

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative effects of Semont Liberatory Maneuver Versus Cawthorne Cooksey Exercise in posterior canal benign paroxysmal positional vertigo (BPPV)

#### Protocol summary

##### Study aim

To determine the comparative effects of semont liberatory maneuver and Cawthorne Cooksey exercises in patients with posterior semicircular canal BPPV To estimate the effectiveness of both the treatments To evaluate the improvement in patient's symptoms

##### Design

Pragmatic, parallel group, single blinded, randomised controlled trial

##### Settings and conduct

Allied Hospital Faisalabad National Hospital Faisalabad

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Gender female 2. Willing participants 3. Age 25-45 years 4. Acute cases of BPPV 5. Participants physically capable of undergoing the Semont maneuver. 6. Positive Dix-Hallpike test 7. Absence of other vestibular disorders Exclusion Criteria 1. Patients with progressive vascular pathology 2. Patients with active vertigo complaints were excluded 3. Patients having neck fragility or neck instability 4. Patients who had some brainstem or cerebellar signs. 5. Mentally unstable patients 6. patients with cognitive and perceptual problems

##### Intervention groups

Intervention Group A Group A will receive Semont liberatory maneuver. Group B Group B will receive Cawthorne Cooksey Exercises. Both groups will receive intervention 3 times per week for 3 weeks. Pre readings will be calculated before the start of intervention. 1st reading post treatment will be taken after 2 weeks, 2nd reading post treatment will be taken after 3rd week.

##### Main outcome variables

Dizziness Visual analogue scale (VAS) Dizziness handicap inventory (DHI)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240315061294N1**

Registration date: **2024-05-31, 1403/03/11**

Registration timing: **retrospective**

Last update: **2024-05-31, 1403/03/11**

Update count: **0**

##### Registration date

2024-05-31, 1403/03/11

##### Registrant information

##### Name

Ruhma Tariq

##### Name of organization / entity

The university of Faisalabad

##### Country

Pakistan

##### Phone

+92 323 6617619

##### Email address

2022-ms-pt-017@tuf.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-20, 1402/09/29

##### Expected recruitment end date

2024-05-20, 1403/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparative effects of Semont Liberatory Maneuver Versus Cawthorne Cooksey Exercise in posterior canal benign paroxysmal positional vertigo (BPPV)

### Public title

Effects of Semont Liberatory Maneuver Versus Cawthorne Cooksey Exercise in posterior canal benign paroxysmal positional vertigo (BPPV)

### Purpose

Health service research

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Gender female Willing participants Age 25-45 years Acute cases of BPPV Participants physically capable of undergoing the Semont maneuver Positive Dix-Hallpike test Absence of other vestibular disorders

#### Exclusion criteria:

Patients with progressive vascular pathology Patients with active vertigo complaints Patients having neck fragility or neck instability Patients who had some brainstem or cerebellar signs Mentally unstable patients Patients with cognitive and perceptual problems

### Age

From **25 years** old to **45 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **28**

### Randomization (investigator's opinion)

Randomized

### Randomization description

method of randomization is simple random sampling. 1- population was selected i.e. females of age 25-45 2- sample size of 28 was taken 3- two groups were made 4- each group was assigned to have 14 patients 5- We used "Drawing Lots" as a method to select and allocate population into groups. 6- we gave group A semont liberatory maneuver 7- and group B the Cawthorne cooksey exercises 8- then collected data for 3 weeks from both the groups 9- we then analyzed the data using SPSS

### Blinding (investigator's opinion)

Single blinded

### Blinding description

The primary aim of a single-blinded study is to reduce or eliminate the placebo effect and other forms of bias that might affect the participants' behavior or self-reported outcomes. By blinding the participants, researchers can obtain more accurate and objective data regarding the efficacy and safety of the intervention being tested. Develop a Protocol: Created a detailed study plan, including the hypothesis, inclusion/exclusion criteria, intervention details, and outcome measures. Recruit Participants: Selected a sample that meets the study

criteria. Randomize Participants: Randomly assigned participants to be in any of the group. Implement Blinding: Ensured participants do not know which group they are in. This may involve using identical-looking placebos for the control group. Administer the Intervention: Provide the treatment or placebo to the respective groups according to the study protocol. Collect Data: Gathered data on the outcomes of interest while maintaining blinding. Analyze Results: Compared the outcomes between the treatment and control groups using appropriate statistical methods. Report Findings: Present the results, discussing the implications, limitations, and potential biases.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research and Ethics Committee of the University of Faisalabad

##### Street address

university avenue faisal town canal road faisalabad

##### City

Faisalabad

##### Postal code

38000

#### Approval date

2024-01-05, 1402/10/15

#### Ethics committee reference number

TUF/addl Reg/SB /761

## Health conditions studied

### 1

#### Description of health condition studied

Benign paroxysmal positional vertigo (BPPV) is one of the most common causes of vertigo — the sudden sensation that you're spinning or that the inside of your head is spinning. BPPV causes brief episodes of mild to intense dizziness. It is usually triggered by specific changes in your head's position.

#### ICD-10 code

H81.1

#### ICD-10 code description

Benign paroxysmal vertigo

## Primary outcomes

## 1

### **Description**

This study will help to improve the different aspects of patients' problems with posterior canal benign paroxysmal positional vertigo (BPPV) as this is one of the most common problems now a days. It will improve the understanding of clinicians about two major techniques of treating BPPV. It will improve the quality of life of patients and their attendants.

### **Timepoint**

Before intervention and 1,2,3 weeks after intervention

### **Method of measurement**

VAS for vertigo and Dizziness questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: receives semont liberatory maneuver The Semont Liberatory Maneuver is a physical therapy technique used to treat Benign Paroxysmal Positional Vertigo (BPPV), particularly when it affects the posterior semicircular canal of the inner ear. Here is a summary of how to perform the maneuver The Semont Maneuver aims to move the dislodged otoliths (calcium carbonate crystals) in the inner ear back to their correct position, alleviating the vertigo symptoms associated with BPPV. Starting Position: The patient sits on an examination table with their legs hanging off the side and head turned 45 degrees toward the unaffected side. First Movement: Quickly move the patient to a lying position on their affected side (the side experiencing vertigo), with the head still turned 45 degrees. The patient's head should now be facing upward. Maintain this position for about 30 seconds or until the vertigo stops. Second Movement: Without changing the head position, rapidly move the patient to the opposite side. The patient's head will now be turned 45 degrees downward, lying on the unaffected side. Hold this position for about 30 seconds or until the vertigo subsides. Returning to Sitting Position: Slowly bring the patient back to a sitting position, keeping the head turned toward the unaffected side.

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group 2: receives cawthorne cooksey exercise The primary goal of Cawthorne-Cooksey exercises is to facilitate vestibular compensation, which involves retraining the brain to adapt to changes in balance and spatial orientation signals caused by inner ear problems. The exercises are typically performed in progressive stages, starting with simple movements and gradually advancing to more complex tasks. Here's a

summary of the typical exercises included: Early Stage Exercises (Performed while sitting or lying down) Eye Movements: Look up and down, then left and right, keeping the head still. Gradually increase speed. Head Movements: Turn the head from side to side, then up and down, initially with eyes open and then with eyes closed. Shrugging and Circling Shoulders: Perform shoulder shrugging and shoulder circling exercises to enhance coordination and reduce neck tension. Intermediate Stage Exercises (Performed while sitting) Sitting and Standing Movements: Sit down and stand up repeatedly, first with eyes open and then with eyes closed. Throwing and Catching: Throw a small ball from hand to hand above eye level. Advanced Stage Exercises (Performed while standing and walking) Standing Balance: Stand with feet together, then progress to standing on one foot. Repeat with eyes open and then closed. Walking Exercises: Walk across the room with eyes open, then closed. Walk up and down a slope or stairs. Walk in a circle or figure-eight pattern.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

National Hospital Faisalabad and Allied hospital faisalabad

##### **Full name of responsible person**

Dr. Anbreena Rasool

##### **Street address**

university avenue faisal town canal road faisalabad

##### **City**

Faisalabad

##### **Postal code**

38000

##### **Phone**

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info@tuf.edu.pk

##### **Web page address**

<https://tuf.edu.pk/n/contact>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

the university of Faisalabad

##### **Full name of responsible person**

Dr. Anbreena Rasool

##### **Street address**

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**Email**

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**Web page address**

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

the university of faisalabad

**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**

Persons

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Phyesthetic Clinic

**Full name of responsible person**

Dr. Ruhma Tariq

**Position**

Consultant physiotherapist

**Latest degree**

Specialist

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**Province**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Phyesthetic Clinic Faisalabad

**Full name of responsible person**

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**Position**

specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

physthatic clinic faisalabad

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**Position**

specialist

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

comparative effects of semont liberatory maneuver and cawthorne cooksey exercises in posterior canal bppv

**When the data will become available and for how long**

starting 6 months after publication . and it will remain available for everyone

**To whom data/document is available**

this will be available for everyone

**Under which criteria data/document could be used**

drruhmatariq@gmail.com contact # 03236617619

**From where data/document is obtainable**

ruhma19@yahoo.com contact #: 03236617619

**What processes are involved for a request to access data/document**

for any problem contact for data/file at

ruhma19@gmail.com or contact at 03236617619

**Comments**