

# Comparative Effectiveness of Russian Current and High-voltage Pulsed Galvanic Stimulation on Quadriceps Muscle Atrophy and Functional Recovery Following Total Knee Replacement: A Research Protocol

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## ABSTRACT

**Introduction:** Total Knee Replacement (TKR) improves joint function and relieves pain, but postoperative quadriceps atrophy impedes recovery. Neuromuscular Electrical Stimulation (NMES), including Russian Current (RC) and High-Voltage Pulsed Galvanic Stimulation (HVPGS), may counteract atrophy. The present prospective study will compare how well they help quadriceps strength and functional recovery in the early stages of post-TKR rehabilitation.

**Need of the study:** Quadriceps atrophy following TKR significantly delays functional recovery, limits mobility, and increases fall risk. Conventional rehabilitation is often insufficient in the early postoperative phase due to pain and Arthrogenic Muscle Inhibition (AMI). The NMES, particularly RC and HVPGS, offers potential benefits in enhancing muscle strength and reducing atrophy. However, limited evidence exists comparing their effectiveness. In order to guide clinical rehabilitation strategies and improve early post-TKR outcomes, the present study is necessary.

**Aim:** To compare the efficacy of RC and HVPGS in reducing quadriceps muscle atrophy and enhancing functional outcomes following TKR.

**Materials and Methods:** The present research protocol is for a prospective, single-blinded, randomised controlled trial that will be conducted from Feb 2025 to Feb 2026 to evaluate and compare the effectiveness of RC and HVPGS in managing quadriceps muscle atrophy and enhancing functional recovery after unilateral TKR. The study will be conducted at Tertiary

health care centre i.e., Acharya Vinoba Bhave Rural Hospital (AVBRH) Sawangi, Wardha, Maharashtra, India. The study commenced from Feb 2025 and will be completed in Feb 2026, including recruitment, intervention, and follow-up assessments. A total of 40 participants will be enrolled and randomly allocated into two equal groups (n=20 in each group) using a block randomisation method with allocation concealment via the SNOSE (Sequentially Numbered, Opaque, Sealed Envelopes) technique. After screening for eligibility and obtaining consent, participants will be randomised into:

- Group A: Received RC stimulation (2500 Hz, 50 Hz burst frequency)
- Group B: Received HVPGS (100-150 V, 50 Hz)

Both groups will undergo standard physiotherapy (Range of Motion (ROM) exercises, strengthening, gait training) for four weeks, five sessions per week. Each NMES session lasted 20 minutes, supervised by a physiotherapist. Pre and post-intervention assessments will be recorded for each outcome measure. Demographic details such as age, gender, Body Mass Index (BMI), limb dominance, and surgical side will be recorded and analysed to ensure baseline comparability between groups. In Statistical Package for Social Sciences (SPSS), using mean  $\pm$  Standard Deviation (SD) for baseline descriptive, groups will be compared with independent t-tests or Mann-Whitney U (and paired t-tests or Wilcoxon for pre-post), considering  $p < 0.05$  significant, and report the effect sizes via Cohen's d for parametric tests (0.2=small, 0.5=medium, 0.8=large) or  $r = Z/\sqrt{N}$  for non-parametric ones.

**Keywords:** Electrical stimulation therapy, Knee prosthesis, Muscle strength, Neuromuscular electrical stimulation

## INTRODUCTION

The TKR is a widely performed and highly effective surgical procedure used to treat individuals with severe joint conditions such as advanced osteoarthritis and rheumatoid arthritis. It offers substantial relief from pain, improves joint structure, and helps patients regain mobility and quality of life [1]. However, one of the main challenges after surgery is the loss of quadriceps muscle mass and strength, which can delay recovery and reduce overall function [2]. This weakness in the quadriceps muscle—a key group responsible for stabilising the knee and supporting everyday movements like walking and climbing stairs—can occur due to several reasons. These include the trauma from surgery, limited movement during recovery, swelling of the joint, pain, and a condition known as AMI, where inflammation or injury reduces the brain's ability to fully activate the muscle. As a result, patients often experience a sharp decline in

quadriceps strength, especially within the first month after surgery. This weakness increases the risk of falling, limits independence, and slows rehabilitation [2].

Although traditional rehabilitation exercises such as resistance training and mobility drills are essential, they may not be effective in the early stages due to pain or the inability to actively contract the muscle. To address this, additional treatments that stimulate muscle activity without needing voluntary effort are being explored. One such method is NMES, which sends electrical pulses through the skin to make muscles contract. This can help maintain muscle size, improve blood flow, reduce swelling, and support quicker strength recovery [3,4].

The two NMES techniques that are commonly used in physiotherapy are RC and HVPGS. RC uses a medium-frequency alternating current that creates strong muscle contractions while keeping discomfort low,

making it suitable for building strength in weak muscles [5]. HVPGS, on the other hand, delivers high-voltage, short-duration pulses that not only activate muscles but also help manage swelling and enhance circulation- useful during the initial recovery phase [5]. Despite their frequent use, there is limited research directly comparing the effects of RC and HVPGS in patients recovering from TKR. Knowing which approach is more effective in restoring muscle strength and improving function could help guide better rehabilitation strategies. Therefore, the present study aimed to assess and compare the effectiveness of RC and HVPGS in managing quadriceps muscle loss and improving recovery during the early stages after TKR.

To compare the effectiveness of RC and HVPGS in reducing quadriceps muscle atrophy and enhancing muscle strength, pain relief, and functional recovery in patients following unilateral TKR during the early postoperative rehabilitation phase.

**Null Hypothesis (H<sub>0</sub>):** There will be no significant difference in the effects of RC and HVPGS on quadriceps muscle strength, muscle girth, pain intensity, and functional recovery in individuals following TKR.

**Alternative Hypothesis (H<sub>1</sub>):** There will be a significant difference between RC and HVPGS in improving quadriceps muscle strength, muscle girth, pain intensity, and functional recovery in individuals following TKR.

## REVIEW OF LITERATURE

The study by Nilsdotter AK et al., focused on the long-term outcomes of TKR by evaluating patient-relevant outcomes over a 5-year period. The results showed that TKR provides significant improvements in pain relief, functional capacity, and quality of life for patients with knee osteoarthritis. However, some patients experienced persistent symptoms even after the surgery, such as limited mobility and pain. These findings highlight the importance of comprehensive postsurgical rehabilitation strategies to maximise functional recovery. Understanding the long-term outcomes and the challenges patients face post-TKR is critical for shaping effective rehabilitation protocols, including addressing quadriceps muscle atrophy and strength loss, which may hinder the recovery process [6].

Mizner RL et al., examined the early loss of quadriceps strength following TKA and its implications on postsurgical recovery. It was found that quadriceps strength was significantly reduced shortly after TKA, with a marked decline in strength observed in the first four to six weeks postsurgery. This weakness was linked to poor functional recovery and delayed return to daily activities. The study emphasised the need for targeted interventions to address quadriceps weakness early in rehabilitation. Quadriceps weakness is a common issue following TKR, and the study reinforces the importance of early interventions, such as NMES, to mitigate strength loss and accelerate recovery [2].

Stevens JE et al., assessed the effectiveness of NMES in treating quadriceps weakness following TKA. The review found that NMES is effective in increasing quadriceps strength, reducing muscle atrophy, and improving functional outcomes in post-TKA patients. It also highlighted that NMES can enhance muscle activation even in the presence of pain or inhibition due to post-surgical inflammation. The study recommended that NMES be integrated into rehabilitation programs, especially in the early phases of recovery. The review supports the inclusion of NMES in the rehabilitation protocols for TKR patients, particularly for addressing quadriceps weakness, which is the focus of the present study comparing RC and HVPGS [4].

The study by Park SH et al., investigated the effects of RC electrical stimulation on muscle strength and functional outcomes in patients with knee osteoarthritis. The study demonstrated that RC stimulation significantly improved quadriceps strength, reduced pain, and enhanced overall functional ability in patients with knee

osteoarthritis. The results suggested that RC could be a beneficial adjunct therapy for patients with muscle weakness, particularly in the early stages of rehabilitation. The study provides evidence for the effectiveness of RC in improving muscle strength and function in knee-related disorders, supporting its use as an intervention in post-TKR rehabilitation [7].

## MATERIALS AND METHODS

The present study is conducted at Tertiary health care centre i.e., Acharya Vinoba Bhave Rural Hospital (AVBRH) Sawangi, Wardha, Maharashtra, India. The study commenced from Feb 2025 and will be completed in Feb 2026, including recruitment, intervention, and follow-up assessments. This study will be conducted following ethical standards and received approval from the institutional ethics committee. IEC Number-DMIHER (DU/IEC/2025/608). CTIRI Registration Number-CTIRI/2025/04/085834. Written informed consent will be obtained from all participants before beginning the trial.

It will be carried out involving 40 Individuals who had undergone unilateral Total Knee Replacement (TKR). These participants will be randomly divided into two equal groups. Group A received RC therapy, while Group B was treated with HVPGS. Both groups followed a standard physiotherapy programme and received their respective treatments five days per week for four weeks.

**Inclusion criteria:** Participants will be included if they:

- Aged between 45 to 75 years;
- Had undergone unilateral TKR within the previous 2 to 4 weeks;
- Demonstrated quadriceps muscle weakness or visible atrophy on the operated limb;
- Are able to walk independently, with or without assistive devices;
- Have no contraindications to electrical stimulation;
- Are mentally competent to understand and follow instructions
- Provided written informed consent.

**Exclusion criteria:** Participants will be excluded if they:

- Have a revision or, bilateral TKR;
- Experienced postoperative complications such as infection, delayed healing, or Deep Vein Thrombosis (DVT);
- Have neurological disorders (e.g., stroke, Parkinson's disease);
- Have severe pathology in the opposite knee impacting mobility;
- Have contraindications to electrical stimulation, including:
- Implanted pacemaker or metal implants at stimulation sites;
- Seizure disorders or epilepsy;
- Peripheral neuropathy or sensory loss;
- Skin infections or open wounds at electrode sites.
- Have serious systemic illnesses (e.g., uncontrolled diabetes, hypertension, Chronic Obstructive Pulmonary Disease (COPD), heart failure);
- Are cognitively impaired or had psychiatric illness;
- Are unable to adhere to the intervention schedule or follow-up.

## Study Procedure

Participants will be randomly allocated into two groups using block randomisation and SNOSE technique for allocation concealment:

- Group A (n=20) received RC stimulation (2500 Hz, burst at 50 Hz) to the quadriceps of the operated leg;
- Group B (n=20) received HVPGS (100-150 V, 50 Hz, pulse duration 100 µs) to the same area.

Both groups will be following a standardised physiotherapy regimen for four weeks, five sessions per week. Each stimulation session lasted 20 minutes under physiotherapist supervision. Exercises included:

- Active-assisted range of motion;
- Isometric quadriceps strengthening;
- Straight leg raises;
- Heel slides;
- Sit-to-stand training;
- Gait and stair training.

Outcome measures will be assessed pre and post-intervention, including:

- Quadriceps muscle strength using handheld dynamometry (Primary outcome);
- Quadriceps girth, NPRS for pain, and LEFS for functional status (Secondary outcomes);

Demographic variables (age, sex, BMI, side of surgery, baseline strength) will be recorded for all participants.

**Sample size calculation:** The required sample size will be determined using G\*Power statistical software, based on a two-tailed t-test. Assuming a large effect size (Cohen's  $d=0.8$ ), a statistical power of 80%, and a significance level of 0.05, a minimum of 35 participants was needed to detect meaningful differences between the two intervention groups. To accommodate possible attrition or loss to follow-up, the sample was increased to 40 participants, with 20 individuals allocated to each group through randomisation.

**Randomisation procedure:** Eligible participants will be assigned to one of two intervention groups using a block randomisation method to ensure balanced group sizes. Allocation will be conducted in a 1:1 ratio using the SNOSE technique to preserve allocation concealment. The randomisation and allocation process will be illustrated using a CONSORT flow diagram, in accordance with reporting guidelines [Table/Fig-1].

### Intervention Protocol

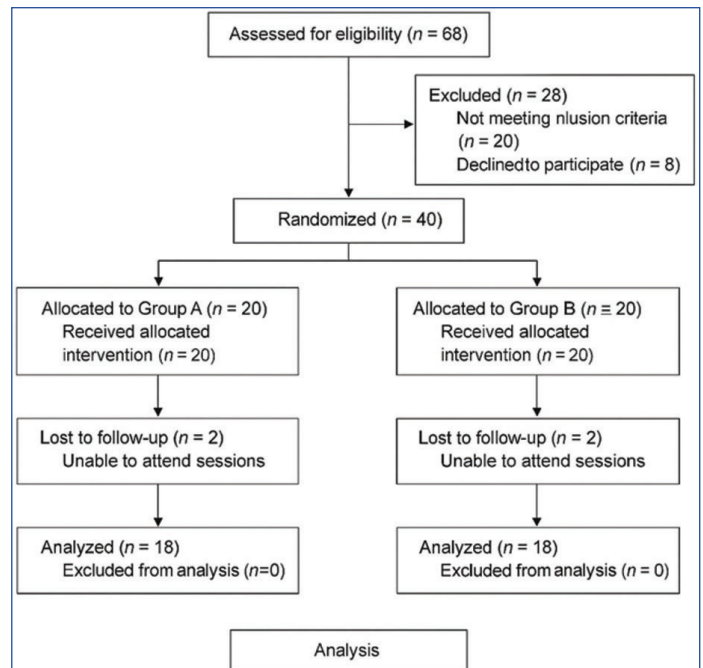
The present study will evaluate the effects of two distinct NMES modalities as adjuncts to standard physiotherapy over a four-week intervention period (five sessions per week, 20 session total) in post-TKR patients experiencing quadriceps muscle atrophy.

### Group A: Russian Current (RC) Group

Participants in this group received RC stimulation applied to the quadriceps muscle of the operated leg. RC is a medium-frequency alternating current (2500 Hz) delivered in burst mode at 50 Hz, known for inducing strong, tetanic muscle contractions. Stimulation was administered using surface electrodes placed over the motor points of the vastus medialis and rectus femoris [5].

#### Criteria for deciding parameters:

1. Clinical relevance to quadriceps atrophy and function
  - Quadriceps muscle strength (primary outcome) is the most direct indicator of recovery after TKR and is critical for mobility and joint stability [2].
  - Muscle girth reflects changes in muscle mass, which is relevant for assessing atrophy [8].
  - Pain intensity impacts a patient's ability to participate in rehabilitation and is a key barrier to recovery [9].
  - Lower limb function is a patient-centered outcome indicating the ability to perform daily activities, which is a goal of rehabilitation [10].
2. Standardisation and Validity in Literature
  - Tools like handheld dynamometry, Numeric Pain Rating Scale (NPRS), and Lower Extremity Functional



[Table/Fig-1]: CONSORT diagram.

Scale (LEFS) are widely used, validated, and reliable in orthopaedic and rehabilitation research [11].

- These are standard outcome measures recommended by research on post-TKR recovery and NMES interventions.
3. Objectivity and Ease of Measurement
    - Parameters like handheld dynamometry and girth measurement offer quantifiable, reproducible data [11].
    - NPRS and LEFS are easy to administer, require minimal time, and capture patient-reported outcomes effectively [10].
  4. Ability to Capture Both Impairment and Function
    - The combination of strength, pain, muscle mass, and function covers impairment-level (strength, girth) and activity-level (LEFS) changes as per the ICF framework (International Classification of Functioning, Disability and Health) [12].
    - Duration: 20 minutes
    - Duty cycle: 10 seconds ON/50 seconds OFF
    - Intensity: Adjusted to patient tolerance to achieve visible, forceful, yet comfortable muscle contractions
    - Patient positioning: Long sitting with the knee slightly flexed and supported
    - Supervision: All sessions will be monitored by trained physiotherapists for correct electrode placement and patient response.

In addition to RC, participants will complete a structured rehabilitation programme that included:

- Active-assisted range of motion;
- Isometric quadriceps strengthening;
- Heel slides;
- Straight leg raises;
- Gait training with progression based on clinical improvement.

### Group B: HVPGS Group

The participants of this group will receive HVPGS, a monophasic pulsed current used for muscle activation and oedema control. Electrodes will be positioned over the same quadriceps motor points used in the RC group, using carbon rubber electrodes with moistened sponge covers [13].

**Criteria for deciding HVPGS parameters:**

1. Established Evidence from Literature the selected HVPGS settings were adapted from prior clinical studies and published guidelines that demonstrated positive effects on muscle activation, pain reduction, and oedema control in postsurgical rehabilitation [13].

2. Therapeutic Goals for Early Post-TKR Rehabilitation the parameters were tailored to meet three main therapeutic objectives:

Stimulate quadriceps contraction without voluntary effort, Reduce postoperative swelling and inflammation, Promote circulation and tissue healing [5].

To achieve this, the following were selected [13]:

- Voltage: 100-150 V - to reach deeper motor nerves and produce visible, comfortable muscle contractions
- Pulse Duration: 100 microseconds - short enough to reduce discomfort while still effective
- Frequency: 50 Hz - ideal for generating sustained tetanic muscle contractions
- Duty Cycle: 10 sec ON/50 sec OFF - allows recovery between contractions, minimising fatigue
- Duration: 20 minutes - long enough to have a therapeutic effect without overworking the muscle

3. Patient Safety and Tolerance [5]

- High-voltage stimulation with short pulse duration is less painful and safe in the early postoperative period.
- The voltage was adjusted per individual tolerance ensuring sessions were both comfortable and effective.
- Electrode placement over motor points (vastus medialis and rectus femoris) was used to maximize targeted stimulation.

4. Clinical Supervision

- All sessions were monitored by trained physiotherapists to ensure [14]:
- Proper electrode contact
- Safe intensity levels
- Effective contraction without adverse effects
- Stimulation parameters [13]:
- Voltage: 100-150 V (patient tolerance-based)
- Frequency: 50 Hz
- Pulse duration: 100 microseconds
- Duty cycle: 10 seconds ON/50 seconds OFF
- Session duration: 20 minutes
- Patient positioning: Matched to the RC group for consistency
- Supervision: All treatments were administered under physiotherapist supervision

Participants will undergo the same rehabilitation exercises as the RC group, ensuring that the only variable between groups was the type of NMES applied.

**Standard Rehabilitation Protocol (Applied to Both Groups)**

All participants will engage in a standardised physiotherapy protocol tailored to post-TKR recovery. The regimen include:

- Pain management: Cryotherapy and manual techniques
- Range of motion: Passive and active-assisted movements to improve joint mobility
- Muscle strengthening: Focused on isometric quadriceps and hamstring activation

- Functional training: Heel slides, straight leg raises, sit-to-stand exercises, and stair training

- Gait and balance training: Introduced progressively, with or without assistive devices as needed

Sessions will be conducted five days per week for four weeks, and all interventions were documented for adherence. Any adverse effects or complications were recorded and promptly managed.

**Primary Outcome**

**Quadriceps Strength - Handheld Dynamometry [11]:** Quadriceps strength is measured using a handheld dynamometer, which provides an objective quantification of force output during voluntary muscle contraction.

- Procedure: The patient performs an isometric contraction of the quadriceps while the examiner resists at the lower leg, typically at a knee flexion angle between 60° and 90°.
- Measurement: The peak force is recorded in kilograms (kg) or Newtons (N), with multiple trials conducted and the highest value retained for analysis.

This method allows precise tracking of strength gains, which are critical for restoring knee function and stability post-TKR, and for monitoring the effects of neuromuscular inhibition or muscle disuse.

**Secondary Outcomes**

**Numeric Pain Rating Scale (NPRS) [15]:** The NPRS is a subjective measure used to assess pain intensity. Participants are asked to rate their pain on a scale from 0 to 10, where:

- 0 indicates no pain,
- 10 represent the most severe pain imaginable.

Two pain scenarios are assessed:

- Resting pain: Pain experienced while at rest.
- Pain during activity: Pain felt during functional movements such as walking, stair climbing, or standing.

This tool is quick and easy to administer, making it ideal for tracking changes in pain over time and evaluating the effectiveness of pain management strategies during rehabilitation, particularly in the early postoperative stages.

**Quadriceps Muscle Girth - Circumferential Measurement [8]:** Muscle girth is assessed using a flexible inch tape, placed circumferentially around the thigh at a standardised location (typically 10 cm proximal to the superior border of the patella).

- Positioning: The measurement is taken with the patient in a relaxed, supported posture, usually with the knee extended or slightly flexed.
- Purpose: A reduction in circumference suggests muscle wasting, while an increase implies hypertrophy or recovery.
- Consistency: To ensure accuracy, measurements are consistently taken at the same anatomical site across sessions.

Girth measurement serves as an indirect yet valuable indicator of muscle mass and the physiological impact of rehabilitation on muscle volume postsurgery.

**Lower Extremity Functional Scale (LEFS) [11]:** The LEFS is a self-reported outcome measure assessing a patient's ability to perform daily activities involving the lower extremities. It includes 20 items, each rated on a 5-point Likert scale:

- 0=Unable to perform
- 1=Extreme difficulty
- 2=Moderate difficulty
- 3=Slight difficulty
- 4=No difficulty

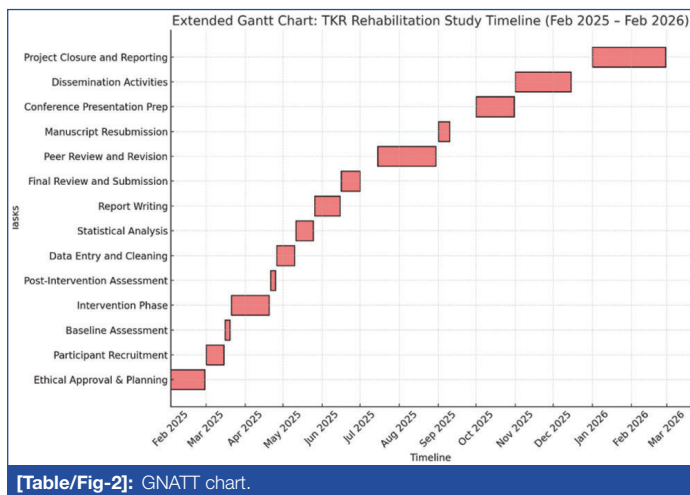
- Scoring: The total score ranges from 0 to 80, with higher scores indicating better functional ability.
- Application: LEFS provides a comprehensive view of a patient's mobility, independence, and progress throughout rehabilitation. It is particularly useful for quantifying the impact of interventions on functional recovery post-TKR.
- Quadriceps Muscle Strength Measured using Handheld Dynamometry, this outcome reflects the maximal voluntary isometric contraction of the quadriceps muscle on the operated leg. It is a direct indicator of the effectiveness of RC and HVPGS in improving muscular strength post-TKR.

## STATISTICAL ANALYSIS

Data analysis will be conducted using SPSS software. Descriptive statistics (mean and standard deviation) will summarize baseline characteristics. For inferential analysis:

- Between-group comparisons will use independent t-tests or Mann-Whitney U tests, depending on data distribution.
- Within-group changes from baseline to post-intervention will be assessed using paired t-tests or Wilcoxon signed-rank tests.
- Analysis of Covariance (ANCOVA) will adjust for any baseline differences when comparing outcomes between groups.
- Effect sizes (Cohen's d) will be calculated to determine the practical significance of observed differences.
- Significance level is set at  $p < 0.05$ .
- Missing data will be addressed using multiple imputation or Last Observation Carried Forward (LOCF) methods.
- A post-hoc power analysis will be conducted to confirm whether the achieved sample size was sufficient to detect significant effects.

The timeline for the present study is explained in [Table/Fig-2].



[Table/Fig-2]: GNATT chart.

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