15th Mar 2025

Study Protocol

Title:

Comparative Analysis of Different Physiotherapy Interventions on Craniovertebral Angle in Individuals with Myofascial Pain Syndrome and Radiculopathy: A Randomized Controlled Trial

METHODOLOGY

7.1 Study Design: This study will be a randomized controlled trial (RCT) with multiple treatment arms.

7.2 Sampling Technique: Convenient Non-Probability Sampling technique will be used to select the sample. Selected participants will be randomly assigned to any of the intervention groups.

7.3 Sample Size Calculation: Sample size of the study will be total 100 participants, divided into four groups. Each group will comprise of 25participants. It is calculated by G-Power 3.1 software, based on a medium effect size (f) of 0.25, alpha level of 0.05, power (1-β) of 80%, correlation ® of 0.5, four groups and a non-sphericity correlation (€) of 1.

7.4 Study Setting: Study will be conducted at Department of Rehabilitation at National Hospital, Bahawalpur, Punjab, Pakistan.

7.5 Sample Selection Procedure:

Sample will be selected according to following criteria:

7.5.1 Inclusion Criteria:

1. Age: Participants must be between 20 and 40 years old.
2. Gender: Both genders, Male and Female have equal chance of selection as participant in the study.
3. Diagnosis: Participants must have a confirmed diagnosis of myofascial pain syndrome (MPS), altered cervical posture, restricted range of motion of cervical spine due to muscular spasm etc, altered craniovertebral angle, pain in cervical region or upper extremity and/or radiculopathy by a qualified healthcare professional, based on standardized diagnostic criteria (e.g., clinical examination, imaging studies).
4. Severity: Participants should have mild to moderate symptoms of MPS and/or radiculopathy, as determined by the assessing healthcare provider.

5. Willingness to Participate: Participants must be willing and able to comply physically and mentally with the study procedures, including attending scheduled physiotherapy sessions and completing outcome assessments.

6. Informed Consent: Participants will have to provide written informed consent mendatorily to be selected as participant in the study after receiving detailed information about the study aims, procedures, potential risks, and benefits.

7.5.2 Exclusion Criteria:

1. Severe Comorbidities: Participants with severe comorbidities or medical conditions that may interfere with their ability to participate in the study or confound the interpretation of results will be excluded. C1, C2 compression… vertigo

2. Surgeries: Participants who have undergone surgeries in the cervical or head region in past will be excluded due to potential confounding effects on outcomes.

3. Pregnancy: Pregnant individuals will be excluded from the study due to the potential risks associated with certain physiotherapy modalities and the need for specialized considerations in this population.

4. Contraindications: Participants with contraindications to specific physiotherapy modalities included in the study protocol (e.g., contraindications to dry needling, electrotherapy) will be excluded to ensure participant safety.

5. Inability to Attend Sessions: Participants who are unable to attend scheduled physiotherapy sessions due to logistical constraints (e.g., transportation issues, scheduling conflicts) will be excluded.

6. Cognitive Impairment: Participants with significant cognitive impairment or communication difficulties that may impede their ability to understand and follow study instructions will be excluded.

7. Participation in Other Research: Participants who are currently participating in other research studies involving treatment interventions for MPS and/or radiculopathy will be excluded to avoid potential confounding effects on outcomes and treatment adherence.

8. Malignancies: participants suffering from any kind of malignancies will be excluded from the study.
9. Trauma: Participants having a history of trauma and fractures in head and neck region will also be excluded from the study.

These inclusion and exclusion criteria are designed to ensure the safety of participants, minimize confounding factors, and optimize the internal validity of the study results.

7.5.3 Randomization and Group Allocation:

- Participants meeting the inclusion criteria will be randomly assigned to one of the treatment groups using systematic allocation method (patients 1-4 will be allocated to each group with their respective numbers and the serial will be repeated accordingly).
- Allocation concealment will be ensured to prevent selection bias, with treatment assignments concealed from both participants and investigators until after enrollment.

7.6 Intervention and Group Allocation:

7.6.1 Group Allocation:

Participants will receive physiotherapy interventions based on their assigned treatment group.

1. **Group-A:** Dry Needling & Myofascial Release Group.
2. **Group-B:** Trigger Point Therapy and Stretching Group.
3. **Group-C:** Mobilization Grade-1 & Grade-2 And Cupping Therapy Group.
4. **Group-D:** (Control group) Electrotherapy (TENS, Ultrasound) with stretching and Range of Motion Exercises.

Intervention Duration: Interventions will be applied for four weeks.

Intervention Frequency: Frequency of interventions will be twice a week. Total 08 sessions will be applied to each participant at regular intervals as per standard clinical practice.

7.6.2 Intervention Procedures:

Dry Needling:

The patient will be lying prone; the sterile acupuncture needles of 0.25x25 mm (Hua Long) will be placed over the palpated trigger points at300 angle and pushed deeply into the taut bands/trigger points. We will make sure the trigger point is immobilised between the thumb and index finger. Considered suitable needle site is reproduction of pain or local twitch response. Left in situ for ten minutes, needles will be spun clockwise at the tenth minute and then left in situ for ten more minutes. The needles will be withdrawn after twenty minutes overall. We call this approach deep dry needling. (DDN) (Tasoglu O. et al, 2017) (Tekin L et al, 2013).

Trigger Point Therapy:

The subject will be in sitting position. Trigger points will be palpated by the expert physical therapist/healthcare provider in the upper trapezius region. The trigger point will be marked by marker. The trigger point will then be pressed with thumb by increasing pressure gradually until patient reports that pressure has been converted into pain. The subject will be instructed to indicate this by saying "Yes" when pressure sensation converts to pain. The examiner will then hold for 5seconds and will release the pressure. This procedure will be repeated 5-6times for each trigger point.

Stretching:

Passive static stretching of different neck muscle groups will be performed. The subject will be in supine lying position. Contralateral side flexion will be performed by the therapist to stretch upper trapezius on both sides, simultaneous ipsilateral flexion and rotation will be performed to stretch scalenes on both sides, flexion will be performed to stretch extensor muscles of neck. Similarly, extension will be performed to stretch flexors of neck. All above stretches will be held for 30 seconds and will be repeated for 4-5times with a gap of 10-15seconds between each stretch. Lastly, neck straightening exercises will be performed by retruding the head (chin tucks) to stretch suboccipital muscles, held for 3-5seconds and repeated for 4-5times with a gap of 10-15sconds (Hakkinen A et al, 2007).

Mobilization:

Maitland mobilization techniques will be used for this purpose. Patient will be in sitting position. Grade-I and Grade-II Maitland mobilizations will be applied at all the cervical joints

as well cervicothoracic junction. Frequency of mobilizations shall be 2-3 oscillations per minute for 3-4minutes (Shabbir M et al, 2021).

Cupping therapy:

On each day of the trial, the participants will experience dry cupping intervention with a negative pressure of 400 mmHg following their regular training. This intervention will last for up to 15 minutes each time, twice a week, with a minimum of two days between each session. When performing cupping therapy, there will be a total of six cups utilised, and each cup will be positioned at the upper, middle, and lower fibres of the trapezius muscles simultaneously on both sides. On the basis of the distribution map of common myofascial sites in the upper back, the position of the cups will be determined. (YC Cheu et al, 2020).

7.6.3 Variables:

- **Craniovertebral Angle (CV Angle)**
- **Pain**
- **Range of motion**
- **Balance**
- **Quality of life**

7.7 Outcome Measures:

Following outcome measures will be used to assess the effects of applied interventions:

Primary Outcome Measures:

1. **Craniovertebral (CV) Angle:** CV angle will be measured with digital photography and MicroDicom software.
2. **Pain:** Numeric Pain Rating Scale (NPRS) will be used for pain severity measurement.

Secondary Outcome Measures:

1. **Range of motion:** Range of motion of different joints will be measured by Goniometer.
2. **Balance:** Balance of participants will be measured by Y balance test.
3. **Quality of life:** Quality of life will be measured by SF-36 Questionnaire.

7.8 Data Collection Procedures:

Data will be collected at three levels during application of interventions as follows.

- **Pre-Intervention (Baseline):** Baseline assessments of all participants will be conducted before the interventions to establish initial measurements.
- Interventions will be implemented as per the assigned groups, ensuring consistency in treatment delivery and adherence to the defined protocols.
- **Mid-Intervention:** Assessment of all participants will be conducted at the end of 2nd week.
- **Post-Intervention:** Outcome data will be collected at the end of defined intervention duration i.e four weeks to assess the effects of implemented interventions.

7.8.1 Data Collection Tools and procedures:

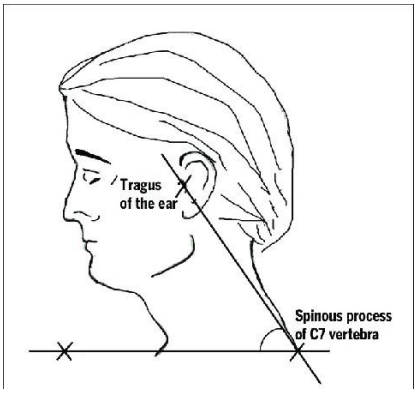
- Digital camera
- MicroDicom Software
- Tripod stand
- Numerical Pain Rating Scale (NPRS)
- CROM Deluxe
- Y Balance kit (safety belt use)

Craniovertebral Angle (CVA) Measurement:

CVA is defined as the angle formed between two reference lines: one passing via the centre of the tragus of ear to the tip of spinous process of seventh cervical vertebra (C7); other is the horizontal line passing from same point of spinous process of seventh cervical vertebra (C7). There are several tools and techniques at hand for CV angle measurement. Using Digital Photography and MicroDicom Software is one of the less expensive approaches of gauging this angle.

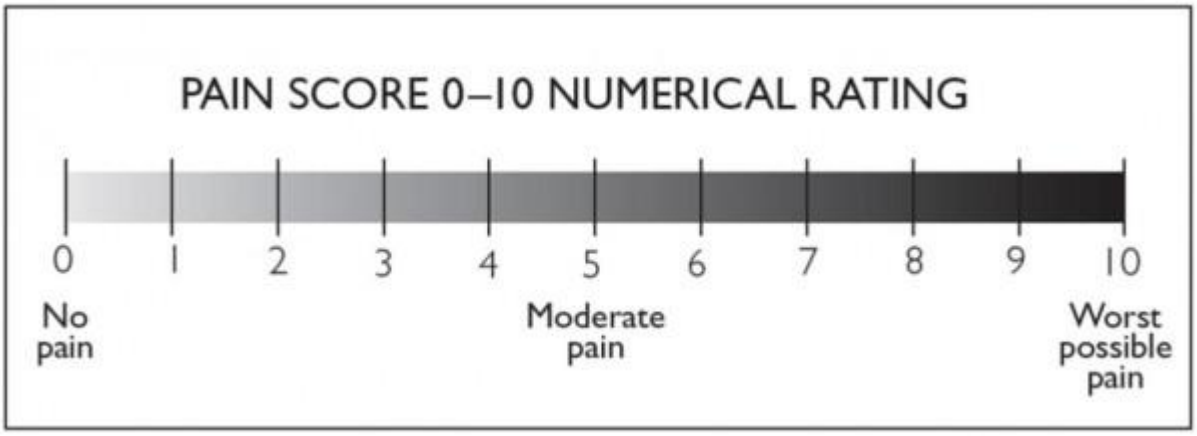
According to this method, measurements will be carried out in room with non-reflective background. The subject will be standing relaxed in a neutral posture in front of this non-reflecting background. Tip of C7 and tragus of ear will be marked by a reflective material to highlight the points for better clarity. External body landmarks will be palpated by atleast two experts before plotting the markers. 20MP Photography camera will be positioned on tripod stand such that upper level of tripod stand is at the level of shoulder point of subject and camera fixed on it. Distance of camera from the subject shall be 2.90meters. For assuring accuracy, points for feet of tripod as well as for the subjects will be marked from start of study till completion of data collection. Subject will stand relaxed at the marked area (with feet six inches apart) with arms on sides and relaxed.

Photograph(s) then will be taken with camera at zero zoom. The subject will be asked then to move around few steps, come back to the marked point again, attain the same posture and photograph(s) will be taken again. Procedure will be repeated three times for each subject. After that, photographs will be imported to computer and analyzed in MicroDicom Software. Average of three photographs will be taken as final value of CV angle. Normal value of CV angle is 48-50degrees. (Mazhar et al. 2021; Shinde et al. 2022)



Pain Measurement:

An outcome assessment with a uni-dimensional scale, the Numeric Pain Rating Scale (NPRS) gauges personal pain intensity. With "0" being the least degree of pain possible, the eleven-point numerical scale runs from "0" indicating one pain extreme—for example, "no pain"—to "10" representing the opposite pain extreme—for example, "pain as bad as you can imagine" or "worst pain imaginable". (Jensen MP, 1993, Rodriguez CS , 2001).



Range of Motion Measurement:

Range of motion of following neck movements will be measured:

- Cervical flexion (Normal range)
- Cervical extension
- Cervical rotation
- Cervical lateral flexion (left)
- Cervical lateral flexion (right)

For collection of range of all these movements, a standard instrument, CRom Deluxe, manufactured by Baseline, is a specially designed and standardized instrument for measuring cervical ranges of motion. Instrument will be worn by the subject, sitting comfortably in a chair. Ranges of all movements will be then be checked by asking the subject to perform each movement while therapist will be checking and recording values. Procedure will be repeated three times to have better accuracy. (Audette et al. 2010)

CROM

Balance Assessment:

Y balance test is a reliable and valid instrument for balance measurement. It is a very useful tool to assess dynamic balance in different subjects.

The Y Balance Test (YBT) is a dynamic balance assessment tool that evaluates an individual's balance and functional symmetry through reaching tasks. The participant stands on one leg (the stance leg) with the opposite leg positioned behind them, maintaining a slight bend in the knee and keeping their hands on their hips for balance. The test consists of three reach directions: anterior (forward), posteromedial (diagonal backward toward the stance leg), and posterolateral (diagonal backward away from the stance leg). For each direction, the participant leans while keeping the stance leg straight and touches the reach indicator with the toes of the opposite leg, performing three attempts per direction and recording the best distance reached. After completing the reaches on one leg, the participant switches to the opposite leg and repeats the procedure. The distances reached are measured and recorded, allowing for a composite score to be calculated by summing the best reach distances from each direction. This test helps identify balance capabilities and potential risks for injury by comparing scores between the two legs.

Quality of life assessment:

The status of one's general health can be determined by using the SF-36. Eight scaled scores are included; these scores are weighted sums of the questions that are included in each section. Scores range from 0 - 100 (McHorney CA,1994, Ware JE, 1993, Ware JE, 1992)

Sections:

1. Vitality
2. Physical functioning

3. Bodily pain
4. General health perceptions
5. Physical role functioning
6. Emotional role functioning
7. Social role functioning
8. Mental health

Lower scores = more disability, higher scores = less disability

7.10 Ethical Considerations:

- Intervention environment (lighting, cleanliness, comfortability, temperature control, waiting area) will be managed to be satisfactory, minimizing any distress to the participants during study.
- Any research study must justify the potential benefits of the study against the any possible harm/distress caused to the participant(s). This involves considering the scientific significance of the research, its potential impact on human health, and whether the benefits outweigh the ethical concerns raised.
- Prior to enrolment, an informed consent form that was self-designed will be utilised for all participants, and the protocol for the study will be evaluated and approved by the ethical committee of the institution.
- It is guaranteed that participants will be kept anonymous, and they will have the choice to withdraw from the study at any moment without incurring any penalty.
- Helsinki guidelines will be duly followed during conduction of study.
- Safety and well-being of participants will be given a top priority.
- Research study will adhere to obligation of accurately reporting findings of study, whether positive or negative, without manipulation or selective reporting.
- Study will adhere to principle of beneficence as well by ensuring that intervention programs and protocols are designed to provide potential health benefits to

participants. Participants should not be exposed to unnecessary risks. Protocols should be in accordance with the proper guidelines which must be followed during the conduction of study.

- Participants autonomy about taking his/her decisions about his/her health must be respected at all times.

7.11 Limitations:

1. Finding Target Population with Proper Diagnosis and Referral: Identifying a target population that meets specific diagnostic criteria can be challenging. This limitation arises from the need for accurate and consistent referrals from healthcare professionals. If the referral process is not standardized, it may lead to a sample that is not representative of the broader population. Additionally, variations in diagnostic practices among different healthcare providers can result in discrepancies in the population selected for the study. This inconsistency can affect the generalizability of your findings, as the sample may not accurately reflect the characteristics of the larger population you aim to study.

2. Finding Equal Samples from Both Genders: Achieving gender balance in your sample is crucial for ensuring that your findings are applicable to both males and females. However, this can be difficult due to inherent biases in the population or the nature of the condition being studied. For instance, if the condition is more prevalent in one gender, it may be challenging to recruit an equal number of participants. This limitation can lead to skewed results and may affect the interpretation of how the condition impacts different genders. Furthermore, if the sample is not balanced, it could limit the ability to draw meaningful comparisons between genders, thereby affecting the overall conclusions of your research.

3. Getting Permission to Take Body Images for Calculating the Required Angle: Obtaining consent for taking body images can pose ethical and logistical challenges. Participants may have concerns about privacy, body image, and the potential misuse of their images, which can lead to reluctance in providing consent. This limitation can result in a smaller sample size or a biased sample if only those who are comfortable with body imaging agree to participate. Additionally, the process of obtaining permission can be time-consuming, potentially delaying the research

timeline. If the sample is limited to those who consent, it may not adequately represent the broader population, thus affecting the validity of the results.

4. Resource limitations: Resource limitations, such as funding and proper staffing, may undermine the ability to follow guidelines fully and provide a comprehensive medical supervisory approach and support.

5. Generalizability: Study findings can be confidently applied to limited geographic area where study is being performed, sample not being homogenized for a bigger geographic territory which may affect the generalizability of the study.

8. GANTT CHA

Gantt Chart for Research Progress of PhD in Health Sciences (Pysical Therapy)

Title: Comparative Analysis of Different Physiotherapy Interventions on Cranioverterbral Angle in Individuals with Myofascial Pain Syndrome and Cervical Radiculopathy: A Randomized Controlled Trial

Researcher Name: Dr. Nasir Mehmood, PT | University: Lincoln University | Student ID: 131221122225

Project Start Date: 1st March 2024

Project End Date: 31st June 2025

WBS	Task	Start	End	Duration	% Done
1	**Proposal**				
1.1	Literature search for Available Study Gap	1st Mar-24	31st May-24	90Days	100
1.2	Idea & Title Generation	1st Jun-24	30th Jun-24	30Days	100
1.3	Writing Proposal and Submitting	16th Jun-24	31st Jul-24	45Days	100
2	**Research Conduction**				
2.1	Research Work	1st Aug-24	15th Sep-24	45Days	0
2.2	1st Progress Report	16th Sep-24	30th Sep-24	15Days	0
2.3	Research Work	1st Oct-24	15th Nov-24	45Days	0
2.4	2nd Progress Report	16th Nov-24	31st Nov-24	15Days	0
2.5	Research Work	1st Dec-24	15th Jan-25	45Days	0
2.6	3rd Progress Report	16th Jan-25	31st Jan-25	15Days	0
2.7	Research Work	1st Feb-25	15th Mar-25	45Days	0
2.8	4th Progress Report	16th Mar-25	31st Mar-25	15Days	0
2.9	Writing Thesis	1st Apr-25	15th May-25	45Days	0
2.10	Submission of Thesis	16th May-25	15th Jun-25	30Days	0