Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Gong’s Mobilization Vs Mulligan Mobilization on Pain, Proprioception and Sleep Quality In Adhesive Capsulitis Patients

Protocol summary

Study aim

To find out and compare the effect gong’s mobilization and mulligan mobilization on pain of adhesive Capsulitis patients. To find out and compare the effect of gong’s mobilization and mulligan mobilization on proprioception of Adhesive Capsulitis patient. To find out and compare the effect of gong’s mobilization and mulligan mobilization on sleep quality of Adhesive Capsulitis patient

Design

The study was a single blinded randomized clinical trail

Settings and conduct

The study was conducted in Benazir Bhutto hospital, randomly allocated 15 patients to Group A and 15 patients to Group B through sealed envelope method, to ensure fairness and randomness

Participants/Inclusion and exclusion criteria

Inclusion Criteria Both male and female patients with age between 40-65 years. Patients with unilateral Adhesive Capsulitis. History of Shoulder joint pain and shoulder stiffness for more than 3 months Person with bad sleep quality, and diagnosed with ≥5 score in PSQI. Person with Abduction ≥ 50º 3.3.2. Exclusion Criteria Participants failing to fell in this category were excluded from the study. Participants with history of shoulder surgery Post traumatic shoulder pain & stiffness Recent History of fracture Diagnosed instability and history of dislocation Congenital abnormalities of Shoulder Systemic inflammatory conditions (RA)

Intervention groups

The subjects were randomized into two groups with equal participants in each group. Each group was assessed at baseline and after 2 weeks (6 sessions per week) of intervention which included pain through VAS, proprioception through laser pointer angle reproduction test and sleep quality through Pittsburg Sleep Index. Experimental group 1 received Gong’s mobilization and experimental group 2 received Mulligan mobilization.

Main outcome variables

VAS Laser-Pointer Assisted Angle Reproduction Test (LP-ART) for proprioception Pittsburgh sleep index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250207064675N1**
Registration date: **2025-02-19, 1403/12/01**
Registration timing: **retrospective**

Last update: **2025-02-19, 1403/12/01**
Update count: **0**

Registration date

2025-02-19, 1403/12/01

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-05, 1402/07/13

Expected recruitment end date

2024-04-15, 1403/01/27

Actual recruitment start date

2023-10-10, 1402/07/18

Actual recruitment end date

2024-04-20, 1403/02/01

Trial completion date

2024-04-25, 1403/02/06

Scientific title

Effects of Gong’s Mobilization Vs Mulligan Mobilization on Pain, Proprioception and Sleep Quality In Adhesive Capsulitis Patients

Public title

Effects of Gong’s Mobilization Vs Mulligan Mobilization on Pain, Proprioception and Sleep Quality In Adhesive Capsulitis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with unilateral Adhesive Capsulitis History of Shoulder joint pain and shoulder stiffness for more than 3 months Person with bad sleep quality, and diagnosed with ≥5 score in PSQI Person with Abduction ≥ 50º

Exclusion criteria:

Participants with history of shoulder surgery Post traumatic shoulder pain & stiffness Recent History of fracture Diagnosed instability and history of dislocation Congenital abnormalities of Shoulder Systemic inflammatory conditions (RA)

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Methodology In this study, simple randomization was used to allocate participants into two intervention groups: Gong Mobilization and Mulligan Mobilization. Simple randomization ensures that each participant has an equal chance of being assigned to either group, reducing selection bias. Unit of Randomization The individual was used as the unit of randomization. Each participant was independently randomized into one of the two intervention groups, ensuring that treatment allocation was not influenced by external factors such as therapist preference or participant characteristics. Randomization Strata in Stratified Randomization Stratification was not used in this study. However, in future studies, stratified randomization could be applied to ensure balance among important variables such as age, gender, and severity of adhesive capsulitis. Tools Used for Randomization The randomization process was conducted using the sealed envelope method, a widely accepted technique for ensuring allocation concealment. A total of 30 sealed envelopes were prepared, with 15 assigned to the Gong Mobilization group and 15 to the Mulligan Mobilization group. Each envelope contained a card labeled with one of the two interventions. The envelopes were identical in appearance, shuffled, and drawn by participants to determine their group assignment. Construction of the Random Sequence A computer-generated random sequence was used to determine the group assignments before placing them into the sealed envelopes. The sequence was generated using Microsoft Excel’s RAND function to ensure an unbiased allocation process. The sequence was then printed and enclosed in the sealed envelopes to maintain allocation concealment. Allocation Concealment Allocation concealment was ensured in this study to prevent selection bias. The sealed envelope method was used, ensuring that neither the participants nor the principal investigator knew the group assignments in advance. The envelopes were only opened after the participant provided informed consent, ensuring an unbiased allocation process. By implementing this method of randomization, the study minimized selection bias and maintained the integrity of the intervention comparisons.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding Methodology Blinding was implemented in this study to minimize bias and improve the reliability of results. While a full double- or triple-blind design was not feasible due to the nature of physiotherapy interventions, the following groups were blinded to various extents: 1. Participants Participants in this study were not blinded to their intervention group, as they were actively engaged in the Gong Mobilization or Mulligan Mobilization treatment sessions. Given the hands-on nature of the interventions, it was not possible to conceal the treatment they received. However, participants were not informed of the specific hypothesis regarding which intervention was expected to be more effective. 2. Principal Investigator The principal investigator, who also supervised the study, was not blinded, as they were involved in the randomization process and oversight of treatment administration. However, to minimize bias, the principal investigator did not participate in data collection or outcome assessment. 3. Healthcare Providers (Physiotherapists Administering the Intervention) The physiotherapists who administered the interventions were not blinded, as they needed to apply the respective mobilization techniques according to protocol. However, they were instructed to follow standardized treatment procedures and not discuss expected outcomes with participants. 4. Data Collectors Blinding was ensured for data collectors. They were not aware of the participants' group allocation when recording data. The assessments of pain (VAS), sleep quality (PSQI), and proprioception (LP-ART) were conducted using standardized measurement tools, reducing subjective bias in data collection. 5. Outcome Assessors The outcome assessors were blinded to group allocation. To achieve this, participants were instructed

not to disclose their treatment details during assessments. Additionally, data were recorded in a way that did not indicate the intervention group, ensuring that assessors remained unbiased when analyzing the results. 6. Data Safety and Monitoring Board (DSMB) This study did not involve a formal Data Safety and Monitoring Board (DSMB), as it was a short-term, non-pharmacological intervention with a low risk of adverse effects. However, ethical oversight was maintained by the Institutional Review Board (IRB). 7. Manuscript Writers The individuals involved in manuscript writing were partially blinded during the initial data analysis. The dataset used for statistical analysis was coded to obscure the intervention groups, ensuring that data interpretation remained objective until final results were compiled.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Riphah College of Rehabilitation Sciences, Riphah International University Islamabad EMAIL: waqar.ah

Street address

Gulberg Green Campus D Block Gulberg Express way

City

Islamabad

Postal code

32034

Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

Riphah/RCRAHS-ISB/REC/MS-PT/01799

Health conditions studied

1

Description of health condition studied

Adhesive Capsulitis is a disorder affecting the muscles and soft tissues of the shoulder progressively limiting the range of motion in both passive and active, stiffness, and pain which is present in night and daytime in glenohumeral joint.

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Visual Analog Scale Pain

Timepoint

Each group was assessed at baseline and after 2 weeks (6 sessions per week) of intervention which included pain through VAS.

Method of measurement

VAS is described as a 10-cm line. No pain at left end of line and the worst conceivable pain at right end of the line. Patient is asked to mark at 10 cm line to inform pain magnitude. Visual Analog Scale is an extremely reliable and synchronously valid pain measurement tool.

2

Description

Laser-Pointer Assisted Angle Reproduction Test (LP-ART) Proprioception

Timepoint

Each group was assessed at baseline and after 2 weeks (6 sessions per week) of intervention which included proprioception through laser pointer angle reproduction test.

Method of measurement

The person being tested was standing at a dotted line on the floor that was drawn parallel and one hundred CM distance to a target board fixed on the opposite wall. The target board was adjusted in height to the subject so that point zero could be aligned individually with the glenohumeral joint of every subject. A standardized coordinate system drawn on the target board with successive 4cmmarkings up to a distance of 22 cm. A laser pointer was be fixed at the back side of the patient’s wrist with a strap. The test subject was asked to raise their affected arm from hanging (neutral) position to aim for assigned points at 55°,90° and 125°. The90°position was defined as zero point. The patient was required to memorize the different joint positions at different degrees. In the next step, the patient’s eyes was blind folded to inhibit visual control. Then they were asked to reproduce the same joint positions as before in a randomized order. The coordinated distance of the position where the laser pointer finally comes to rest was marked, documented by an independent checker, without telling the subject. This procedure was repeated 3 times for flexion and abduction respectively. The deviations of the given angles (55°,90°, 125°) was measured on the x- and y-axis in CM.

3

Description

Pittsburgh sleep index

Timepoint

Each group was assessed at baseline and after 2 weeks (6 sessions per week) of intervention which included sleep quality through Pittsburg Sleep Index

Method of measurement

Sleep quality was assessed by PSQI tool, an instrument with known validity and reliability . The PSQI tool consists of 19 self-reporting questions, each having an ordinal

grading scale ranging from 0 to 3, where 0 represents no current issues and 3reflects the most negative quality of sleep. These 19 questions are further divided into7 subjective sub-categories that include sleep quality, sleep duration, sleep latency, sleep disturbance, habitual sleep efficiency, use of sleep-inducing medications, and daytime dysfunction. The 7 subcategories are then summed up to yield a global PSQI score, which has a range of 0 to 21, with higher scores indicative of poorer sleep quality. This sleep index tool (PSQI) has satisfactory internal consistency with a Cronbach reliability coefficient of 0.83 and has been validated in multiple languages. A global sum of 5 or greater indicates a poor sleeper based on a sensitivity of 0.90, specificity of 0.87 with a k value of 0.75 in distinguishing sleep quality

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Gong's Mobilization
Category
Rehabilitation

2

Description
Intervention group: Mulligan Mobilization
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation Department of Benazir Bhutto Hospital, Rawalpindi
Full name of responsible person
Dr.Rab Nawaz Khan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Riphah International University Islamabad
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
More work will be done on the data for further studies and analysis will be performed which is very confidential.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Study Protocol will be shared.

When the data will become available and for how long
Data will be available from August 2025 for a year

To whom data/document is available
Any researcher doing work on same disease or condition with same variables.

Under which criteria data/document could be used
Under auth data will be provided for confidential use.

From where data/document is obtainable
Principle Investigator Muhammad Zeshan ptzeshankhan@gmail.com

What processes are involved for a request to access data/document
7 working days will be needed to access data

Comments