Study Protocol

EFFECTIVENESS OF PROGRESSIVE RESISTED EXERCISE ALONG WITH CONVENTIONAL EXERCISE AND CONVENTIONAL EXERCISE PROGRAM ALONE IN SUBJECTS WITH TEXT NECK SYNDROME

ABSTRACT

Background-: "Text neck" is a term coined to describe the posture created by leaning forward for lengthy periods of time, such as when reading and texting on a cellphone which has been linked to stress injuries. Neck pain, upper back discomfort, shoulder pain, frequent headaches, and greater curvature of the spine are all dangerous indications of text neck. According to a survey, 35% of smartphone users suffer from text neck syndrome. People between the ages of 15 and 18 are more likely to have neck pain. This protocol has been created that describes the design of comparative study to evaluate effectiveness of progressive resisted exercise along with conventional exercise and conventional exercise program alone in text neck syndrome.

Methods-The participants (n=80) will be recruited in the study suffering from text neck syndrome and meeting the inclusion criteria. Two groups will be formed such that patients in group A will be treated with conventional therapy and group B will be treated with progressive resisted exercise (PRE) along with conventional therapy. The protocol will cover 4 weeks of treatment. In the rehabilitation period, we will evaluate the pain intensity, strength of neck muscles and functional activity. Our outcome measures will be- Numerical pain rating scale (NPRS) and Neck disability index (NDI).

Discussion-Efficacy of the intervention will be evaluated by analyzing the pain intensity by using Numerical pain rating scale (NPRS) and level of functional disability by using Neck disability index (NDI). The result of the study will significantly provide affirmation on either using combination therapy of PRE with conventional exercise or conventional exercise alone.

Keywords- Text neck syndrome, Progressive neuromuscular facilitation, Conventional Therapy, Physiotherapy.

INTRODUCTION:

Text Neck Syndrome is a common problem among students who use their phones for long periods of time and hang their heads down. This causes pain, disability, and a decrease in the cervical muscles' strength and endurance. Dr. Dean L. Fishman, a US chiropractor, invented the word "Text Neck" to define neck pain and muscle damage caused by stress injury or overuse syndrome from repeated and sustained staring down at mobile phones in poor posture.(1)

In today's world, where mobile technology has progressed so far, an increasing number of people are spending more time on portable devices like smartphones, computers, tablets, and e-readers. Text neck causes neck pain, shoulder pain, upper back pain, frequent headaches, and increased spine curvature, to name a few side effects.(2)

According to recent figures, at least 77 percent of the world's inhabitants owns a mobile phone. The key reason why cell phone usage is growing in popularity around the world is that it is a secure communication and entertainment system.(3)

According to a survey, 79 percent of people between the ages of 18 and 44 have a smartphone with them at all times. Eighty-two percent of the Swedish population between the ages of 15 and 24 had a smartphone and used it regularly for text messaging (SMS)(4)

The conventional treatment for text neck syndrome usually includes isometric exercises to the cervical muscles, active range of motion exercises, manual therapy etc. Post isometric relaxation can be more helpful in lowering discomfort and disability while also enhancing cervical range of motion in patients with non-specific neck discomfort..(5)

Dynamic neck strength exercise, as well as isometric training, have been shown to help with chronic neck pain.(6) Physiotherapy (aerobics, mobilisation, electrotherapy, and ultrasound), spinal manipulation, behavioural therapy, and ergonomic steps or occupational therapy are examples of conservative treatments that are prescribed or done in the care of Complain of the Arm, Neck, and Shoulder (e.g. working practices, splints)(7)

Progressive resistance exercise (PRE) is a way to improve the muscles' ability to produce force. PRE can be a valuable intervention in physical therapy because of the health benefits it provides. A diminished capability of muscles to produce force as a result of injury, disease, or disuse is a prevalent impairment among clients seen by physical therapists. If a lack of force production by muscles is a factor in an individual's inability to perform daily tasks, physical therapists may use PRE concepts to create treatment plans. (8)

Progressive resistance exercise (PRE) of the neck and shoulder muscles appears to be helpful for chronic neck and shoulder pain in some studies (2–6). Despite the fact that PRE tends to be effective in the treatment of chronic neck pain, a recent Cochrane Review concluded that there is insufficient evidence to make firm recommendations.(9)

According to one study, conducting progressive shoulder-neck resistance training three times a week for six weeks can improve deep and superficial cervical muscle strength dramatically.(10) Clinically substantial reductions in discomfort and soreness, as well as improved muscle strength, can be achieved with as little as 2 minutes of regular progressive resistance training for 10 weeks in people with frequent neck/shoulder problems.(11)

AIM-

This study aims to evaluate effectiveness of progressive resisted exercise along with conventional exercise and conventional exercise program alone in text neck syndrome

METHODOLOGY-

Study setting-

The study will be carried out in Musculoskeletal-Physiotherapy OPD of Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha after getting approval from Institutional Ethical Committee of Datta Meghe Institute Of medical sciences, Deemed to be university.

Study design and sample size-

The design of the study is cross sectional study enrolling 80 participants. The participants enrolled in this study will be randomized in 1:1 manner into Conventional Therapy intervention group (Group A) and rehabilitation program of PRE with conventional therapy (Group B), for 4 weeks each. Before inclusion, the participants will be explained about objectives and approaches of the study, and written informed consent forms will be signed by them. The study schedule of

enrollment, intervention and assessment of study (as recommended by standard protocol items: a recommendation for intervention trials (spirit),2013) is illustrated in fig 1.

	STUDY PERIOD						
	Enrolment	Allocation	Post- allocation				Follow-up test
TIMEPOINT	$-t_1$		Intervention (t_1-t_6) t_1 t_3 t_6			**Post-test** T_7	t_x
ENROLLMENT:							
Eligibility screen	X					X	
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
[PNF +Conventional]			X	X	X		
[PNF+NMES]			X	X	X		
ASSESSMENTS:							

Baseline Variables- MAS, GCS,MMSE	X						
Outcome Variables: MBI, ARAT		X		X	X	X	X

Table. 1 schedule of enrollment, assessment and intervention.

PARTICIPANTS-

The inclusion criteria of participants are under-

1. Either gender between 17 and 22 years of age
2. Those who are having NPRS <5/10
3. Those who are having medical research council manual muscle testing scale >2/5.
4. Those who intend to take part in the study.

Exclusion criteria for participants are under-

1. Those who are less than 17 years and more than 22 years of age.
2. Those who are having NPRS >5/10
3. Those who are having medical research council manual muscle testing scale <2/5.
4. Individuals with any neurological defect, any recent shoulder and neck or arm injury or with any history of cervical or head trauma or surgical intervention in the neck area.
5. Individuals with severe neck pain which require medical treatment or with any cervical disc disease like radiculopathy or inflammatory or malignant type of pain or suffering with any systematic diseases.
6. Those who are registered in another clinical trial.

PARTICPANT TIMELINE-

As study duration is of 6 months and intervention duration is 4 weeks so participant will be enrolled mostly during first 2 months of study so 4 week intervention will be completed successfully. Assessment will be done on 1st day of visit then in 2nd week and last on 4th week of intervention. Participant will have to visit 5 days a week for 4 weeks for treatment.

RECRUITMENT-

The Physiotherapists and health care practitioners working under DMIMSU are invited to refer the prospective subjects to our Out-patient department (OPD). After enrollment in the study participants will be randomized in one of the group A or B and accordingly will undergo the rehabilitation program for 4 weeks with intermediate assessments. Informed patient consent will be taken before allocation and after explaining the purpose of the study, procedure, prospective benefits and after effects of intervention.

IMPLEMENTATION

Randomization will be supervised by the research coordinator and principal investigators. Participants will be asked to handpick a sealed group allocation for the recruitment into either group from the envelope.

BLINDING

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

STUDY PROCEDURE

The participants will be categorized into two groups-

Intervention for Group A- The participants in this group will undergo a 4 week treatment program. It will comprise of conventional modalities like Cryotherapy, active range of motion exercises, isometric exercises and chin tuck in. Isometric exercises include contracting a single muscle or a group of muscles in a controlled manner. The muscle length does not shift during

isometric exercises, and the affected joint does not move. Isometric exercises aid in the maintenance of resilience. They can also help you gain power, but only in a limited way.

Intervention for Group B- The participants in this group will undergo a 4 week treatment program. It will comprise of using theraband for resisted exercises. The theraband used will be from low resistance to maximum resistance. To improve muscle strength, progressive resistance exercise (PRE) is commonly used. Participants exercise their muscles against a resistance that is gradually increased as strength increases during the exercise. Exercise machines, free weights, and elastic bands are some of the most popular pieces of PRE equipment.

OUTCOMES-

1. **Numerical pain rating scale (NPRS)-** The NPRS is a numeric version of the visual analogue scale (VAS) in which a respondent selects a whole number (0–10 integers) that best describes the intensity of his or her discomfort.A horizontal bar or line is the most popular format**.** For self-completion, the NPRS can be provided verbally or graphically. On the segmented scale, the respondent is asked to select the numeric value that best represents their pain severity. (12)
2. **Neck disability index (NDI)-** A patient-completed, condition-specific functional status questionnaire includes ten items: pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and leisure. The NDI has enough support and value to keep its position as the most extensively used self-report neck pain measure. The NDI is accessible in a number of languages, each with its own set of validity and reliability outcomes (Greek, German, Dutch, Korean, Spanish, and French). The NDI can be used to evaluate a patient's current state as well as their treatment progress.(13)

DATA COLLECTION AND MANAGEMENT

Data collection

The evaluation data will be obtained from a pre-established spreadsheet with variable baseline characteristics. Research data will be placed in a secure database. Non-electronic records, such as hard copies of assessment forms, signed informed consent, etc., will be stored safely in the study setting.

Data management

Data collection and reporting will be carried out under the supervision of the principal investigators. The research reports must be carefully checked for accuracy. The Excel spreadsheet will be published at the conclusion of the study and given to the statistician for the required analysis. Checklist can be used to avoid lost data due to incorrect staff procedures.

STATISTICAL ANALYSIS PLAN

Data analysis will be undertaken utilizing qualitative and interpretation statistical data through using Chi-square test and the student's unpaired t test. The device used for interpretation will be SPSS24. 0version, Graph pad prism version 7.0 and $p<0.005$ are considered to be of relevance ($p>0.005$).

BIAS

Measures will be taken to prevent this from happening attrition bias by giving reminder calls prior to each intervention and by providing travel assistance to those who need it. So, we expect a low percentage of dropouts.

RESULT-

Successful completion of this study will provide evidence on the best treatment strategy out of individual conventional or PRE combined with conventional for text neck syndrome subjects to improve their functional activity and result of this study will lead us to better understanding on both treatments. Once the study result is complete data will be analyzed using paired t-test and will be submitted in form of research paper.

DISCUSSION-

Text neck is a name for a repetitive stress injury or overuse ailment in which a person's head hangs or curves forward while bent over for long periods of time gazing at a phone or other electronic device.(14) The purpose of this study is to see how progressive resisted exercise (PRE) combined with traditional exercise or a traditional exercise programme alone affects pain intensity and functional activities in people with text neck syndrome. Progressive resistance exercise (PRE) is a way to improve the muscles' ability to produce force. PRE can be a valuable intervention in physical therapy because of the health benefits it provides. As per the study by Kenneth Jay, In adults with frequent neck/shoulder pain, small regular doses of progressive resistance training improve rapid force development and, to a lesser degree, maximum force capability. (15) If a lack of force production by muscles is a factor in an individual's inability to perform daily tasks, physical

therapists may use PRE concepts to create treatment plans.(8) As per the study by Laura G. W. Cox, A neck-specific progressive resistance training intervention significantly improved neck strength, pain, and impairment in a clinical population.(16)In conclusion, this research seeks to explore the effect of PRE and conventional therapy in subjects with text neck syndrome. The result of the study will help subjects for faster recovery and improve their quality of life. Major Outcome measures of the study are NPRS, NDI scales. These 2 major scales will help to assess pain intensity, and functional activities. Strength training is advised for boosting muscular strength, reducing age-related muscle degradation, and treating individuals with musculoskeletal problems. Strength training is required to improve muscular performance, which aids in the rehabilitation of musculoskeletal problems such as pain, weakness, stiffness, and limited range of motion.(17) Physiotherapy has been demonstrated to be useful in the treatment of patients following surgery.(18) After reconstruction surgery, physiotherapy rehabilitation regimens have been shown to be helpful.(19) Cardiopulmonary fitness and ADL (activities of daily living) training are always reinforced in addition to orthopaedic therapy, and it is also required to avoid subsequent problems.(20) Physiotherapy treatments are frequently used to help people recover faster after a fracture.(21)

ETHICAL APPROVAL AND DISSEMINATION

Ethical approval will be taken from institutional ethical committee. The DMIMS who will fund for research and the subjects who will be participating in the study can access the main findings of the research. Data held safely for the enrolled subjects a minimum of five years. After completion of data collection, statistical analysis a completion report will be formed and after review by institutional research cell will be send for publication.

PATIENT CONSENT

Principal Investigator will obtain the informed consent from the subject on a printed form with signature and given the proof of confidentiality.

Confidentiality

The study program will be elaborated to the participant, and principal investigator will take personal information as a part of procedure. If required to disclose some information for the study, consent will be obtained from the patient with complete assurance of his/her confidentiality.

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