



A Research Protocol to Evaluate the Efficacy of Powerball versus Mulligan Mobilization with Movement on Pain and Function in Patients with Lateral Epicondylitis

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Authors' contributions

This work was carried out in collaboration between both authors. The study's design was recommended by author SU. The study was created and designed by authors SU and PP. This article's draft was written by author SU. The final text was examined and authorized for publication by authors SU and PP. Both authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i45B32831

Editor(s):

(1) Dr. Francisco Cruz-Sosa, Metropolitan Autonomous University, México.

Reviewers:

(1) Yenew Alemu Mihret, Injibara University, Ethiopia.

(2) Sabah Abdellatif Hussein Ali Beza, Cairo University, Egypt.

Complete Peer review History: <https://www.sdiarticle4.com/review-history/74474>

Study Protocol

Received 28 July 2021
Accepted 04 October 2021
Published 09 October 2021

ABSTRACT

Background: Amongst the most frequently repeated stress conditions within the elbow joint includes lateral epicondylitis (LE). The extensor carpi radialis brevis muscle attachment is affected mostly. The management of an individual with LE that manifests itself in repetitive upper extremity motions is the purpose of this research. There seems to be no study on the effects of PowerBall device training on the pain and function in individuals with Lateral Epicondylitis. "PowerBall device" practice is a type of strength training.

Methods / Design: After conducting initial evaluations and allocation, the subjects (n=50) with LE will be involved in a randomized controlled study and classified either in an intervention group or a conventional group. The intervention group will do "PowerBall device" exercises, while others in the control group, doing MMWM. These groups will receive basic movements and ultrasound in accordance with the procedures.

Discussion: The PRTEE scale measured the intervention's impact on pain and function in patients with LE, and a Hand-held Dynamometer was utilized to quantify grip strength. The findings will give considerable support for the use of the "PowerBall device" exercise and MMWM on LE patients.

Conclusion: Conclusion will be drawn post study so as to see whether PowerBall device is more helpful or Mulligan Mobilization with Movement on pain and function in patients with LE. This study will give better approach to the therapist in managing the condition.

Keywords: "PowerBall device"; MMWM; LE; extensor carpi radialis brevis muscle; pain & function; grip strength.

ABBREVIATIONS

MMWM : Mulligan mobilization with movement
LE : Lateral Epicondylitis
PRTEE: Patient Rated Tennis Elbow Evaluation
RCT : Randomised Control Trial
QOL : Quality Of Life
AVBRH: Acharya Vinobha Bhawe Rural Hospital
OPD : Out-patient Department
IPD : In-patient Department

1. INTRODUCTION

Amongst the most common arm lesions is Lateral Epicondylitis (LE), also known as Lateral Elbow Tendinopathy (LET) or Tennis Elbow [1]. Morris was the only one to coin the term "lawn tennis arm" in 1882 [2]. The word tendinopathy refers to a collection of pathologies, comprising recurrent overuse tendon conditions. This condition can affect the extensor tendons mostly on lateral side of the forearm which is most common in middle-aged people, with a highest incidence of 40 to 60 years [3].

It's usually a job or sports-related ailment characterized by extended, consistent, repetitive eccentric contractions and wrist grasping. In the normal community, a reported incidence of 1-3 percent is found, with the dominant arm being the most commonly afflicted [4]. Whereas the name "tennis elbow" is misleading as tennis players account for just 5 to 10% of cases, racket sports involvement raises the risk of this issue and therefore can trigger it in 40 to 50% of athletes [5].

Both men and women have similar rates of incidence. Approximately 75% of the people is afflicted in their dominant arms, according to studies. Diagnostically and therapeutically, the extensor carpi radialis brevis muscle with episodic participation of the extensor digitorum communis, extensor carpi radialis longus, and extensor carpi ulnaris muscles is perhaps the most commonly pulled in muscle [6].

Frequent upper - limb activities, such as computer use, dominant forearm pronation and supination, lifting heavy, and repeated vibration, are perhaps the most common causes in men and women [7]. Since this upper limb relies on peripheral muscles, ligaments, and capsules to direct action, it is frequently seen [8]. Despite its name, commonly found in sports such as badminton, swimming, squash, baseball, and throwing activities.

Although the typical presentation of LE are obvious and simple to identify, no optimum treatment has yet been discovered. According to evidence, corticosteroid injections are associated with lower results in the intermediate and long-term compared to controls [9]. Several more practitioners recommend for a conservative approach as the possible treatment for LE. Physiotherapy is a conservative treatment option for those who have LE. The exercise regimen for LE is the most common physical therapy rehabilitation. In general, an exercise program consists of exercises conducted in a therapy room as well as activities completed at home [10].

There is a higher frequency among individuals engaged in high-risk sectors involving loading, frequent gripping, and/or wrist extension activities, as well as racquet sports participants [11]. Extreme loading hastens the transition from healthy tendons to degenerative tendinosis, irrespective of individual risk factors including age, occupation, hobbies, or previous injury [12].

In addition, the impact of resistance training on increasing shoulder and elbow muscular strength is being investigated, although eccentric exercises have previously demonstrated some relief in the symptoms of tennis elbow [13]. Recent research has discovered that vibrating instruments (PowerBall device) had a greater influence on muscular strength, pain, ROM, and health quality in patients with tennis elbow injuries than dumbbell exercise [14]. Throughout

the chronic stage, using a "PowerBall device" to impart extrinsic and intrinsic strain to the wrist, elbow, and shoulder muscles is believed beneficial resistance training [6].

According to research, using the "PowerBall gadget" resulted in enhanced power. Despite the fact that using a dynamic PowerBall has been demonstrated to enhance strength, function, range of motion, tennis elbow discomfort, and quality of life in overhead sportsmen, the majority of frequent concerns have yet to be validated [15].

Mulligan Mobilisation with movement (MMWM) is a kind of manual treatment that integrates continuous lateral glide with physiological elbow mobility [16]. MMWM concentrates on mobilizing the joint during physiological movements, as compared to conventional mobilisation approaches that concentrate on mobilisation in a static posture. According to studies, MMWM is effective in reducing pain and improving the functional capacity of elbow joints in LE patients [17].

1.1 Aim

The purpose of this research is to see how the PowerBall Device, when compared to Mulligan Mobilisation with Movement, affects pain and function in patients with Lateral Epicondylitis.

2. METHODOLOGY

2.1 Study Setting

Trial will be carried out in Ravi Nair Physiotherapy College, Musculoskeletal OPD, AVBRH Sawangi, Meghe, Wardha.

2.2 Study Design and Sample Size

The study design for patients who have been diagnosed with Lateral Epicondylitis is a single-blinded RCT method. The total number of subjects in this experimental study is 50 (n=50). For three weeks, the participants would be randomly assigned to one of the two groups: an experimental group (Group A) and a conventional group (Group B). Goals and methods of the study will be informed to the Participants before being accepted, and written patient consent form will be signed by them.

2.3 Participants

2.3.1 Inclusion criteria are as follows:

1. All subjects having symptoms for more than 2 weeks

2. Between the ages of 20 and 50
3. Pain present on elbow's lateral side
4. Tenderness persists on palpation over the forearm extensor carpi radialis tendon.
5. Diagnosis confirmed on the basis of physical test (Cozens Test, Mill's Test, Maudsley's Test)

2.3.2 Exclusion criteria are as follows:

1. Fractures present around elbow
2. Any old surgical history around elbow
3. Any previous pathology of bone around elbow.
4. Absence of clinical signs of tennis elbow.
5. Any underlying deformities (Increased carrying angle/ hyperextended elbow)
6. Steroid injection taken recently for LE within 3 months.
7. Any history of acute trauma
8. Having neurological involvement.
9. Any other systemic illness like metabolic, metastatic, infective disorders.

2.4 Recruitment

The orthopaedician working under AVBRH (DMIMSU) are invited to refer the prospective patients to our in-patient department (IPD). Patients having Lateral Epicondylitis that are currently undergoing physiotherapy in the IPD will be carefully screened for research criteria. Once the study's eligibility requirements are fulfilled, the participants are randomly assigned to one of two groups. Approval from patients will indeed be accumulated before the allocation and after elaborating the purpose, nature, procedure, prospective benefits and aftereffects of the intervention.

2.5 Procedure

2.5.1 Participant Timeline

Study duration is of 1 year and intervention duration is of 3 weeks so participants will be enrolled and three weeks of intervention will be completed successfully. Assessment will be done on 1st day of the visit and on the 21st day i.e. completion or at the end of the intervention.

2.5.2 Implementation

Randomization will be supervised by the research coordinator and principal investigators. Participants will be asked to hand-pick a sealed

group allocation for the recruitment into either group from the envelope.

2.5.3 Blinding

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

3. STUDY PROCEDURE

The individuals, divided in two groups where Group A would be the experimental group, and Group B will become the conventional group. Prior to conducting Powerball exercises and MMWM, both Groups will always get ultrasound [18] and the exercises [19]. Pulsed mode will be used for Ultrasound at 1 w/cm² for 10 minutes using gel Binder on lateral epicondyle or at the site of tenderness [20,21].

• Exercises

- i. Clenching the fist powerfully
- ii. Resisted exercises to wrist flexor and extensor muscles.
- iii. Wrist pronation and supination.
- iv. Stretching wrist flexors and extensors for 30 seconds at the end range

Each exercise written above will be performed in 3 series for 10 times.

3.1 Group A (Experimental)

"PowerBall device", utilized for this group for a strength training program that will be delivered for 5 sessions per week, following 3 weeks, each session lasts for 20-64 minutes. Then frequency of the "PowerBall device" will be set by total rounds per minute, which will range from 2000 to 10000, depending on the subject's capacity.

The exercise protocol of Powerball which will be performed is presented below in the Table 1.

3.2 Group B (Control Group)

In this group, Mulligan Mobilisation with movement (MMWM) will be performed in the patients with LE. This is a kind of manual treatment wherein the participants lie in a supine manner with their elbow extending and their forearm pronated, while performing continuous lateral glides with concomitant physiological movement to the elbow joint. The clinician stays by the patient's side, wrapping the belt over his

or her shoulder and the forearm of the sufferer, near to the elbow joint. While doing prolonged lateral glides with the belt, the participants are told to create a fist and release it without discomfort. In a single session, the therapist did the technique 30 times. After ten repeats, there will be a one-minute rest time. Each session is 30-60 minutes long. Mobilizations with movement were conducted in three sets every session, five sessions planned every week for the following three weeks. The Exercise protocol of MMWM which will be performed is present below in the Table 2.

4. OUTCOME MEASURES

4.1 Primary Outcome Measure

1. Patient-Rated Tennis Elbow Evaluation (PRTEE)

Before and after therapy, the PRTEE score is used in LE patients for pain and functional impairment assessment. The PRTEE measure is segregated into two: pain and functional impairment [22].

2. Hand Dynamometer

Grip strength is measured using Hand held dynamometer, a special clinical tool to determine and calculate the most intense isometric properties of the hand and forearm muscles. Dynamometers are used to measure hand strength in sports like baseball and tennis, where the hand is used for flipping or lifting.

3. VAS

Visual Analogue Scale (VAS), tool used for evaluating a trait or behaviour that is thought to vary across a number of values and cannot be calculated directly. It is often used in observational and clinical studies to assess the severity or duration of pain while at rest or while moving.

4.2 Secondary Outcome Measure

1. Range of Motion

It will be measured using the goniometer instrument. It will help in measuring wrist and elbow movements. Subjects will be assessed in sitting position as well as supine position with full support to the elbow. During assessment subjects should uncover the forearm and arm and should not have accessories.

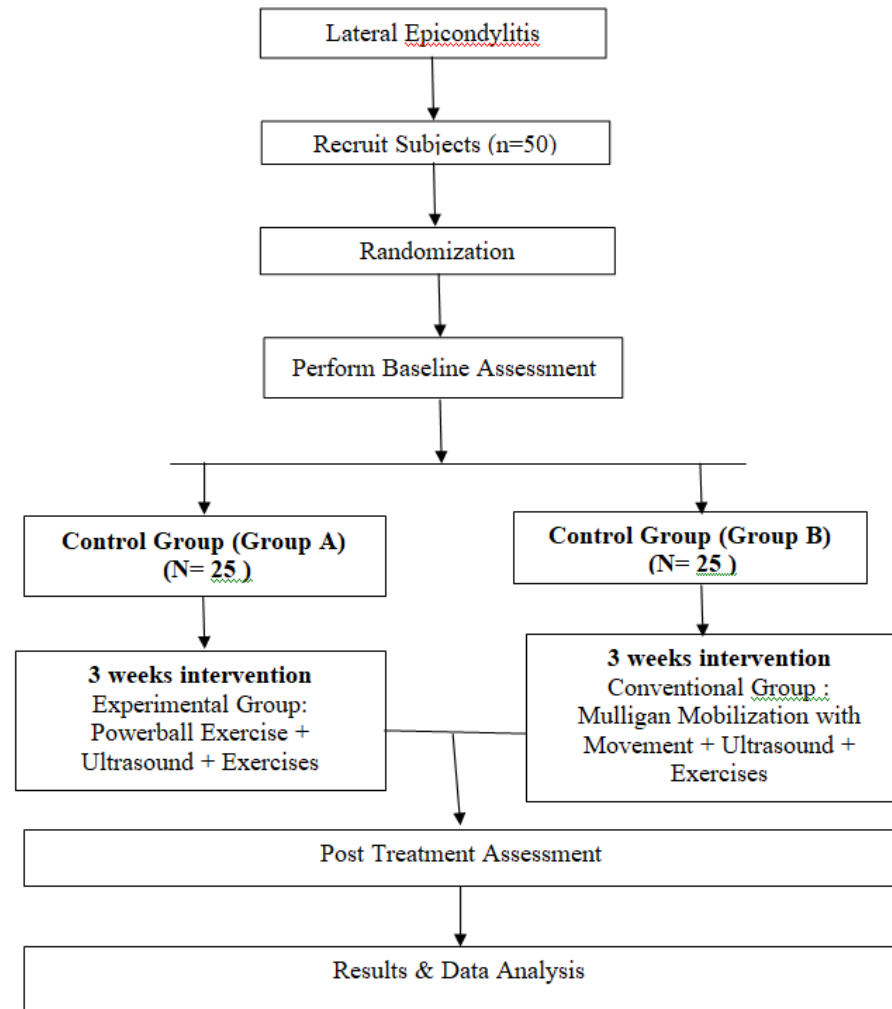


Fig. 1. Show's the flow chart of the study

Table 1. The Exercise protocol of PowerBall (Levels of exercise, where A - Mild, B - Moderate, C – Severe)

Weeks	Type of group	Exercise (set*time)	Name of training	Rest between sets	Rest between each exercise	Situation Implementation of Exercise	Total duration of the exercise
1 st week	A	Exercise 1: (3*30s)	Wrist Flexion	1 min	2 min	Sitting on the table	20 mins
	A	Exercise 2: (3*30s)	Wrist Extension	1 min	2 min	Sitting on the table	
	A	Exercise 3: (3*30s)	Elbow Flexion	1 min	2 min	Standing	
	A	Exercise 4: (3*30s)	Elbow Extension	1 min	2 min	Standing (Trunk flexion)	
2 nd week	B	Exercise 1: (4*45s)	Wrist Flexion	1min 30 sec	3 min	Sitting on the table	39 mins
	B	Exercise 2: (4*45s)	Wrist Extension	1min 30 sec	3 min	Sitting on the table	
	B	Exercise 3: (4*45s)	Elbow Flexion	1min 30 sec	3 min	Standing	
	B	Exercise 4: (4*45s)	Elbow Extension	1min 30 sec	3 min	Standing (Trunk flexion)	
3 rd week	C	Exercise 1: (5*60s)	Wrist Flexion	2 min	4 min	Sitting on the table	64 mins
	C	Exercise 2: (5*60s)	Wrist Extension	2 min	4 min	Sitting on the table	
	C	Exercise 3: (5*60s)	Elbow Flexion	2 min	4 min	Standing	
	C	Exercise 4: (5*60s)	Elbow Extension	2 min	4 min	Standing (Trunk flexion)	

Table 2. The Exercise protocol of MMWM

Week	Exercise (set*reps)	Rest between sets	Situation Implementation of Exercise	Total duration
1 st week (5 sessions)	(3*10)	1 min	Sitting on the table	32 mins
2 nd week (5 sessions)	(3*15)	1 min	Sitting on the table	47 mins
3 rd week (5 sessions)	(3*20)	1 min	Sitting on the table	62 mins

5. DATA COLLECTION AND MANAGEMENT

5.1 Data Collection

The initial parameters variable will be used to obtain assessment information from a pre-created database. Testing data will be put into a secure REDCap database. Paper records of evaluation forms, signed permission forms, and other data will be securely maintained in the research setting. Electronic information - collected from the Hand-held dynamometer in DMIMSU's electronic repository as per participant ID. To enhance participant retention, financial incentives will be given for attending testing sessions. Additionally, the employment of regular feedback concerning adherence and reminder phone-calls (for attending the in-person therapy) will be done. The administrator access rights will lie with the principal investigators (PI).

5.2 Data Management

The primary researchers will be in charge of collecting data and documentation. The integrity of the research information will be extensively examined. The Excel spreadsheet will be released at the end of the study to an allocation blinded statistician for conducting the necessary analysis, following which unblinding of the groups will be done. Checklists are used to prevent missing data due to the improper staff procedure.

5.3 Statistical Analysis

The SPSS 24.0 V software will be used and Graph Pad Prism 7.0 V with level of significance, $p < 0.05$. Statistical analysis will be done by using descriptive and inferential statistics with the use of chi-square test, student's paired and unpaired t-test.

1. Chi-square test

It is a non-parametric test which involves calculation of a quantity. It will be used to find the significance of difference in patient who are using PowerBall and the one who is getting treated with Mulligan Mobilization. Assumption of any difference between the experimental and control group will be made using this test.

2. Student's paired t-test

This test is applied to paired data of dependent observation to compare the effect of PowerBall

device and Mulligan Mobilization with movement on patients who are having tennis elbow or LE.

3. Student's unpaired t-test

This test is applied on the unpaired data of the independent observation made on individuals to see the difference between means of the control and the experimental groups.

6. DISCUSSION

Our study aims to estimate the efficacy of PowerBall device exercises compared to the MMWM, conventional physiotherapy on LE patients' pain and function. According to Babaei-Mobarakeh et al. [6] resistance training with the "PowerBall" increased grip strength, shoulders and wrists strength, performance of upper extremity also proprioception in patients with Tennis Elbow aged 22-28 years. According to researchers, using the "PowerBall device" resulted in enhanced power. Although it has been proven that utilizing a dynamic PowerBall improves strength, function, range of motion, pain due to Tennis Elbow, and QOL among overhead athletes, the bulk of common concerns have yet to be verified. The primary (i.e. PRTEE index, Hand held dynamometer and VAS) and secondary (i.e. Range of motion) outcome measures will assess the efficacy PowerBall device exercises compared to the MMWM, conventional physiotherapy in Lateral epicondylitis patients pain and function. The survey's benefits provide a customized approach to the rehabilitation protocol and the ability to adapt to the individuals' improved competencies during the treatment. The results of the study will aid future patients with lateral epicondylitis by providing a better and advanced technique of rehabilitation.

7. CONCLUSION

By all counts and with proven results, it is no wonder that Mulligan Mobilization was considered by many to have the greatest effect on pain in patients with LE. Conclusion will be drawn post study so as to see whether PowerBall device is more helpful or Mulligan Mobilization with Movement on pain and function in patients with LE. This study will give better approach to therapist in managing the condition.

DISCLAIMER

The goods utilized in this study are widely and often used in our field of study and in our nation.

There is no conflict of interest between the writers and manufacturers of the goods because we do not aim to use them as a means of pursuing legal action, but rather to promote knowledge. Furthermore, the study was not financed by the production business, but rather by the author's own efforts.

CONSENT

Principal Investigators will obtain the informed consent from the patient and one of the relatives on a printed form with signatures and give the proof of confidentiality.

ETHICAL APPROVAL

The protocol is designed after getting an approval from Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences, Deemed to be University. The protocol is designed as per the Declaration of Helsinki. The main findings concerning the efficacy of the PowerBall device exercises to enhance pain and function will be published in a peer-reviewed journal and presented at an international conference. The subjects participating in the study and the DMIMSU who will fund this research can access the main findings of the study. The data of the enrolled subjects stored securely for a minimum of 5 years. The data will be stored in the DMIMSU data repository after the study is complete and the results are published

CONFIDENTIALITY

The study program will be explained to the participant and one of his/her relative, and the principal investigator will take personal information. 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 taken from the patient with complete assurance of his confidentiality.

FUNDING

No direct support will be taken for funding this research from any public and private organizations. The Department of Physiotherapy under Datta Meghe Institute of Medical Sciences, Deemed to be University, will provide the necessary material for the research.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:

The peer review history for this paper can be accessed here:
<https://www.sdiarticle4.com/review-history/74474>