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Comparison the Impact on TENS and Conventional Physiotherapy in Stroke Patients with Upper Limb Dysfunctions: A Research Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. Author AB suggested the design of the study. Author SSL and AB led to the creation and design of the study. Author SSL wrote the manuscript of this article. Authors SSL and AB read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Stroke is a sudden neurological explosion resulting from poor blood flow perfusion to the brain. Stroke prevalence rates in India are expected to range from eighty-four to two hundred sixty-two strokes every 100,000 persons in remote regions and from three hundred thirty-four to four hundred twenty-four strokes every 100,000 persons in metropolitan areas. It causes brain cells to die abruptly due to inadequate oxygen and is a neurological condition characterized by blood flow blockage.
Aim & Objective: to examine the impact of TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscle Stimulation), and ROM (Range of Motion) exercises on upper-limb functioning in hemi paretic stroke victims.
Methods: The current study subjects (n=39) would be stroke survivors. Patients will be divided into three groups: group A will receive TENS, group B will receive EMS, and group C will get ROM

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exercises. The protocol will cover 2 weeks of treatment. We will assess upper limb functioning, activities of everyday living (ADLs), and mental condition at frequent intervals. By using the MHQ (Michigan Hand Outcomes Questionnaire), Hand Grip Strength (HGS), Brunnstrom Hand Function Recovery stages.

Results: The successful completion of this study will provide evidence on the best treatment strategy for stroke patients to improve their upper extremity motor function using individual TENS, EMS, or ROM exercises.

Conclusion: This study will be beneficial to treat Stroke patients with upper limb dysfunction by treating by TENS modality which might be an option for EMS treatment.

Keywords: Stroke, transcutaneous electrical nerve stimulation, electrical muscle stimulation, range of motion exercises, physiotherapy.

1. INTRODUCTION

Stroke is a sudden neurological explosion resulting from poor blood flow perfusion to the brain [1]. Stroke is described as "rapidly developed clinical symptoms of focal (or global) disruption of cerebral activity, lasting more than 24 hours or leading to death, with no clear cause other than vascular origin," according to the World Health Organization [2]. It is indeed a neurological disease marked by an obstruction of blood flow [1]. It causes brain cells to die abruptly due to inadequate oxygen [1]. Inflammation, energy depletion, lack of homeostasis, acidosis, increased cellular calcium levels, oxidative damage, free radical-mediated damage, cytokine-mediated cytotoxicity, complement activation, weakening of the blood–brain barrier, glial cell activation, oxidative stress, and leukocyte infiltration are all significant considerations in stroke pathology [1]. Stroke is now one of India's major leading causes of mortality and disabilities [3]. It is considered a worldwide pandemic since it is one of the leading causes of disability and mortality [4]. Stroke prevalence rates in India are expected to range from eighty four-two hundred sixty-two strokes every 100,000 persons in remote regions and from three hundred thirty four-four hundred twenty-four strokes every 100,000 persons in metropolitan areas [5]. According to latest population-based surveys, the incidence rate is 119-145/100,000(3). It impacts around 13.7 million individuals globally and fatalities around 5.5 million people per year [1].

This frequently encountered condition has a tremendous impact on a person's experience, including physiological, emotional, and social impacts [6]. The far more serious condition following a stroke is hemiparesis, which is followed by aphasia, visual problems, facial paralysis, stiffness, instability, post-stroke discomfort or bodily irritability, & swallowing [7]. Upper extremity paresis, which is marked by muscular weakness in the afflicted limb over one side of the body, is among the most prevalent instances (up to 85 percent of stroke survivors) [6]. These symptoms have a huge impact on stroke victims' everyday lives as well as their quality of life [7]. Differences in the size and power of skeletal muscles across both paretic and non-paretic limbs have been seen in post-stroke subjects [7]. The number of extra motor units recorded in the hypothenar muscles of paretic limbs reduces gradually as soon as four to thirty hours following the onset of an acute ischemic stroke (IS) compared to non-paretic limbs [7]. The paretic muscles in prolonged post-stroke patients exhibited a continuous drop in the amount of motor units, a disturbance in motor neuron firing rate, and long-term muscle denervation [7]. These factors can play a role in muscle atrophy and weakening [7]. Owing to broken interactions seen between brain and the hand muscles, the hands can exhibit increased tone or weakness after a stroke. This is known as spasticity [8]. Without this distinct neural link, it may be more difficult to totally straighten the fingers or hold an object [8]. Hand grip, power, and general function are often harmed, making it impossible to lift, grab, or release objects entirely [8]. Other problems involve lack of touch (which may feel like pins and needles) and episodes of swelling [8]. Hand function is essential for performing everyday tasks [6]. The upper extremity is an integral part including its human body since it is quite mobile and helps in gripping, lifting, transferring, & contacting various item [9]. Since the majority of daily tasks necessitate the use of both hands, bimanual actions attract a lot of focus in the recovery environment [6]. Enhanced arm and hand function improves social involvement as well as (health-related) quality of life [6].

Transcutaneous electrical nerve stimulation (TENS), on the other hand, has also been used

to treat chronic hemiplegia for the last ten years [10]. TENS elicits afferent signals in both sensory and motor cortices, according to research [10]. It has already been found to increase motor skills in healthy individuals and to aid in the recovery of motor control among stroke victims [11]. Transcranial magnetic stimulation studies have revealed that electrical stimulation improves blood circulation in the primary sensory cortex, primary and secondary motor cortices, including motor cortical activity [11]. These findings suggest that Transcutaneous electrical nerve stimulation could enhance motor output in stroke survivors [11].

Electrical stimulation of the upper extremity with an Electrical Muscle Stimulator is another technique that has gained a lot of attention as a psychotherapeutic intervention in post-stroke rehab [12]. Electrical stimulation can help stroke victims stimulate damaged areas of the brain by giving strong stimulation [13]. In turn, this stimulation activates neuroplasticity, the process through which the brain rewires itself and heals from traumas such as stroke [13]. Based on the application of an electrical current to induce repeated contractions of muscles, it aids in the restoration or augmentation of motions that would otherwise be difficult due to hemiparesis [14]. In a large investigation, De Kroon & colleagues discovered that electrical stimulation may enhance motor skills and power of the affected upper extremity, especially in individuals with little remaining motor skills [12].

1.1 Aim

The aim of the study is to compare the impact of TENS, EMS, and ROM exercises on post-stroke survivors regaining upper limb function.

1.2 Objectives

1) To find out the effect of TENS on gaining Motor function in subjects with post-stroke upper limb dysfunction.
2) To find out the effect of EMS on gaining Motor function in subjects with post-stroke upper limb dysfunction.
3) To find out the effect of ROM exercises on gaining Motor function in subjects with post-stroke upper limb dysfunction.
4) To compare the effect of TENS, EMS and ROM exercises in gaining Motor function in subjects with post-stroke upper limb dysfunction.

2. METHODOLOGY

2.1 Study Design and Sample Size

Study Design: Randomized Controlled Trial.

Study Type: Experimental study.

Targeted Population: Post Stroke survivor's acute condition.

Duration of Study: 6 months.

Type of Sampling: Purposive Sampling.

Sampling Technique: Simple Random Sampling.

Sample Size: 39 Subjects (13 subjects in each group).

Allocation: Random Patients who fulfil the Inclusion Criteria.

The design of the study is experimental study enrolling 39 participants. The participants enrolled in this study will be randomized in 1:1:1 manner into TENS intervention group (Group A), EMS intervention group (Group B) and Conventional ROM exercises group (Group C), for 2 weeks each. Before inclusion, the participants will be explained about the objectives and approaches of the study, and written patient consent forms will be signed by them. Stroke patients with Hand Dysfunction who satisfied the selection criteria were accepted in the analysis.

The primary researcher, a physiotherapy final year student, will do the randomization and distribution. Prior to the start of the analysis and after it is completed, outcome assessments will be measured.

2.2 The Study's Outcome Measures are as Follows

1) The MHQ (Michigan Hand Outcomes Questionnaire)
2) Hand Grip Strength (HGS)
3) Brunnstrom Hand Function Recovery stages

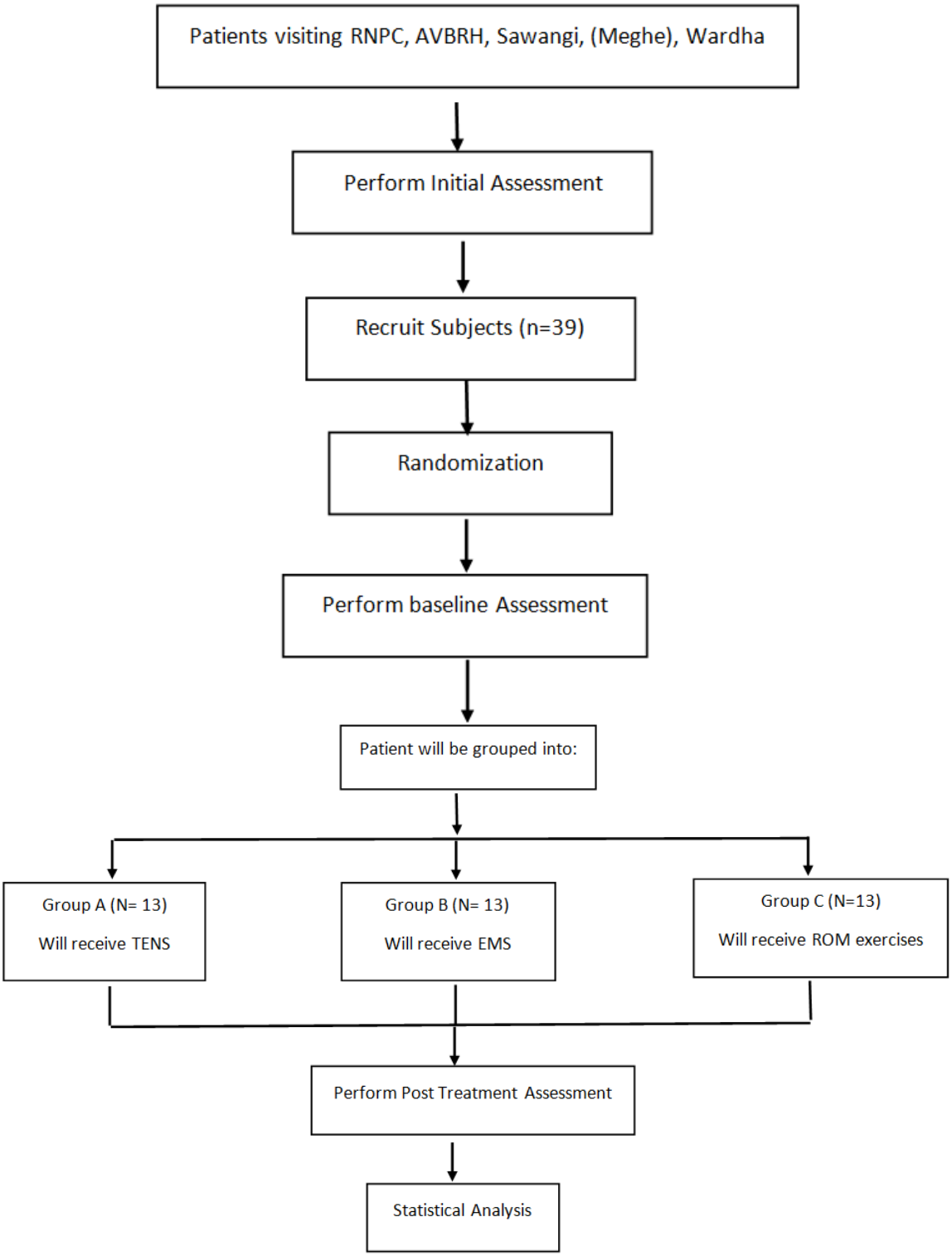

Fig. 1. Showing theme of conducting the current study

2.3 Participants

The Inclusion Criteria of Participants are Under: Either gender between 25 and 85 years of age [15]. Those who are in the sub-acute phase of stroke i.e., 2 weeks after stroke. Those who are diagnosed with hemiparesis or hemiplegia after a single stroke history. Those who have an ability to understand and follow instructions. Those who intend to partake in the

study. Those who need to continue physiotherapy during outpatient care to improve hand competency or physical condition or both.

Exclusion Criteria for Participants are Under: Those who are less than 25 years and more than 85 years of age. Those who have joint or muscular problem arising from condition other than stroke. Those who have any unstable cardiovascular condition, as determined by the physician. Those who are diagnosed with the failure of vital organs, such as lung, heart, kidney and liver. Those who are registered in another clinical trial. Those who have chronic, progressive medical condition (i.e., Parkinson's disease).

Participant Timeline: Each patient will be required to complete 2 weeks of rehabilitation after enrolment in the study. The evaluations will be performed at baseline that is pre intervention and at their last session.

2.4 Recruitment

The Neurologists and health care practitioners working under DMIMSU are invited to refer the prospective patients to our In-patient department (IPD) and Out-patient department (OPD). The patients who are already undergoing rehabilitation in our IPD and are diagnosed with stroke will be systematically assessed for the eligibility in the study as per inclusion and exclusion criteria. After enrolment in the study participants will be randomized in one of the group A, B or C and accordingly will undergo the rehabilitation program for 2 weeks with intermediate assessments. Informed patient consent will be taken before allocation and after explaining the purpose of the study, procedure, prospective benefits and after effects of intervention.

2.5 Implementation

Randomization will be supervised by the research coordinator and principal investigators. Participants will be asked to handpick a sealed group allocation for the recruitment into either group from the envelope.

2.6 Blinding

Tester(s) will be blinded to assign the subjects to the group. To ensure blinding, subjects will be mandated not to reveal any details of their treatment to the tester.

2.7 Study Procedure

The subjects will be divided into 3 different groups, each group will be consisting of 13 subjects and their demographic data will be collected.

Group A: Will be subjected to transcutaneous electrical nerve stimulation (TENS)
Group B: Will receive Electrical Muscle Stimulator (EMS)
Group C: Will receive ROM Exercises (Passive, Active assisted, Active and Resisted exercises)

Group A: The participants in this group will undergo for application of TENS by using TENS stimulator. TENS for forearm muscles (flexors and extensors) will be given with patient in supine position for 20 minutes to the affected side upper extremity daily, 7 days per week for 2 weeks. It will be performed by a physiotherapist. The stimulus strength is regulated to around double the individual patient's sensitivity thresholds, which is defined as the least amount of tingling sensation perceived by the patients. After administering TENS, the skin under the electrode will be evaluated for aberrant responses or unexpected changes in skin coloration for a moment. If no aberrant responses were observed during the initial check, this will be redone after 5 minutes. Burst type TENS current with 100 Hz frequency will be used. Carbon rubber electrodes are used for stimulation. For first 10 minutes the active electrode of the TENS machine will be placed above the wrist joint on the muscle belly with forearm in supination and indifferent electrode will be placed near common flexor origin (medial epicondyle of humerus). For next 10 minutes the active electrode will be placed above the wrist joint on the muscle belly with forearm in pronation and indifferent electrode will be placed near common extensor origin (lateral epicondyle of humerus). Progression of patient's muscle function should be recorded pre and post stimulation per session.

Group B: The participants in this group will undergo for application of electrical stimulation by using EMS stimulator. EMS for forearm muscles (flexors and extensors) will be given with patient in supine position for 20 minutes to the affected side upper extremity daily, 7 days per week for 2 weeks. It will be performed by a physiotherapist. Low frequency current of

frequency 50Hz and pulse duration of 300 microsec is used for stimulation. The stimulus strength is regulated to around double the individual patient's sensitivity thresholds, which is defined as the least amount of tingling sensation perceived by the patients. After administering EMS, the skin under the electrode will be evaluated for aberrant responses or unexpected changes in skin coloration for a moment. If no aberrant responses were observed during the initial check, this will be redone after 5 minutes. For first 10 minutes the active electrode of the TENS machine will be placed above the wrist joint on the muscle belly with forearm in supination and indifferent electrode will be placed near common flexor origin (medial epicondyle of humerus). For next 10 minutes the active electrode will be placed above the wrist joint on the muscle belly with forearm in pronation and indifferent electrode will be placed near common extensor origin (lateral epicondyle of humerus). Progression of patient's muscle function should be recorded pre and post stimulation per session.

Group C: The participants in this group will receive Conventional (ROM) exercises in step wise manner according to the patient's condition and progression. Start with passive movements then active assisted, then Active and resisted exercises. The workouts sought to enhance muscular strength and functional capability in the afflicted upper limb. The participants in this group will undergo 10RM for each joint (shoulder, elbow, wrist and small joints of hand) of affected upper extremity. Exercises are performed 7 days per week for 2 weeks provided by a physiotherapist. ROM of each joint should be recorded pre and post therapy per session.

2.8 Outcome Measures

The MHQ (Michigan Hand Outcomes Questionnaire) [16]: The MHQ is a 57-item self-administered checklist that assesses six dimensions: general hand performance, daily functioning, discomfort, job performance, aesthetics, and patients' contentment with functional outcome. It depicts the impact of stroke on hand function using the appropriate ICF criteria. The left- and right-hand activities are carried out separately (except for the domains pain and work performance). Every item is rated on a scale of One to five, with domain scores ranging from zero to hundred. A better result implies greater hand function in each category. The pain index is inverted (100 – pain score) to provide a range from the worst (0) to (1) excellent (100). The overall score (the mean including all categories) is between 0 and 100, with a higher score reflecting superior hand function. The overall score is calculated by adding the values from all six scales and then splitting by 6. On scales with fewer than 50percent missing items, the mean of the current scale items was used to infer the missing items. If half of the elements are lacking, the scale was not evaluated. If scores for more than two scales were lacking, an overall MHQ rating was not estimated. Patients completed the MHQ without help. The survey takes 15-152 minutes to finish.

2.9 Hand Grip Strength (HGS) [7]

Hand Grip Strength (kilograms) can be measure using a Hand-Held Dynamometer. Participants stood or sat erect with each arm in flexion and couldn't make contact with the trunk. Thereafter, for each hand, participants are instructed to execute maximum voluntary hand muscular contractions with the dynamometer twice, 2 minutes apart to avoid muscle fatigue. This will help to assess the strength of affected hand in post stroke patients.

2.10 Brunnstrom Hand Function Recovery Stages

Brunnstrom recovery phases are used to measure patients' motor recovery. It is a six-stage recuperation procedure. Dependent on the extent of spasticity as well as the emergence of voluntary movement, this assessment summarises the processes of motor recovery following stroke.

2.11 Data Collection and Management

Data Collection: The evaluation data will be obtained from a pre-established spreadsheet with variable baseline characteristics. Research data will be placed in a secure database. Non-electronic records, such as hard copies of assessment forms, signed informed consent, etc., will be stored safely in the study setting.

Data Management: Under the supervision of the chief investigators, data will be collected and reported. The documentation for the report will be thoroughly reviewed for consistency. At the conclusion of the report, the Excel spreadsheet will be sent to an allocation blinded statistician to do the required analysis, after which the groups will be unblinded. The trial's data will be held in a safe, password-protected location with limited

access for further review by a biostatistician and the lead researcher. Checklists are used to prevent data loss due to insufficient personnel procedures.

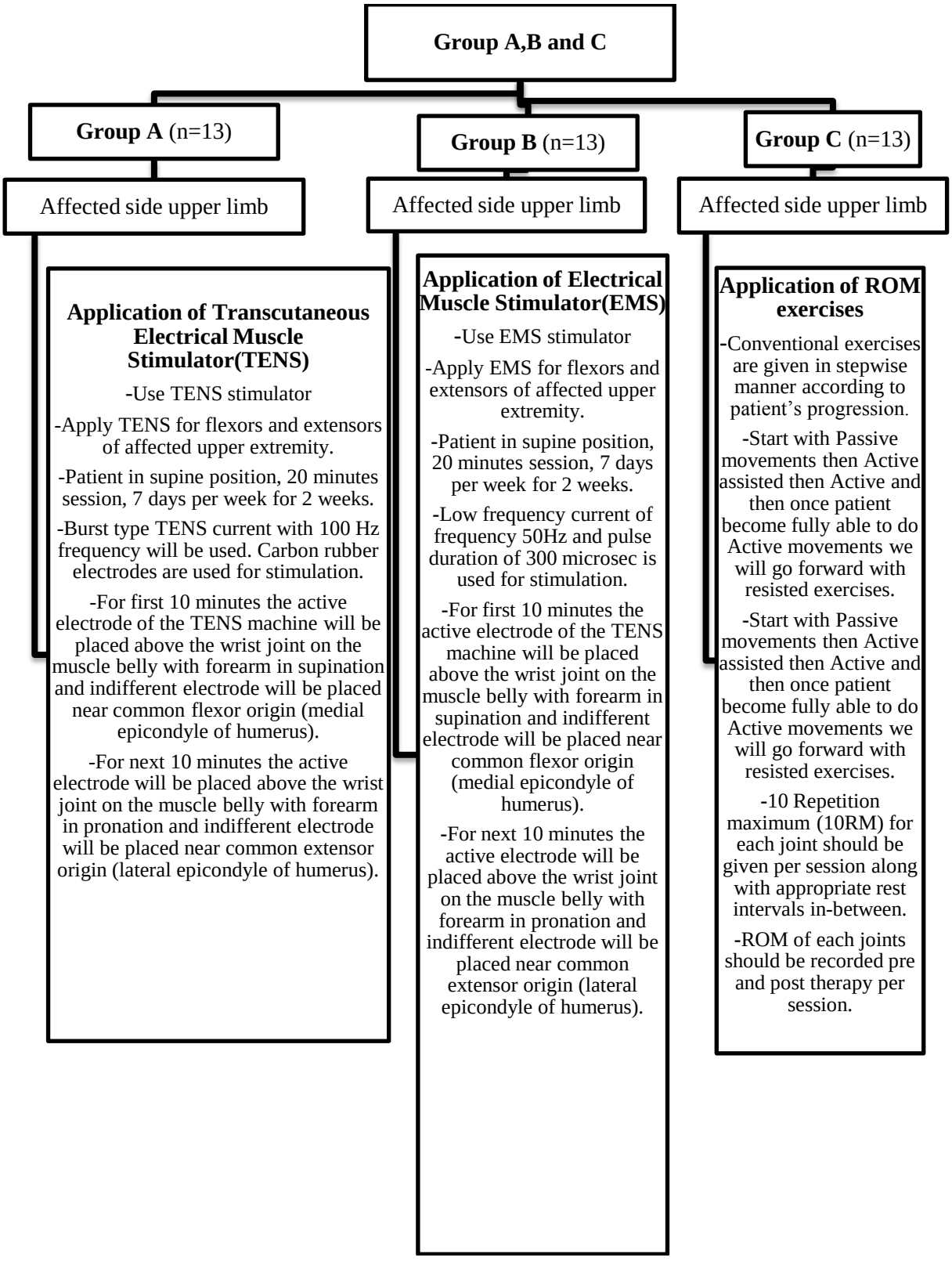

Fig. 2. Interventions carried out during the study process

2.12 Statistical Analysis Plan

To conduct statistical analysis, the current edition of SPSS (27.0U) will be used. The influence of each group will indeed be evaluated using analysis of variance (ANOVA). In individual investigations, the student's t test would be employed to screen for homogeneity of the two sample classes. Both statistical analyses should be conducted with a 95% confidence interval to assess the effect of two measures (p-value 0.05). To begin, the Mann-Whitney U test will be employed to compare groups.

Bias: Measures will be taken to prevent this from happening attrition bias by giving reminder calls prior to each intervention and by providing travel assistance to those who need it. So, we expect a low percentage of dropouts.

3. RESULTS

Successful completion of this study will provide evidence on the best treatment strategy out of individual TENS, EMS or ROM exercises for Stroke patients to improve their upper extremity motor function and the result of this study will lead us to better understanding of all the above treatment measures.

4. DISCUSSION AND CONCLUSION

Stroke is described as “rapidly established clinical symptoms of focal (or global) impairment of brain function lasting longer than 24 hours or leading to death, with no evident aetiology other than vascular origin.” [2]. Upper Limb impairment affects about 60 percent of stroke victims, restricting involvement in daily activities [17]. The aim of the study is to compare the impact of TENS, EMS, and ROM exercises on post-stroke survivors regaining motor function (for hand dysfunction). For the past 10 years, transcutaneous electrical nerve stimulation (TENS) has indeed been utilized to treat persistent hemiplegia [10]. It has been shown to strengthen muscle function in healthy adults and to help stroke patients regain motor activity. TENS has the ability to help stroke patients improve their muscle control [11]. In stroke patients, neuromuscular electrical stimulation (NMES) is often used as a therapy to increase motor recovery, alleviate pain and stiffness, and build strength [18]. There's really mounting evidence suggesting NMES improves upper extremity motor recovery in stroke victims [19]. According to Sheffler et al. research, NMES triggers the paralytic muscle in a specific sequence and amplitude to directly achieve a functional activity. It also has therapeutic effect of motor-learning thus improving the functional recovery [20]. Improving joint range of motion and reinforcing weak muscles with conventional exercises such as passive, active aided, active, and resisted exercises has been shown to be beneficial in post-stroke survivors. For one thing, it aids in the reduction of spasticity and muscle stiffness [21]. It also aids in the prevention of painful contractures by increasing muscle flexibility. It can also aid in the reduction of swelling [21]. In conclusion, this research seeks to compare the effect of TENS, EMS and ROM exercises in hemiplegic stroke patients. The result of the study will help patients for faster recovery and improve their quality of life. Major Outcome measures of the study are MHQ, HGS and Brunnstrom Hand Function Recovery Stages. These 3 major scales will help to assess spasticity, activities of daily living and ability to do activities with upper extremity.

CONFIDENTIALITY

The study program will be elaborated to the participant and one of his/her relative, and principal investigators will take personal information as a part of procedure. The consent form will include the confidentiality statement and signatures of the principal investigator, patient and 2 witnesses. If required to disclose some information for the study, consent will be obtained from the patient with complete assurance of his/her confidentiality.

CONSENT

Principal Investigator will obtain the informed consent from the patient and one of the relatives on a printed form with signature and given the proof of confidentiality.

ETHICAL APPROVAL

Ethical approval will be taken from institutional ethical committee (IEC: RNPC/2020/I21). The DMIMS who will fund for research and the subjects who will be participating in the study can access the main findings of the research. Data held safely for the enrolled subjects a minimum of five years. After completion of data collection, statistical analysis a completion report will be formed and after review by institutional research cell will be send for publication.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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