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Research Article

Effects of Increases in Plantar Flexor Strength on Gait Impairment after Stroke: Study Protocol of a Randomized Controlled Trial

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Abstract

Background: Gait abnormalities following stroke are often disabling. Reduced ankle dorsiflexion, knee flexion, or hip flexion torques are often postulated causes of compromised toe clearing during the swing phase of gait, leading to an increased risk for falls. Conversely, gait asymmetry and reduced walking speed has been attributed to weakness of the plantar flexors. The aim of this trial is to evaluate the effects of a gait training strengthening the plantar flexors, compared to a gait training stabilizing the trunk and strengthening the dorsi- and hip flexors. Outcome will be defined in terms of gait and kinematic parameters.

Methods/Design: 56 Patients from an in-patient rehabilitation center with a first ever stroke, who can walk with an aid, will be recruited and randomized to one of two interventions. The experimental group will receive training of the extensor synergy with a focus on strengthening the plantar flexors twice daily over four weeks. The control group receives a dose-matched training strengthening the flexor synergy, inhibiting the extensor synergy and stabilizing the trunk. Primary outcome variable is Dynamic Gait Index, which will be assessed before, at the end and three months past intervention. In addition, video gait analysis, gait speed, Functional Ambulation Categories and muscle strength testing will be performed.

Discussion: Based on assumptions about the importance of plantar flexor strength on gait performance, this trial aims to investigate the effectiveness of strengthening the extensor synergy compared to strengthening the flexor synergy on regaining walking ability.

Keywords: Foot drop; Gait impairment; Gait speed; Spasticity; Stroke rehabilitation

Introduction

Gait abnormalities following stroke are often disabling, negatively affecting patients' quality of life. Seventy percent of stroke survivors regain the ability to walk, but residual impairments such as spasticity, muscle weakness, and poor balance may persist and limit functional ambulation [1]. Therefore, regaining of walking is considered one of the primary objectives of the rehabilitation process. Paresis and motor control disturbances, abnormalities of muscle tone, and sensation directly affect the patient's gait. Hemi paretic gait is characterized by disturbances of symmetry, step length, decreased stance time in the paretic limb, and decreased range of motion in the hip and knee joints during the swing phase and balance disturbances. Consequently, stroke patients' gait speed and distance are typically significantly decreased in comparison to healthy people [2]. Walking speeds are reported as less than 0.8m/s even after targeted rehabilitation programs [3]. This is insufficient for walking in the community and therefore limits participation after stroke [4].

Abnormal lower-limb torque coupling, especially abnormal hip adduction and knee extension torque coupling has been considered a crucial factor for gait impairment after stroke [5]. Neckel and colleagues also described that patients after stroke inappropriately extended their impaired knee at pre-swing, while during swing they tended to abduct their impaired leg. Both were typical abnormal torque synergy patterns common to stroke gait [6] and increase the risk of falling. Considering the strong association between strength of lower limb muscles and walking speed in people with stroke, Dorsch and colleagues reported that the strength of the ankle dorsiflexors alone explained nearly one third of the variance in walking speed [7]. They even demonstrated that the most severely affected muscle groups were hip extensors, ankle dorsiflexors and hip adductors, and the least severely affected muscle groups were ankle invertors, ankle plantar flexor, and hip flexors [8].

Then again, at self-selected speed of gait the utilization of plantar flexors is more pronounced than of hip flexors and extensors while the strength deficit of plantar flexors is proportionally larger than that of the proximal hip muscles in a hemi paretic population [9]. Dietz and Sinkjaer also postulated that spasticity of the plantar flexors does not relate to the problems in walking after stroke, but rather the reduced strength of the plantar flexors may lead to an insufficient toe off during the pre-swing phase [10]. Also, the strength of the plantar flexors during the push-off stage of walking entails the driving energy

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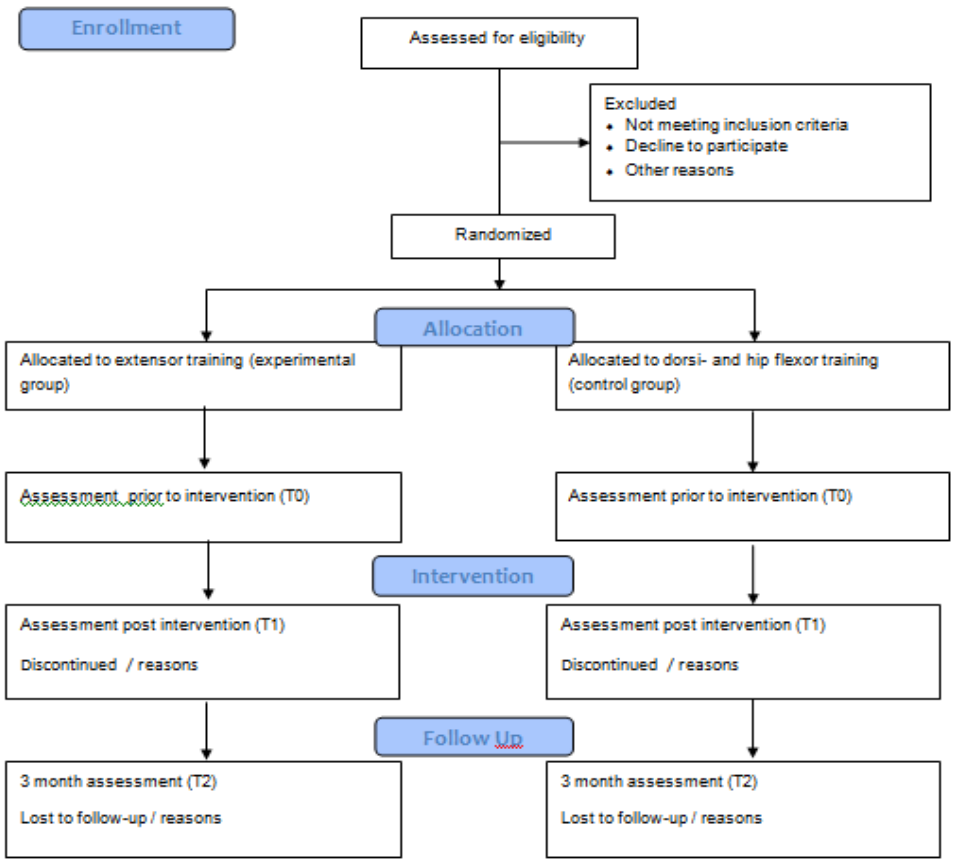

Figure 1: Flow diagram of the progress from screening to the final follow-up assessment.

for the forward movement of the affected lower limb [11]. Further the reduced plantar flexor strength may also prevent from adopting a more symmetrical gait pattern after stroke [12]. Thus, strengthening the plantar flexors may improve gait speed, gait symmetry and reduce effort.

The study whose protocol is presented here intends to investigate and compare the effectiveness of two types of gait training strategies provided during physical therapy treatment at an inpatient rehabilitation center. We hypothesize that training of the extensor synergy with a focus on strengthening the plantar flexors will be a better strategy to improve gait performance than strengthening the dorsiflexors, hip flexors, inhibiting the extensor synergy and stabilizing the trunk.

Methods and Design

Design

We will conduct a single-center, patient-assessor-blinded, randomized controlled trial to evaluate and compare the efficacy of two types of gait training strategies provided during physiotherapy treatment at an inpatient rehabilitation center in Leipzig, Germany (NRZ Leipzig-Germany). Patients will be allocated to a specific extensor synergy training (experimental group) or strengthening the flexor synergy with stabilizing the trunk (control group). After randomization and first assessment (T0), an intervention period will take place with the allocated training twice daily on weekdays for four consecutive weeks. The effects of the intervention are examined using a pretest-posttest design. The pretests (T0) are performed in the week prior to intervention and posttests (T1) are performed in the week after intervention. The degrees to which changes are sustained are examined using retention tests (T2) 3 months after completion of the intervention (Figure 1).

The study has been approved by the medical ethics committee of the University of Leipzig (AZ: 086-14-10032014) and registered by the German Clinical Trial Registry (DRKS00011874).

Setting

For inclusion and intervention, the study will be embedded within the rehabilitation center and includes a group of specifically trained physical therapists. The trial assessments will be performed by specifically trained physical therapists not employed at the rehabilitation center. The assessment 3 months after completion of intervention will take place at the patient´s home.

Participants

Eligible subjects will have to meet the following inclusion criteria: (1) a first-ever ischemic or hemorrhagic stroke in one of the hemispheres, as verified by CT and/or MRI scan; (2) ability to walk a minimum of 10 m with or without some physical assistance from a therapist (Functional Ambulation Categories > 2); (3) maximum gait speed ≤ 0,4 m/s, (4) demonstrate weakness of the foot muscles, measured by muscle function tests according Medical Research

Council (MRC) scale of ≥3 [13]. (5) During gait, they should not be able to reach Initial Contact (IC) with the heel and initiate swing by compensatory hiking of the pelvis. (6) They must show motivation to participate in the training and give informed consent.

Patients will be excluded if they (1) have lower extremity orthopedic limitations; (2) have a Mini Mental State Examination score of < 24 points [14]. There will be no restrictions with respect to age, ethnicity or gender.

Intervention

Interventions will be applied by physical therapists working at the NRZ in a face-to-face setting. During either training the patient receives continuous verbal feedback, and stimulation and, if necessary, hands-on facilitation of movements. Before the start of the trial, the participating physical therapists follow a five-day training to inform them about the study procedures and to train them to treat the patients according to the intervention protocol.

Extensor training (ET)

Patients assigned to the Extensor Training (experimental intervention) will receive 30-minute structured progressive training of the extensor synergy twice daily, on weekdays over a four-week period. The therapy goals are:

(1) To enhance elasticity and eccentric control of the plantar flexors to gain better stability in Mid-stance and to achieve optimal lengthening during the end of Mid-stance to enable better push-off.

(2) To improve and accelerate motoneuron recruitment (intramuscular coordination) of plantar flexors, especially long toe flexors, during Terminal stance to clear toes from the ground for Initial swing and to enable better elongation of tibiales anterior muscle (intermuscular coordination).

(3) To enhance and accelerate recruitment of hamstrings for better stability during Stance (intramuscular coordination) and for better foot clearance during Swing.

(4) To adapt to different environmental conditions, enhance automatization and gain better gait stability to reduce the risk of falling.

Therefore each 30-minute training session includes (1) eccentric activation of the plantar flexors and rectus femoris muscle during descending stairs, (2) explosive strength training of the long toe flexors by performing climbing and jumping exercises, (3) hip extensor training during climbing stairs, (4) push-off training during gait by having the patient push against the therapist or a treatment table during forward gait.

Dorsi- and hip flexor training (Control group (CG))

Patients assigned to the control group will receive 30-minute so-called standard gait therapy entailing dorsi- and hip flexor training, twice daily, on weekdays over a four-week period. The therapy goals are:

(1) Trunk stabilization to achieve better gait stability.

(2) Strengthening of the hip flexors and foot lifters to achieve better initiation of swing and to reduce the risk of falling.

(3) Inhibition of plantar flexors to enable better function of Swing phase during gait.

(4) Inhibition of quadriceps muscle to enable better knee flexion in Pre-swing and Initial Swing.

(5) Aiding foot lift during gait.

Therefore each 30-minute training session includes (1) Exercises for trunk stability by applying the stabilizing reversal technique for the trunk in sitting position, (2) strengthening the hip flexors and foot lifters applying Proprioceptive Neuromuscular Facilitation: Flexion, adduction, external rotation and knee flexion with rhythmic initiation and timing for emphasis of dorsiflexors [15], (3) Inhibition of plantar flexors and rectus femoris by applying a functional massage, (4) supporting foot lift during gait training by using orthotics to clear the floor.

Outcome measures

The following descriptive variables will be used for this study. (1) Barthel Index (BI) [16]. The BI measures independence in Activities of Daily Living (ADL); the maximum score is 100. It has been used frequently in stroke research [17,18] and was found to be reliable and consistent with other stroke evaluations. The ten ADLs assessed are bowel control, bladder control, personal hygiene, toilet transfer, bathtub transfer, feeding, dressing, wheelchair transfer to and from bed, walking (wheelchair management if patient is non-ambulatory), and ascending and descending stairs. (2) National Institutes of Health Stroke Scale (NIHSS) is a systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit. It is an 11-item neurologic examination used to evaluate the effect of acute cerebral infarction on the levels of consciousness, language, neglect, visual-field loss, extraocular movement, motor strength, ataxia, dysarthria, and sensory loss [19]. For each item, a score of 0 typically indicates normal function in that specific ability, while a higher score is indicative of some level of impairment. The individual scores from each item are summed to calculate a patient's total NIHSS score. The maximum possible score is 42, with the minimum score being a 0.

The effect of intervention will be measured at time of inclusion, immediately at the end of intervention and three months past intervention. Primary outcome measure will be the Dynamic Gait Index.

Dynamic gait index

The Dynamic Gait Index (DGI) is an ordinal test of gait function evaluates the capacity to adapt gait to complex walking tasks encountered in everyday life [20,21]. Eight aspects of gait are scored based on observation as the patient walks over a 6.1-m level surface. The rater records an ordinal score that ranges from 0 (unable or done very poorly) to 3 (normal score) for a total point value of 24. Scores of less than 21 appear to suggest risk for falls [22]. Items included in the DGI are ambulation on a level surface, over and around objects, at various speeds, up and down stairs, turning and stopping plus walking with vertical and horizontal head turns. Many studies have examined the psychometric properties of the DGI in several patient populations, including those with stroke [23,24]. Reliability and validity of the instrument has been previously reported [25,26]. The DGI is reported to be responsive to change over time in patients with

lower levels of initial gait and balance performance [27]. Marchetti and colleagues (2014) estimated in their analysis of the DGI that the amount of pre- to post treatment change that exceeds chance variation was 4 points. They also found significant changes in DGI were associated with reductions in self-reported disability [26,27].

Secondary outcome measures will be the following: Functional Ambulation Categories, Ten-Meter-Timed Walk-Test, Medical Research Council Muscle Strength Testing of the lower extremities, and video gait-analysis. All secondary outcome measures will be applied at time of inclusion, immediately at the end of intervention and three months past intervention.

Functional ambulation categories

Walking ability will be determined using the Functional Ambulation Categories (FAC). It includes six categories with scores ranging from 0 to 5; 0 corresponding to the lowest level unable to walk or need help of two or more people and 5 being able to walk to independently anywhere [28]. This 6-point scale assesses ambulation status by determining how much human support the patient requires when walking, regardless of whether they use a personal assistive device.

Ten-meter-timed-walk-test

Gait speed will be measured by the ten-meter comfortable walking speed test (TMTWT). Gait speed is responsive to change and closely related to walking performance in hemiplegic patients [29]. To reduce measurement error, the mean of three repeated walking speed measurements will be calculated [30]. Patients will rest for about one minute between each test. Using a digital stopwatch that records time within 0.01 second, timing will be manually started when the patient crosses the start line (the patient starts walking two meters ahead of the line) and stopped when the subject crosses the 10-meter mark.

Medical research council strength testing

Medical Research Council of Great Britain (MRC) score to assess muscle strength [31], will be used to assess the strength of the lower extremities. MRC system is one of the best known and most commonly used muscle strength grading system for manual muscle testing. The scale uses the numeral grades ranging from 0 to 5; 5 = normal power and 0 = no movement. In this trial ten muscles of each lower extremity will be assessed separately and a sum score for each side will be calculated (50 = normal strength, 0 = complete paralysis).

Video gait-analysis

Gait analysis: using video documentation will be performed to assess the following parameters:

(1) Hip extension, knee control, dorsiflexion, vertical trunk alignment during stance, observed from the sagittal plane.

(2) Knee flexion during pre-swing, observed from the sagittal plane.

(3) Stride length and heel lift during terminal stance, observed from the sagittal plane.

(4) Heel contact during initial contact, observed from the sagittal plane.

(5) Forefoot pronation during mid-stance and terminal stance, observed from fontal in the ventral plane.

(6) Lateral pelvic shift during initial swing, observed from dorsal in the ventral plane.

The assessment will be completed by the same blinded assessor throughout the trial, who is not employed at the rehabilitation center.

Sample size calculation

The number of patients is based on a statistical power of 80% (preventing Type II error) with an alpha of 5% (preventing Type I error) for detecting a meaningful difference of 6 points on the DGI as the primary measurement of outcome and expecting 15% drop-out. The statistical power for detecting 25% or 6 points difference between groups is based on the following power calculation [32].

Sample size=2(SD)2 x (Zα/2 + Zβ)2 / d2

SD= standard Deviation from previous studies =8

Zα/2= 1,96 from Z-table at Type 1 error of 5%

Zβ= 0.84 from Z-table at 80% power

D= effect size= difference between mean values

Sample size=2(8)2 x (1,96 + 0,84)2 / 62 = 1003,52 / 36 = 28 per group

Statistical Analysis

Descriptive statistics

Means, Standard deviations and frequencies will be used to describe outcome, background and baseline values. Data analysis will be performed with the use of statistical software SPSS21. The primary variable for effectiveness will be analyzed in a covariance model with the DGI scores after intervention (T1) and at follow-up (T2) as dependent variable. Two-sided 95% confidence intervals will be calculated. The analysis follows the principle of intention to treat. Similarly, a secondary analysis will be done evaluating the secondary outcome variables.

Discussion

Stroke patients' gait speed and distance are typically significantly decreased in comparison to healthy people [2]. This leads to limited social participation after stroke [4]. Therefore, regaining of walking ability is considered one of the primary objectives of the rehabilitation process. There is a strong association between strength of lower limb muscles and walking speed in people with stroke [7]. Yet there is conflicting evidence in the literature about which muscle groups are especially impaired and limit gait speed after stroke. It has been reported that the strength of the ankle dorsiflexors alone explained nearly one third of the variance in walking speed and that the most severely affected muscle groups were hip extensors, ankle dorsiflexors and hip adductors [7,8]. Other sources explain the reduced speed in a hemiparetic population by the proportionally larger strength deficit of plantar flexors compared to the proximal hip muscles [9,10] leading to a diminished driving energy for the forward movement of the affected lower limb [11]. Despite the clinical relevance of muscle power and walking speed in stroke rehabilitation, no studies have examined the effectiveness of training either muscle group for regaining walking ability and speed. We hypothesize that training of the extensor

synergy with a focus on strengthening the plantar flexors will be a better strategy to improve gait performance than strengthening the dorsiflexors and hip flexors. We expect that the results from this study may guide the development of future programs of gait rehabilitation. If successful, the pragmatic design of the experimental intervention could be easily adopted to routine practice. In addition, the knowledge gained by this proposed trial will further strengthen the concepts of motor learning in stroke rehabilitation and elucidate the underlying mechanisms associated with functional restitution of gait.

Trial status

The status of the trial is ongoing by the time of manuscript submission. The recruitment of participants is expected to be completed by December 2018.

References

1. Eng JJ, Tang PF. Gait training strategies to optimize walking ability in people with stroke: a synthesis of the evidence. Expert Rev Neurother. 2007; 7: 1417-1436.
2. Jorgensen HS, Nakayama H, Raaschou HO, Olsen TS. Recovery of walking function in stroke patients: The Copenhagen Stroke Study. Arch Phys Med Rehabil. 1995; 76: 27–32.
3. Dickstein R. Rehabilitation of gait speed after stroke: a critical review of intervention approaches. Neurorehabil Neural Repair. 2008; 22: 649-660.
4. Schmid A, Duncan P, Studenski S, Lai SM, Richards L, Perera S, et al. Improvements in speed-based gait classifications are meaningful. Stroke. 2007; 38: 2096-2100.
5. Cruz TH, Dhaher YY. Evidence of Abnormal Lower-Limb Torque Coupling After Stroke: An Isometric Study. Stroke. 2008; 39: 139-147.
6. Neckel ND, Blonien N, Nichols D, Hidler J. Abnormal joint torque patterns exhibited by chronic stroke subjects while walking with a prescribed physiological gait pattern. Neuroeng Rehabil. 2008; 5: 19.
7. Dorsch S, Ada L, Canning CG, Al-Zharani M, Dean C. The strength of the ankle dorsiflexors has a significant contribution to walking speed in people who can walk independently after stroke: an observational study. Arch Phys Med Rehabil. 2012; 93: 1072-1076.
8. Dorsch S, Ada L, Canning CG. Lower Limb Strength Is Significantly Impaired in All Muscle Groups in Ambulatory People with Chronic Stroke: A Cross-Sectional Study. Arch Phys Med Rehabil. 2016; 97: 522-527.
9. Milot MH, Nadeau S, Gravel D. Muscular utilization of the plantar flexor, hip flexors and extensors in persons with hemiparesis walking at self-selected and maximal speeds. J Electromyogr Kinesiol. 2007; 17: 184-193.
10. Dietz V, Sinkjaer T. Spastic movement disorder: impaired reflex function and altered muscle mechanics. Lancet Neurol. 2007; 6: 725-733.
11. Nadeau S, Gravel D, Arsenault AB, Bourbonnais D. Plantarflexor weakness as a limiting factor of gait speed in stroke subjects and the compensating role of hip flexors. Clin Biomech (Bristol, Avon). 1999; 14: 125–135.
12. Lauzière S, Miéville C, Betschart M, Duclos C, Aissaoui R, Nadeau S. A more symmetrical gait after split-belt treadmill walking increases the effort in paretic plantar flexors in people post-stroke. J Rehabil Med. 2016; 48: 576-582.
13. Medical Research Council. Aids to Examination of the Peripheral Nervous System. London, England: Medical Research Council. 1976.
14. Kwakkel G, Wagenaar RC, Twisk JW, Lankhorst GJ, Koetsier JC. Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial. Lancet. 1999; 354: 191-196.
15. Knott M, Voss DE. Proprioceptive neuromuscular facilitation. New York: Harper & Row. 1986.
16. Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. Md State, Med J. 1965; 14: 61–65.
17. Granger CV, Albrecht GL, Hamilton BB. Outcome of comprehensive medical rehabilitation: Measurement by PULSES profile and the Barthel Index. Arch Phys Med Rehabil. 1979; 60: 145-154.
18. Loewen SC, Anderson BA. Predictors of Stroke Outcome Using Objective Measurement Scales. Stroke. 1990; 21: 78-81.
19. Lyden P, Lu M, Jackson C. Underlying structure of the National Institutes of Health Stroke Scale: results of a factor analysis. Stroke. 1999; 30: 2347-2354.
20. Shumway-Cook A, Woollacott M. Motor Control: Theory and Practical Applications. 1st edition. Baltimore: Williams & Wilkins. 1995.
21. Shumway-Cook A, Woollacott M. Motor Control: Translating Research into Clinical Practice. 4th edition. Baltimore. Lippincott Williams & Wilkins. 2011.
22. Bishop MD, Patterson TS, Romero S, Light KE. Improved fall-related efficacy in older adults related to changes in dynamic gait ability. Phys Ther. 2010; 90: 1598-1606.
23. Jonsdottir J, Cattaneo D. Reliability and validity of the dynamic gait index in persons with chronic stroke. Arch Phys Med Rehabil. 2007; 88: 1410–1415.
24. Lin JH, Hsu MJ, Hsu HW, et al. Psychometric comparisons of 3 functional ambulation measures for patients with stroke. Stroke. 2010; 41: 2021–2025.
25. Wrisley DM, Walker ML, Echternach JL, Strasnick B. Reliability of the dynamic gait index in people with vestibular disorders. Arch Phys Med Rehabil. 2003; 84: 1528-1533.
26. Matsuda PN, Taylor CS, Shumway-Cook A. Evidence for the validity of the modified dynamic gait index across diagnostic groups. Phys Ther. 2014; 94: 996-1004.
27. Marchetti GF, Lin CC, Alghadir A, Whitney SL. Responsiveness and minimal detectable change of the dynamic gait index and functional gait index in persons with balance and vestibular disorders. J Neurol Phys Ther. 2014; 38: 119-124.
28. Holden MK, Gill KM, Magliozzi MR. "Gait assessment for neurologically impaired patients. Standards for outcome assessment." Phys Ther. 1986; 66: 1530-1539.
29. Kollen B, Kwakkel G, Lindeman E. Time dependency of walking classification in stroke. Phys Ther. 2006; 86: 618-625.
30. Kollen B, Kwakkel G, Lindeman E. Hemiplegic gait after stroke: is measurement of maximum speed required? Arch Phys Med Rehabil. 2006; 87: 358-363.
31. Dyck PJ, Boes CJ, Mulder D, Millikan C, Windebank AJ, Dyck PJ, et al. History of standard scoring, notation, and summation of neuromuscular signs. A current survey and recommendation. J Peripher Nerv Syst. 2005; 10: 158–173.
32. Charan J, Biswas T. How to Calculate Sample Size for Different Study Designs in Medical Research? Indian Journal of Psychological Medicine. 2013; 35: 121-126.

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