outcome measures, which compromise the ability to generalize the results. The subject sample is small, although do appear to be similar to patients seen in the clinic. There was a lack of data reported in the study and statistical quality was relatively low. For all these reasons, the results cannot be extrapolated to a larger population.

**Synthesis/Discussion:** The study by Harvey et al. was a quality study, with good internal and external validity. The target population was exactly what I was looking for and the methodology was good. Having a larger sample size, however, could have enhanced the strength of the evidence. It also would have been nice to have another experimental group, which received just progressive resistance training, so the true contribution of electrical stimulation to increasing strength could be known. The study by Rabischong et al. had a number of flaws. The quality of this study was low, due to low internal and external validity. There was no randomization of subjects, no blinding, no reliability or validity mentioned for the outcome measure. The sample size was very small and subjects did not appear to be similar at baseline. This flawed methodology limits the ability to generalize the results to a larger population. It would have been nice to have the raw data of both the pre and post-tests so I could have run my own calculations for comparison of groups. These subjects had more severe weakness of the quadriceps than I would have liked, making the treatment hard to apply to my clinical scenario. These articles shed some light on the use of electrical stimulation for strengthening in the neurologically weak patients, but more research is needed to be sure of the effectiveness of this treatment, specifically comparing it to typical strengthening used for this population. Future studies should be randomized controlled trials, with larger sample sizes including patients with incomplete spinal cord injuries that have some voluntary control of their quadriceps. One group should receive electrical stimulation combined with voluntary muscle contractions and the control group should receive only voluntary muscle contractions. This study design would better answer my clinical question of whether or not electrical stimulation could augment strengthening in patients with spinal cord injuries.

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