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Research Protocol

Physiotherapy Section

Effect of Pain Neuroscience Education versus Conventional Patient Education on Pain, Quality of Life, Kinesiophobia and Pain Catastrophising in Individuals with Post-Stroke Chronic Shoulder Pain: A Randomised Controlled Trial Protocol

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ABSTRACT

Introduction: Post-Stroke Shoulder Pain (PSSP) is a prevalent complication that affects 10-22% of stroke survivors. Research shows that chronic pain is influenced by biological, psychological and social factors and these factors can impact physical function, kinesiophobia, pain catastrophising, disability and quality of life. These elements may contribute to chronic pain in patients with PSSP. Understanding Post-Stroke Chronic Shoulder Pain (PSCSP) is crucial for developing effective interventions and improving the overall wellbeing of stroke survivors.

Need of the study: This study seeks to address the gap in understanding PSCSP, particularly the overlooked psychosocial factors in physiotherapy. By integrating the biopsychosocial model with Pain Neuroscience Education (PNE) and conventional physiotherapy, it aims to improve pain management and the wellbeing of stroke survivors.

Aim: To compare the effect of PNE versus Conventional Patient Education (CPE) on pain intensity, quality of life, kinesiophobia and pain catastrophising in individuals with PSCSP.

Materials and Methods: This research protocol is planned to conduct a randomised controlled trial in Hubballi, Karnataka, India, with 80 participants (40 per group), calculated at 90% power and 5% significance using G-power software. The duration of the study will be approximately four years, from June 2023 to August 2027. Participants aged ≥18 years with PSCSP (≥3 months), first-ever unilateral ischaemic or haemorrhagic stroke and chronic stroke lasting more than six months, meeting cognitive criteria (Mini-Mental State Examination (MMSE) >24), Visual Analogue Scale (VAS) (>1 mm) and Brunnstrom stages (III–V), will be included. Participants will be excluded if they have pre-stroke shoulder/neck pain, have undergone surgery, experienced acute strokes, have severe deficits, uncontrolled conditions, or contraindications to Transcutaneous Electrical Nerve Stimulation (TENS) (e.g., epilepsy, pacemaker). Group A will receive PNE, while Group B will undergo CPE. Both groups will receive graded motor imagery, TENS and task-specific exercises for six weeks, with a two-week follow-up. Outcomes (VAS, quality of life, Tampa Scale for Kinesiophobia, pain catastrophising and disability) will be assessed at baseline, six weeks and eight weeks.

Keywords: Biopsychosocial model, Disability, Motor imagery

INTRODUCTION

Pain-related diseases are the leading cause of disability and burden worldwide [1]. PSSP is a prevalent complication, affecting 10-22% of stroke survivors, with a prevalence rate of 22-47% globally [2] and 61.43% in India [3]. PSSP arises in the shoulder on the hemiplegic side, in the resting state and during active or passive range of motion for more than three months [4]. The wide variation in prevalence across reports, ranging from 5-84%, is attributed to differences in definitions, timelines and assessment methods across studies [5-9].

Chronic pain is characterised as pain lasting for more than three months and can arise from a range of sources, such as injury, illness, or unknown origins [10]. PSCSP may consist of a wide range of potential factors, such as subluxation of the humeral head [11], lack of sensation, initial flaccid paralysis, emotional factors, hemispatial neglect [12] and spasticity [13]. Research indicates that chronic pain arises from a multifactorial interplay of biological, psychological and social factors, which directly impact physical functions, levels of kinesiophobia, pain catastrophising, disability, and quality of life, and could be possible reasons for PSCSP in patients [14]. PSSP may lead to a decline in the functional recovery of the arm, longer hospital stays [15], and reduced Activities of Daily Living (ADL) [16].

There are many diverse interventions for PSSP that comprise exercises, modalities, and patient education, all of which have shown some effectiveness in alleviating PSSP in clinical settings [17]. However, there remains a lack of studies specifically investigating the role of chronic pain mechanisms as contributing factors in PSCSP, highlighting a gap in targeted research on chronic pain's impact in this context.

Understanding PSCSP is essential for developing effective interventions and improving stroke survivors' wellbeing. Existing research has overlooked the psychosocial aspects of PSCSP, which have not been explored in physiotherapy interventions. This study addresses the gap by integrating the biopsychosocial model into rehabilitation through PNE, alongside conventional physiotherapy, to improve pain management while considering social, psychological, and biological factors.

PNE is recognised as an effective strategy for managing chronic pain, particularly when combined with exercise [18-20]. It reshapes pain perceptions, beliefs, and avoidance behaviours [21] through interventions such as individual/group discussions, phone consultations, or written materials like booklets and emails [22]. PNE addresses psychological factors such as fear-avoidant behaviours, pain catastrophising, pain intensity, and disability in chronic pain conditions [23], which are explained by the biopsychosocial model [24]. Despite its potential, there is insufficient evidence supporting its effectiveness in treating chronic shoulder pain in stroke patients. Therefore, the present study will assess the effects of PNE versus CPE in individuals with PSCSP.

Objectives

Primary objective: To evaluate the effect of PNE compared to CPE on pain intensity in individuals with PSCSP.

Secondary objective: To assess the impact of PNE versus CPE on quality of life, kinesiophobia, pain catastrophising, and shoulder disability in individuals with PSCSP.

Study Hypothesis

To hypothesise that PNE will lead to greater improvements in pain, quality of life, kinesiophobia, pain catastrophising, and disability when compared to CPE.

REVIEW OF LITERATURE

This trial aims to bridge knowledge gaps by integrating PNE, task-specific exercise, graded motor imagery, and TENS to assess their impact on pain intensity, pain catastrophising, fear-avoidant behaviours, and disability in individuals with PSCSP. This is the first controlled trial assessing PNE's potential effects in this group. Available literature indicates a paucity of studies on the effective management of PSCSP.

Meints SM and Edwards RR, emphasise the biopsychosocial model of pain, highlighting the interplay of physiological, psychological, and social factors in chronic pain. Key psychosocial influences include distress, trauma, catastrophising, expectations, and coping strategies, which shape pain perception and disability. Addressing these factors is crucial for effective pain management and rehabilitation [25]. A systematic review of RCTs conducted by Salazar-Méndez J et al., found PNE effective in managing pain and biopsychosocial factors through knowledge and self-regulation [26], especially in chronic conditions like PSCSP. The current study evaluates whether combining PNE with other exercises can influence outcomes in patients with PSCSP.

This randomised controlled study investigates the effects of PNE on multiple outcomes such as quality of life, pain intensity, catastrophising, kinesiophobia, and functional impairments, based on the biopsychosocial model. Statistical methods will provide evidence for innovative cognitive interventions in PSCSP, with interventions conducted in clinical settings to enhance future implementation in healthcare systems. Future studies should account for the use of analgesics and longer follow-up periods to assess prolonged effects.

MATERIALS AND METHODS

This dual-arm, single-blind study will be executed as a randomised controlled trial, adhering to the protocols established by the Institutional Ethics Committee (IEC) in Karnataka, India. The study is designed in accordance with the SPIRIT and CONSORT guidelines for interventional trials. It has been prospectively registered at ctri.gov.in (CTRI/2024/12/078181). The duration of the study will be approximately four years, from June 2023 to August 2027. The trial will take place at the Physiotherapy Outpatient Department (OPD) of a tertiary care hospital in Hubballi, Karnataka, India.

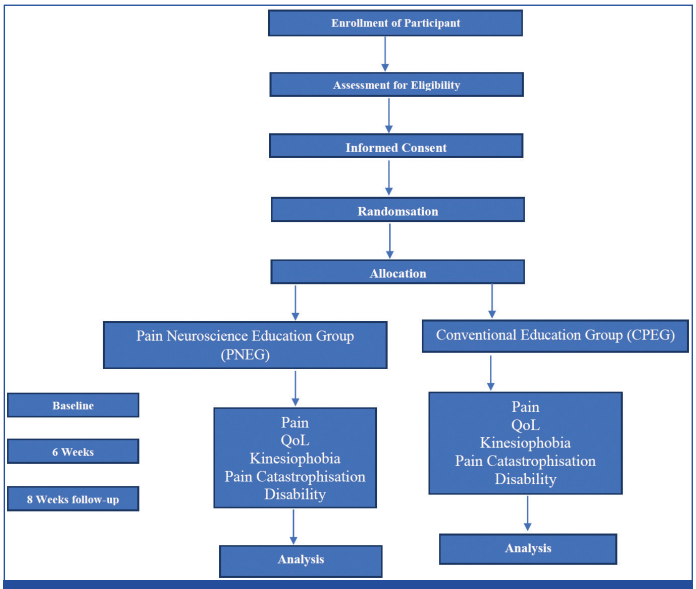
Sample size: The study's sample size was calculated using G*power software (version 3.1.9.4). A repeated measures Analysis of Variance (ANOVA) test was used to calculate the sample size, considering within-between group interactions and three time points. To detect a clinically significant difference of 1 mm in the VAS pain score, the minimum required sample size was estimated at 70, based on a pooled standard deviation of 2.4 units, 90% power, a 5% significance level, a 0.30 correlation between repeated measures, and a non-sphericity correction (ε) of 1, as reported by Jang YY et al., After accounting for a 10% dropout rate, the final sample size was adjusted to 78, rounded to 80 (40 participants per group) [27].

Inclusion criteria: A physical therapist will evaluate potential participants to determine their eligibility based on the following criteria: Participants of all genders aged ≥18 years, diagnosed with PSSP for ≥3 months, and having experienced chronic stroke for ≥6 months. Eligible participants must have had their first-ever unilateral ischaemic or haemorrhagic stroke, demonstrate adequate cognitive ability (MMSE score >24), have PSCSP with a VAS score >1 mm, and be at Brunnstrom recovery stages III to V. Those willing to sign the informed consent will be included in the study.

Exclusion criteria: Participants with history of shoulder pain, neck pain, or cervical radiculopathy in the affected shoulder prior to their stroke. Participants with a history of surgery in the neck or affected shoulder, impaired sensation, an inability to provide feedback on TENS intensity, a history of epilepsy or pacemaker use, acute or subacute strokes, severe language comprehension deficits, severe respiratory illnesses, cardiopulmonary issues, uncontrolled hypertension, or other medical conditions that significantly impact daily activities will also be excluded from the study.

Procedure

Participants will be recruited through flyers, from the medicine and neurology OPD and IPD, and from the physiotherapy OPD of a tertiary care hospital in Karnataka, India. Participants included in the study will undergo a baseline assessment before randomisation. Outcomes will be assessed at multiple time points: Baseline (0 weeks), six weeks, and eight weeks, as outlined in [Table/Fig-1]. Participants will be instructed to continue their home exercises for an additional two weeks after the six-week period. To ensure adherence, regular telephonic reminders will be administered, and only a follow-up assessment will be conducted at the eighth week to better understand the effects of the intervention over a longer period.



[Table/Fig-1]: Flow chart of recruitment/randomisation/assessment.

Primary Outcome Measures

The Visual Analogue Scale (VAS): Pain severity will be subjectively assessed, with scores ranging from 0 to 10, representing the least to the most severe pain presentation [28].

The Short-form 36-item health survey (SF-36): This scale will be utilised to assess quality of life. This instrument comprises eight domains and has been shown to have robust test-retest reliability (ICC >0.7) and validity (R ≥|0.40|) [29].

Tampa Scale of Kinesiophobia (TSK): This 17-item self-reported questionnaire will be employed to quantify fear of movement using a 4-point Likert scale. It demonstrates test-retest reliability (ICC=0.887) and validity (r(s)=0.33 to 0.59) [30].

The Pain Catastrophising Scale (PCS): This 13-item scale will be utilised and can be subdivided into three subscales. Each question is evaluated on a scale from 0 (not at all) to 4 (always). The PCS demonstrates strong total reliability (0.87-0.93) and validity (PCS partial r-value=0.56, p-value <0.001) [31].

Secondary Outcome Measure

The Shoulder Pain and Disability Index (SPADI): This instrument will be used to evaluate pain levels and the extent of difficulty in ADLs involving the upper extremities. The SPADI consists of 13 items, comprising an 8-item disability subscale and a 5-item pain subscale, with reliability coefficients of ICC ≥0.89 and good construct validity [32].

Random allocation: The study will employ a randomised allocation method to distribute participants evenly between two intervention groups. A computer-generated random number sequence will determine group assignments, ensuring unbiased placement. To maintain allocation concealment, randomisation codes will be sealed within consecutively numbered opaque envelopes. A therapist will allocate the participants by drawing the next consecutive envelope. A sticker containing the letter code "A" or "B" will be inside each envelope. After reading the sticker, it will be attached to the participant's file. Participants with the letter code "A" will be assigned to the PNE Group (PNEG) and those with the letter code "B" will be assigned to the CPE Group (CPEG).

Blinding: A therapist who is not involved in the research will serve as the outcome assessor for Group A (PNE) and Group B (CPE). Participants will be instructed to refrain from discussing any details about their treatment with the assessor to prevent unblinding of outcome assessments.

Data monitoring: An independent researcher will oversee the progress of data collection and ensure that safety protocols are followed. Data analysis will occur after the completion of recruitment and data collection, with no interim analyses planned.

Harms: The therapist will document all self-reported adverse effects and report them to the Institutional Ethics Committee. Furthermore, the use of ice packs or hot packs throughout the study will also be recorded.

Auditing: Every six months, an independent researcher will assess the study's progress, conducting audits to evaluate the quality and completeness of the data while confirming that all protocol procedures are being adhered to as planned.

Ethics: The Institutional Ethics Committee has granted approval for this protocol. Any changes to the protocol will be communicated by the lead author to both the Institutional Ethics Committee and the Clinical Trial Registry - India.

Dissemination policy: The findings of this study will be shared through journal publications and conference presentations. Data from the study will be made available upon reasonable request. Researchers who make significant contributions to the design, execution, interpretation, and reporting of the clinical trial will be acknowledged as authors in the final publication.

Interventions

The study will compare two pain management approaches: Group A will receive PNE, while Group B will undergo CPE. In addition, both groups will receive graded motor imagery, portable TENS, and task-specific exercises.

Group A: Pain Neuroscience Education Group (PNEG): The therapist will deliver the PNE intervention for the PNE group. To facilitate this, the therapist has undergone extensive training in Explain Pain through the Neuro Orthopaedic Institute (NOI) group (Adelaide, Australia) via online mode. The content of PNE will be explained in layman's terms (Kannada language), and the explanation will be individually tailored to the patient's needs. It will be delivered using audio-visual materials centred on oral explanations, stories, images, metaphors (in the regional language), videos, the Recognise app from NOI, flashcards, and a summarised PNE booklet handout, which will be distributed as reinforcement. The PNE will be delivered face-to-face at the OPD from the 1st week to the 6th week [Table/Fig-2].

Week	Session description
1st week	Assessing existing pain knowledge of the patient and faulty beliefs and maladaptive behaviour through interview method.
2nd week	Review of the first session and commencement of Pain Neuroscience Education (PNE) using audio-visual materials (oral explanation, stories, images, metaphors in regional language, video, NOI app, flashcards).
3rd week	Repetition of the review process from session 2 and continuation of individualised PNE using different delivery materials.
4th week	Focus on the review, progress of the patient and individualised PNE practice in the presence of the Physiotherapist.
5th week	Usual review and progress, maintaining individualised PNE with other GMI and task-specific exercises.
6th week	Review of the contents covered in the first four sessions, resolution of doubts, shared experiences and distribution of a complementary material booklet for participants.

[Table/Fig-2]: Weekly session plan for Pain Neuroscience Education Group (PNEG).

Group B: Conventional Patient Education Group (CPEG): The therapist will provide evidence-based physiotherapy education derived from recent clinical practice guidelines on PSCSP. The content of CPE will be explained in layman's terms (Kannada language), and the explanation will be individually tailored to the patient's needs. It will be delivered in the form of a CPE booklet handout, which will also be distributed as reinforcement. The CPE will be delivered at the OPD from the 1st week to the 6th week [Table/Fig-3].

Week	Session description
1st week	Positioning and managing the affected shoulder.
2nd week	Joint protection strategies.
3rd week	Exercise Education: Dos and Don'ts of exercises, precautions, potential harm and risk associated with exercises and education related to inactivity.
4th week	Positive reinforcement and reassurance, importance of task-specific exercises by therapist, education related to exercise and pain intensity.
5th week	Education related to home-based exercises, management of symptom provocation at home (ice, hot pack, rest).
6th week	Education on modifying activity during exercise and progression of exercise, self-management at home, lifestyle changes (avoiding painful and repetitive overhead movements in sport or work), positive reinforcement and reassurance.

[Table/Fig-3]: Weekly session plan for Conventional Patient Education Group (CPEG).

All sessions will last for 10 minutes, three days per week, totalling 18 sessions at the OPD. In the 7th and 8th weeks, non-face-to-face/home programme education will be provided by distributing booklets of the PNE and CPE materials to both groups.

Common Treatment for both the Groups

Transcutaneous Electrical Nerve Stimulation (TENS): The therapist will instruct the patient to adopt a reclined position that is conducive to comfort. Subsequently, the positioning of two rubber pads, each measuring 5×5 cm, will be undertaken around the identified painful region of the affected shoulder. The TENS machine, set to a frequency ranging from 50 to 100 Hz and a pulse width spanning 50 to 200 μs, will be applied for a standardised duration of 20 minutes per session. This will occur three sessions per week for six weeks, totalling 18 sessions at the OPD.

Graded motor imagery: The treatment protocol for graded motor imagery will be divided into six weeks at the OPD. Each session will be tailor-made depending on the participant's level of performance.

Step 1: Laterality training: In the first and second weeks, laterality training will aim to enhance the patient's cortical representation accuracy of the body. This will involve participants identifying right and left body parts depicted in various positions using either flashcards or a smartphone app, such as the Recognise app (NOI, Adelaide, Australia). The Recognise Shoulder app will be installed on an Android device for use during OPD sessions, while flashcards will be provided for home practice. The app tracks both accuracy and response times, allowing the therapist to tailor the difficulty of the images by altering their context and background. Participants will be encouraged to practise with 10 images, verbalising, "This is the left shoulder; this is the right shoulder."

Step 2: Imagined movements: In the third and fourth weeks, participants will be instructed to imagine moving the painful shoulder. This step, part of Moseley's graded motor imagery, prepares patients for physical movement. A picture depicting six distinct shoulder movements will be utilised for training during OPD sessions and at home. Participants will be instructed as follows: "Visualise your affected shoulder performing the movement shown in the picture without physically moving it. Imagine each movement twice, then repeat the entire sequence."

Step 3: Mirror therapy: During the fifth and sixth weeks, mirror therapy will be introduced, utilising a mirror to reflect the movement of the unaffected shoulder, creating the illusion of pain-free movement in the affected shoulder. Participants will observe the mirrored image of their unaffected shoulder while performing six specific movements previously practised during imagined movement training. They will complete five repetitions of each movement, resting for five minutes between sets, three times daily for three days a week over two weeks. Once participants can view the mirrored movements without discomfort, they will be guided to gradually perform the same movements with the affected shoulder simultaneously.

Both groups will undergo 18 sessions, each lasting five minutes, with rest time, three times a day for three days, during the two weeks of graded motor imagery, alongside patient education from the 1st to the 6th week. In the 7th and 8th weeks, both groups will continue designated home exercises for two weeks.

Task-specific exercise: A structured task-specific exercise regimen will be introduced during the 3rd and 4th weeks for both groups, comprising two specific tasks. Subsequently, in the following weeks (5th and 6th), two additional tasks will be systematically incorporated, taking into account the individual capacity of each participant. The implementation of these exercises will involve supervised sessions at the OPD for 12 sessions, three days per week, with five repetitions, three sets, lasting five minutes with rest time. Participants will continue their exercises at home on the remaining days. Throughout the 7th and 8th weeks, participants will exclusively engage in home-based task-specific exercises for two weeks. The designated task-specific exercises will include stacking cones, drinking water from a glass, wiping the table, folding towels, and stacking them. The gradual addition of tasks over the weeks is strategically planned to provide a progressive and individualised approach, optimising the efficacy of shoulder pain rehabilitation.

Monitoring compliance of the intervention: Adherence to both graded motor imagery, task-specific exercises, and reading the patient education booklet at home will be recorded through self-report in a diary (including date, time, sets, repetitions, and type of exercise). After the end of the 6th week, participants will be asked to continue the home exercises for another two weeks. To ensure adherence, regular telephonic reminders will be administered.

Data management: Information regarding participant recruitment, characteristics of those who complete or withdraw from the study, and outcome measures will be securely recorded. All data will be input into computer software (Excel™ Microsoft 365, US 2016) and reviewed weekly by other researchers for accuracy, using standard coding protocols to maintain participant confidentiality. Access to the database will be restricted solely to the researchers involved in the study.

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) version 24.0 will be employed for statistical analysis, adopting an intention-to-treat approach. Data normality will be evaluated, and the mean±SD, along with a 95% Confidence Interval (CI), will be calculated. A significance level of 0.05 will be utilised. For normally distributed data, one-way ANOVA followed by post hoc testing will be performed. To assess within-group and between-group interactions across three time points, repeated measures ANOVA will be used. Intergroup comparisons at baseline, six-week, and eight-week measurements will be conducted using either an independent t-test or a Mann-Whitney U test, while intragroup comparisons will employ a dependent t-test or a Wilcoxon signed-rank test, as appropriate.

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