

**EFFICACY OF MOVEMENT CONTROL TRAINING ON REDUCING PAIN AND
DISABILITY IN PEOPLE WITH
NON-SPECIFIC LOW BACK PAIN & MOVEMENT CONTROL IMPAIRMENT – A
RANDOMISED CONTROLLED TRIAL**

By

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Of The Requirements for The Degree Of
MASTER OF PHYSIOTHERAPY (MPT)

In

ORTHOPAEDIC PHYSIOTHERAPY

Under The Guidance of

Prof. Joseph Oliver Raj

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Abhinav Bindra Sports Medicine & Research Institute Bhubaneswar, Odisha

2022 - 2024



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I hereby declare that this dissertation/thesis entitled “**Efficacy of movement control training on reducing pain and disability in people with non-specific low back pain and movement control impairment - A Randomized Controlled Trial**” is a bonafide and genuine research work carried out by me under the guidance of **Prof. Joseph Oliver Raj**.

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LIST OF ABBREVIATIONS

CNLBP- Chronic non-specific low back pain

CTEs- Conventional therapeutic exercises

LBP - Low Back Pain

MVCI - Movement control impairment

NPRS - Numeric pain rating Scale

NSLBP- Nonspecific low back pain

ODI - Oswestry disability Questionnaire

SPSS - Statistical package for social science

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ABSTRACT

EFFICACY OF MOVEMENT CONTROL TRAINING ON REDUCING PAIN AND DISABILITY IN PEOPLE WITH NON-SPECIFIC LOW BACK PAIN & MOVEMENT CONTROL IMPAIRMENT – A RANDOMISED CONTROLLED TRIAL

Background: Low back pain (LBP) is a common condition that affects most people at some point in their lives, with up to an 84% lifetime prevalence. Of people with low back pain, only 15% may receive a definitive diagnosis; in most cases, the pain is non-specific. Non-specific low back pain (NSLBP) can be treated effectively with exercise therapy, there are wide use of exercise protocols, but it is not clear what type of specific exercise is more effective in decreasing pain and disability. Main aim of the study is to assess effect of movement control training on reducing pain and disability in people with non-specific low back pain and movement control impairment.

Methods: 30 participants were selected based on inclusion and exclusion criteria and divided into 2 groups of each 15 subjects. A Pre evaluation was done. Group A experimental group underwent individual specific movement control training and conventional physiotherapy is given to control group and outcome measures used are NPRS, ODI, MVCI test.

Results: After 4 weeks post evaluation, Group A i.e., movement control training group showed better improvement then control group with improvement in pain, disability and impairment. Follow up comparison of three months shows that the treatment group experiences a significantly larger initial improvement in all metrics NPRS, ODI, MVCI compared to the control group. While both groups stabilize from

the 4th to 6th weeks, the treatment group maintains this level of improvement, whereas the control group starts to deteriorate after 6 weeks.

Conclusion: Group A i.e. movement control training experiencing greater benefits than group B i.e. Conventional physiotherapy. The patient- specific functional complaints and disabilities improved significantly after implementation of the individual based specific movement control training programme.

Keywords: Conventional physiotherapy; Movement control impairment; Movement control training; Non-specific low back pain.

INTRODUCTION

EFFICACY OF MOVEMENT CONTROL TRAINING ON REDUCING PAIN AND DISABILITY IN PEOPLE WITH NON-SPECIFIC LOW BACK PAIN & MOVEMENT CONTROL IMPAIRMENT – A RANDOMISED CONTROLLED TRIAL

INTRODUCTION

Low back pain is a common condition that affects the majority of the population with up to 84% of lifetime prevalence(1).

The prevalence depends on factors such as sex, age, educational level and occupation. It results in significant health and socioeconomic problems, being associated with work absenteeism, disability and high costs, both for patient and society(1).

Approximately 85 to 90 percent of LBP cases have no known origin, despite the great range of potentially painful structures and pathological diseases that can cause it(2).

It was believed that bad posture was responsible for most of these cases. The cost to the society and the patient for treatment, compensation, etc. is very high(3).

Only 10% of LBP cases can be attributed to specific disorders like nerve root compression, vertebral fracture, tumour, infection, inflammatory diseases, spondylolisthesis or spinal stenosis(1).

Consequently, NSLBP in which the cause of symptoms is unknown, is diagnosed in about 90% of all patients and is a health problem of high economic importance(3).

Non-specific low back pain -

Only 10% of LBP cases can be attributed to specific disorders like nerve root compression, vertebral fracture, tumour, infection, inflammatory diseases, spondylolisthesis or spinal stenosis. Consequently, Non-specific low back pain, in which the cause of symptoms is unknown, is diagnosed in about 90% of all patients and is a health problem of high economic importance(3).

Non-specific low back pain (NSLBP) is the type of low back pain that has no specific cause, mostly it is associated with an alteration of the spinal alignment and also in the movement patterns in any specific direction; which is also known as movement control impairment (MVCI)(4).

Movement control impairment –

One proposed mechanism driving Non-specific low back pain is movement control impairment (MVCI). The latter is defined as an alteration of the spinal alignment and movement pattern in a specific direction(1).

Patients with MVCI have painfully restricted movements. They mainly complaint of increase in pain during certain positions such as sitting, standing or in twisted positions(4).

MVCI is direction-specific, it can be provoked either by flexion, extension, rotation or multidirectional movements. Up to one- third of patients with LBP are estimated to have MVCI. These impairments can occur secondarily to the presence of pain, due to abnormal tissue loading, lack of proprioceptive awareness(4).

Movement control training –

Exercises which are aimed at restoring movement control, correcting movement patterns and avoiding pain-provoking postures which benefit patients with movement control impairment (MVCI)(1).

The Movement control exercise used to change movement behaviour, through a combination of physical and cognitive learning processes rather than just strengthening a muscle group(1).

Conventional physiotherapy –

Conventional therapeutic exercises (CTEs) are the most widely used evidence-based nonpharmacologic treatment and already proven to be an effective component in treatment of CNLBP(5).

Conventional physiotherapy is the routine treatment of low backache, which is commonly practiced by most of the therapists. It includes electrotherapy modalities, strengthening exercises, stretching, and some specific exercises for home plan(6).

The conventional physiotherapy treatments aiming at reducing pain in patients with Low back pain(6).

NEED OF THE STUDY

- Low back pain (LBP) and movement control impairment (MVCI) can cause altered spinal movement patterns, which affect a person's activities of daily living, normalizing the abnormal movement pattern will decrease functional experienced pain and disability in people with NSLBP.
- Rather than directly exercising the muscles as a part of treatment programme, improvement in low back movement control would be more beneficial and deliver better outcome.
- Due to the high cost of diagnosing NSLBP, treating it is one of the most difficult healthcare concerns which is currently facing by our society.

There is still lack of evidence about one specific treatment programme for non-specific low back pain.

AIM OF THE STUDY

- To Evaluate the effect of movement control training on reducing pain and disability in people with non-specific low back pain and movement control impairment.

OBJECTIVES OF THE STUDY

- To assess the effectiveness of movement control training on reducing pain in people with non-specific low back pain & movement control impairment.
- To assess the effectiveness of movement control training on reducing disability in people with non-specific low back pain & movement control impairment.
- To compare the effect of movement control training and conventional physiotherapy on reducing pain and disability in people with non-specific low back pain and movement control impairment.

HYPOTHESIS -

Null Hypothesis

- There will be no significant effect of movement control training on reducing pain and disability in people with non-specific low back pain & movement control impairment.

Alternative Hypothesis

- There will be significant effect of movement control training on reducing pain and disability in people with non-specific low back pain & movement control impairment.

REVIEW OF LITRATURE

REVIEW OF LITERATURE

1. **Hannu Antero Luomajokia et.al (2018)** in the Journal of musculoskeletal science and practice conducted a study on “Effectiveness of movement control exercise on patients with non-specific low back pain and movement control impairment: A systematic review and meta-analysis. Here A systematic review and meta-analysis were conducted. CINAHL, MEDLINE, PUBMED and PEDro databases were searched for RCT's evaluating MVCE treatment in patients with NSLBP. They concluded that MVCE for people with NSLBP and MVCI appears to be more effective in improving disability compared to other interventions but it has short term effects.
2. **Vesa Lehtola et.al (2016)** in journal of BMC musculoskeletal disorders conducted a study on “Sub-classification based specific movement control exercises are superior to general exercise in sub-acute low back pain when both are combined with manual therapy”: A randomized controlled trial. Study was conducted to compare the effects of general exercise versus specific movement control exercise (SMCE) on disability and function in patients with MCI within the recurrent sub-acute LBP for a patient, who has Flexion and Side flexion-rotation control dysfunction. They concluded that non-specific recurrent sub-acute LBP and MCI an intervention consisting of SMCE and manual therapy combined is superior to general exercise combined with manual therapy.
3. **Jeannette Saner et.al (2011)** in the journal of BMC musculoskeletal disorders conducted a study on “Movement control exercise versus general exercise to reduce disability in patients with low back pain and movement control impairment - A randomised controlled trial”. It is a randomised trial where 106 participants aged 18 - 75 will be recruited and patients are having acute NSLBP and MCI. They concluded that this study will provide insight into the effectiveness of movement control exercise and contribute to our understanding of the mechanisms behind MCI and its relation to NSLBP.
4. **Hannu luomajoki et.al (2010)** in Journal of sports medicine arthroscopy rehabilitation therapy technology conducted a study on "Improvement in low back movement control, decreased pain and disability, resulting from

specific exercise intervention. A prospective study was carried out in two outpatient physiotherapy practices in the German-speaking part of Switzerland. 38 patients (17 males and 21 females) suffering from non-specific low back pain (NSLBP) and movement control impairment were treated. They concluded movement control, patient specific functional complaints and disability improved significantly but having short term effect.

5. **Osama Neyaz et.al (2019)** in journal of THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE conducted a study on “Effectiveness of Hatha Yoga Versus Conventional Therapeutic Exercises for Chronic Nonspecific Low-Back Pain. Seventy subjects were randomized to either yoga (n = 35) or CTE group (n = 35). Data were analysed using intention-to-treat, with last observation carried forward. They concluded that Both yoga and the CTE group have shown significant improvement in back pain intensity and back-related dysfunction within both the groups.
6. **SARA MUMTAZ et.al (2021)** in journal of Pakistan Journal of Medical and Health Sciences conducted a study on “Effect of Core Stability Exercises with Conventional Physiotherapy in Reducing Pain among Patients with Non-Specific Low Back Pain: RCT”. They conducted at Ehsan Rehab Physiotherapy Clinic and Mumtaz Bakhtawar Trust Hospital, Lahore. Patients aging between 25-50 years with nonspecific low backache were randomized into 2 groups. They concluded that conventional physiotherapy treatment in improving pain and function in patients of nonspecific low backache.
7. **Sara Salamat et.al (2017)** in journal of Bodywork & Movement Therapies conducted a study on “Effect of Movement Control and stabilization Exercises in People with Extension related Non -Specific Low Back Pain- A pilot Study”. 32 subjects with active extension pattern chronic low back pain participated in this study. Treatment groups received 4 weeks of exercise therapy. They concluded that Pain and disability reduced in both groups, with no significant difference between the groups.
8. **Darrel S Brodke et.al (2016)** in journal of The Spine Journal conducted a study “Oswestry Disability Index: A Psychometric Analysis with 1610 Patients to identify the benefits and deficiencies of the ODI as an outcome tool for assessing patients with back pain. They concluded that ODI

appears to have good psychometric properties and is generally well suited to assessment of patients with low back pain.

9. **(CRISTIANA KAHL1 et al 2005)** in journal of *Physical Therapy Reviews* this study did a review on Psychometric Properties of VAS, NPRS and MPQ. In their review they reported that when correlated with the VAS, the NPRS is determined to have 0.79 to 0.95 convergent validity. They also identified that NPRS scores high on ease of administration and simplicity for scoring.
10. **(ANNE M. BOONSTRA1 ET AL 2016)** in journal of *Frontiers in Psychology* This study aimed at finding the cut-off points for Mild, Moderate, and Severe Pain on the Numeric Rating Scale for Pain in Patients with Chronic Musculoskeletal Pain and also find the Variability and Influence of Sex and Catastrophizing. They found that NRS scores ≤ 5 correspond to mild pain-related interference with functioning, scores of 6 and 7 to moderate interference and scores ≥ 8 to severe interference independent of the patient's sex.

METHODOLOGY
AND
PROCEDURE

METHODOLOGY

Methods -

Study Design

Randomized Controlled Trial

Study Population

Patient with non-specific Low Back Pain

Sample Size

30

The sample size was calculated by using the formula – $2K \times sd^2 / d^2$

Sampling Technique

Purposive Sampling

Study Setting

Physiotherapy center in & around B.B.S.R and Cuttack.

Study Duration

1 year.

SELECTION CRITERIA -

Inclusion Criteria -

1. Age 18 to 40 years
2. Gender – Both male and female
3. Non-specific low back pain for at least 6 weeks.
4. NPRS score should 3 or more than 3.
5. Individuals who presented with 2 or more positive tests out of 6 for MVCI and also had aggravated pain while attaining any posture or movement of the back while doing ADLs.

Exclusion Criteria -

1. Individuals having specific LBP (Fractures, malignancy, neurological signs (leg weakness), radicular pain to leg).
2. Prior back surgery.
3. Pregnancy.
4. Known case of osteoporosis.
5. Participants should not have a SLR under 50 degree or any positive sacroiliac joint pain provocation test.

Outcome Measures -

PRIMARY OUTCOME MEASURE

PAIN ASSESSMENT = NPRS

SECONDARY OUTCOME MEASURE

FUNCTIONAL DISABILITY ASSESSMENT = Oswestry Disability index.

MOVEMENT CONTROL IMPAIRMENT ASSESSMENT = Movement control test.

Instruments And Tools –

1. PEN AND PAPER
2. CONCENT FORMS
3. ASSESSMENT FORMS
4. COUCH, CHAIR AND PILLOW
5. DUMBELLS AND BARBELLS



Fig 1.1- COUCH AND PILLOW



Fig 1.2- BARBELL



Fig 1.3- DUMBELLS

PROCEDURE

Sample selection and Randomization:

The institutional Ethical Committee evaluated and approved the current study. A total of 40 samples were screened by using purposive sampling. 30 participants were selected based on inclusion criteria and exclusion criteria and 10 subjects were excluded. They were chosen for this study based on certain criteria, such as Non-specific low back pain for at least 6 weeks.

NPRS score should 3 or more than 3. Then diagnosis of the condition was made based on movement control impairment test. Everyone who participated in the study was informed of the protocol and their informed consent were taken.

Then 2 chits were kept and named 'A' as the intervention group and 'B' as the control group.

'Group A' received (MVCT) Movement control training and 'Group B' received Conventional physiotherapy exercise for non-specific low back pain.

15 subjects were placed in Group A (Experimental Group)

15 subjects were placed in Group B (Control Group)

Procedure:

- The intervention program was 45 min, 5 days for 4 weeks for both the groups.
- On the first visit a proper assessment was taken using the outcomes i.e. (MVCI) Movement control impairment, (NPRS) Numeric pain rating scale, (ODI) Oswestry Disability Index,
- Study participants were requested to continue normal activities and avoid other forms of treatment for the duration of the study.

Exercise program for movement control impairment of the low back pain

& Basic progression -

- The exercises are impairment direction specific.
- First priority is to learn to control the movement: to keep the lumbar spine in neutral whilst moving the neighbouring area (e.g. the hip)
- Then exercises with loading can be implemented: spine kept in neutral whilst moving and using weights.
- After the movement control has been regained in the neutral spine position, stretching / lengthening can be started, of the muscles which are too short specifically in this impairment direction.
- Once a good control of the back is reached, normal core strength training can be started.
- After 20 days of treatment again the assessment of outcome was taken using NPRS, ODI, MVCI.

Exercise for extension control impairment –



Fig 2.1- Tilt your pelvis backward



Fig 2.2- Pelvic tilt prone lying



Fig 2.3- Bend your knee and keep your spine in neutral. Don't let your spine extend



Fig 2.4- Lift your leg while keeping your spine in neutral. Don't let your spine extend.



Fig 2.5- Tilt your pelvis backwards, extend your arms forward. Don't let your lumbar spine extend

STRENGTHENING EXERCISE –



Fig 2.6- Lower abdominals - Keep your spine in neutral, 20 reps & upwards



Fig 2.7- Gluteus muscles – 20 reps and upwards



Fig 2.8-Iliopsoas muscle – keep the position 10 reps x 10 seconds

STRETCHING EXERCISES-



Fig 2.9 – Rectus femoris muscle



Fig 2.10- Rectus femoris sidelying stretch



Fig 2.11 – Upper abdominal muscles stretch

Exercise for flexion control impairment –

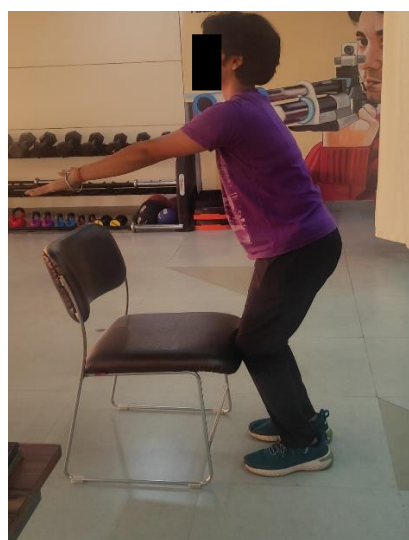


Fig 3.1- Squatting- put a chair against your knees so that the knees don't slide forwards. You have to push your pelvis backwards. "Keep your back in neutral, don't let it bend"



Fig 3.2- Bend forwards, keep your spine in neutral”



Fig 3.3- “Move your pelvis backwards, keep your spine in neutral”



Fig 3.4- Sit straight. Extend your knee. Don't let your spine move (in flexion)

STRENGTHENING EXERCISE –

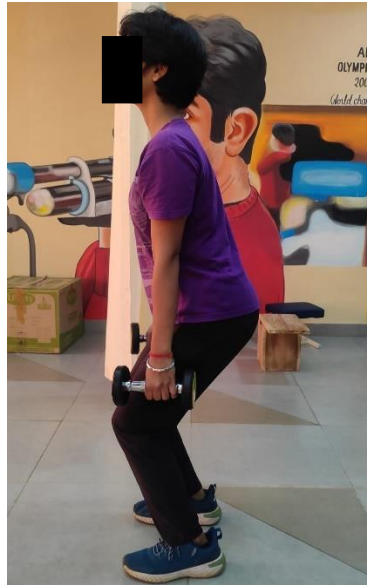


Fig 3.5- Squatting with spine in neutral, start with small weights in your hands.



Fig 3.6- Squatting with spine in neutral & weights in your neck.



Fig 3.7- Prone, lift your legs to strengthen your erector spinae muscles.

STRETCHING EXERCISE-



Fig 3.8- Try to actively extend your knee to stretch your hamstring muscles.



Fig 3.9- Pull your hip to maximal flexion adduction to stretch your gluteus muscles.

Exercise program for conventional physiotherapy of the low back pain

Basic progression –

- Patients will perform lumbar conventional physiotherapy exercise-
- 5 days/week sessions.
- Progression of these exercise includes a 4 weeks treatment.
- During the first week, all patients performed 2 sets of 10 repetitions for each exercise.
- During the second week, the number of repetitions was increased to 2 sets of 15 repetitions of every exercise.
- During the third and fourth weeks, we increased the training routine to 3 sets, 20 repetitions, and 25 repetitions, respectively.

- Single and double knee to chest (for stretching and flexibility of the back extensor strengthening of the rectus-obliques muscles)
- Pelvic tilt exercise (can stretch and strengthen the abdominal muscles)
- Cycling in supine (for strengthening the abdominal muscles and coordinating anterior and posterior lumbar muscles)
- Bridging exercises (for strengthening back extensor muscles).
- Abdominal curl; with patients in supine lying, flexed both knees and supports the head with both hands around the occiput. Patients then actively lift the trunk and head simultaneously.
- Cat and camel exercise (stretching and mobilization exercise for trunk muscle and also works on stretching and strengthening of core muscles)
- Upper back extension in a prone lying position with hands on the couch.

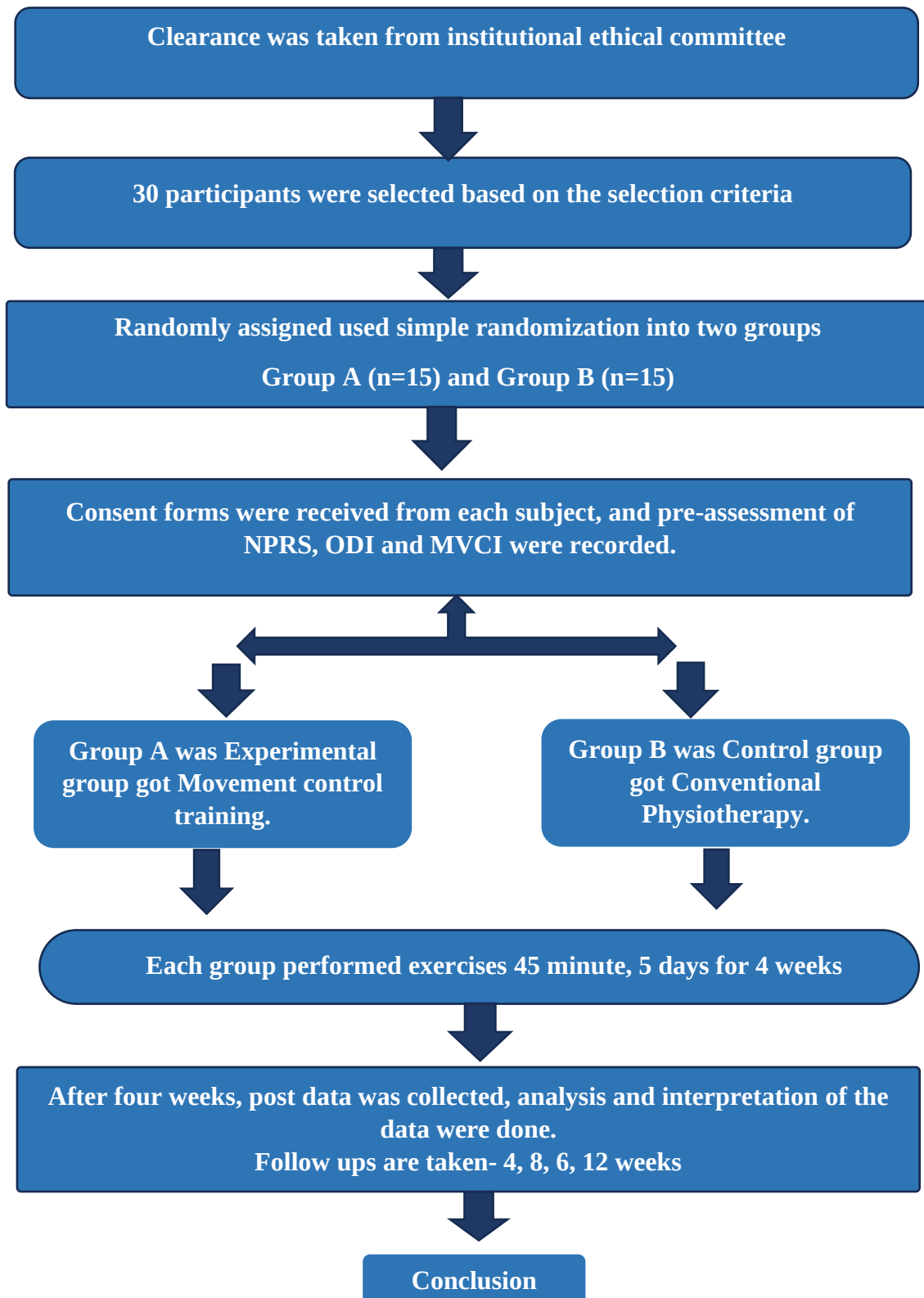


Fig 4.1- FLOW CHART OF STUDY PROCEDURE

SAMPLE SIZE OF ESTIMATION

SAMPLE SIZE ESTIMATION

Sample size calculation was done by using the formula for experimental studies

(Outcome – Modified T-test)

$$n=2k SD^2 / d^2$$

Where,

n= Number of samples

k= Power

SD=Standard Deviation

d = MCID Value

K =10.5

SD= 1.05

d (MCID value) =1.85

$$n= 2k * SD^2/d^2$$

$$2 \times 10.5 \times (1.05)^2 / (1.85)^2$$

$$= 21 \times 1.52 = 31.92, 1 \text{ drop out}$$

$$= 15 \text{ per group (2 groups are there so total of 30 subjects)}$$

RESULTS

RESULTS

STATISTICAL ANALYSIS

Data was analysed using statistical package SPSS 22 and level of significance was set at $p < 0.05$. Descriptive statistics was performed to assess the mean and standard deviation of specific groups. Normality of the data was assessed using Shapiro-Wilk test.

Experimental Group Analysis

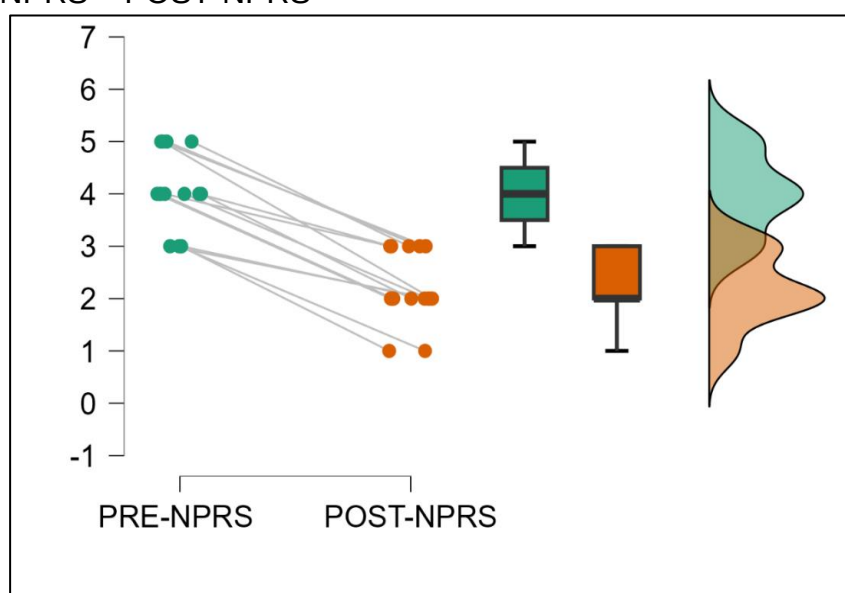
Outcome measure Mean Analysis-

	N	Mean	SD
PRE-NPRS	15	4	0.756
POST-NPRS	15	2.2	0.676
PRE ODI	15	13.447	4.965
POST ODI	15	6.6	2.354
PRE MVCI	15	2.467	0.516
POST MVCI	15	0.6	0.507

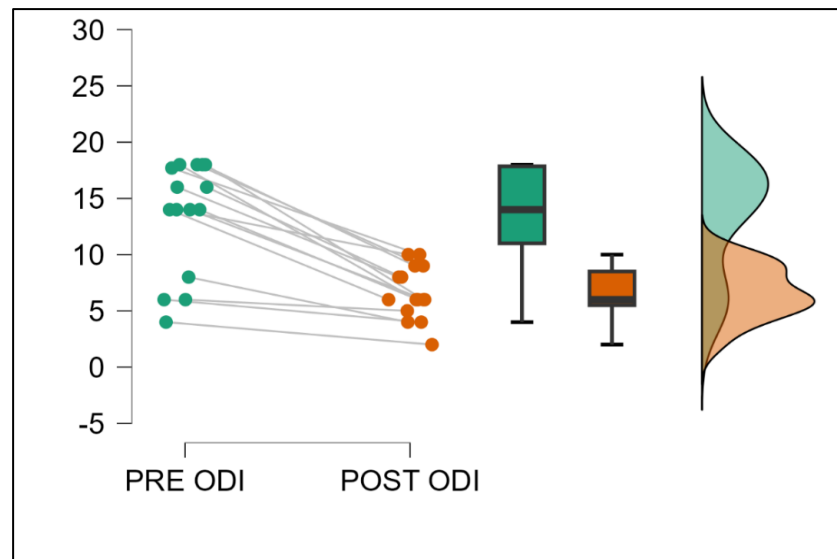
Table 1.1 – Descriptive data of mean and standard deviation for GROUP A

Raincloud Plots

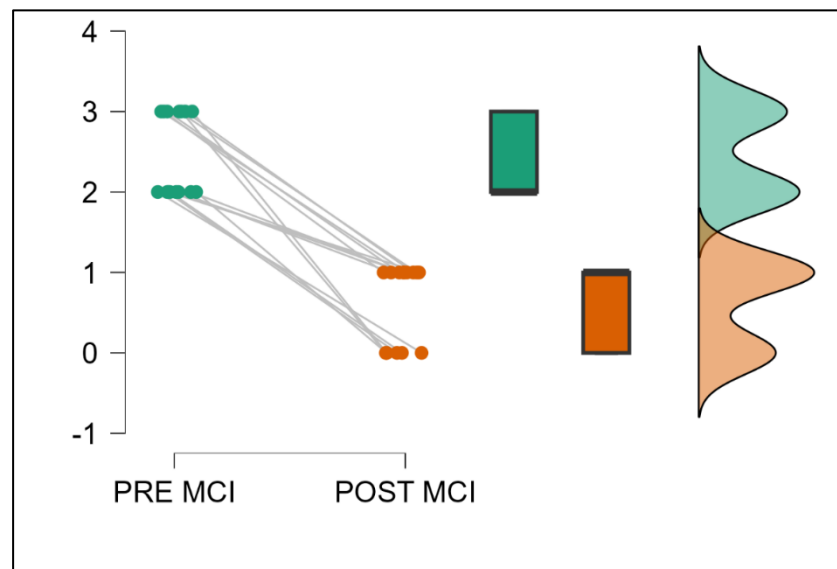
PRE-NPRS – POST-NPRS



PRE-ODI- POST-ODI



PRE MVCI – POST MVCI



Test of Normality (Shapiro-Wilk)

			W	p
PRE-NPRS	-	POST-NPRS	0.734	< .001
PRE ODI	-	POST ODI	0.894	0.077
PRE MVCI	-	POST MVCI	0.79	0.003

Note. Significant results suggest a deviation from normality.

Control Group Analysis

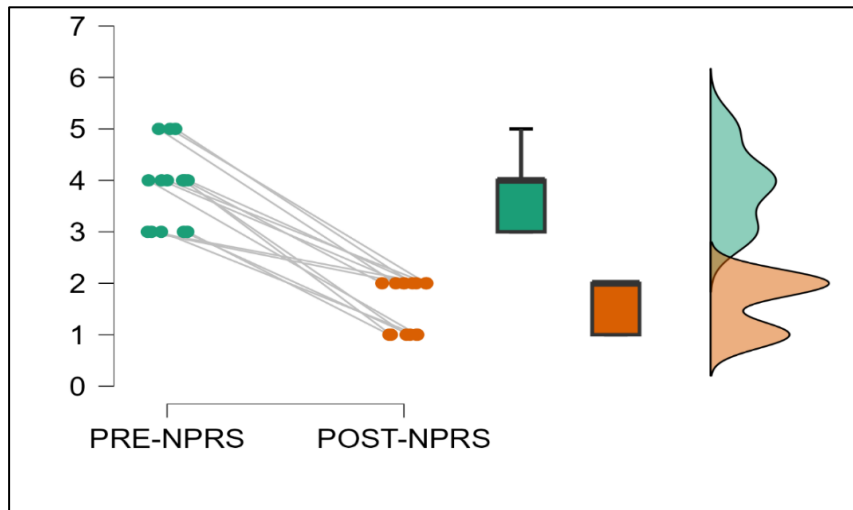
Outcome measure Mean Analysis-

	N	Mean	SD
PRE-NPRS	15	3.867	0.743
POST-NPRS	15	1.6	0.507
PRE ODI	15	12.867	4.998
POST ODI	15	6.8	3.005
PRE MVCI	15	2.467	0.516
POST MVCI	15	1.667	0.488

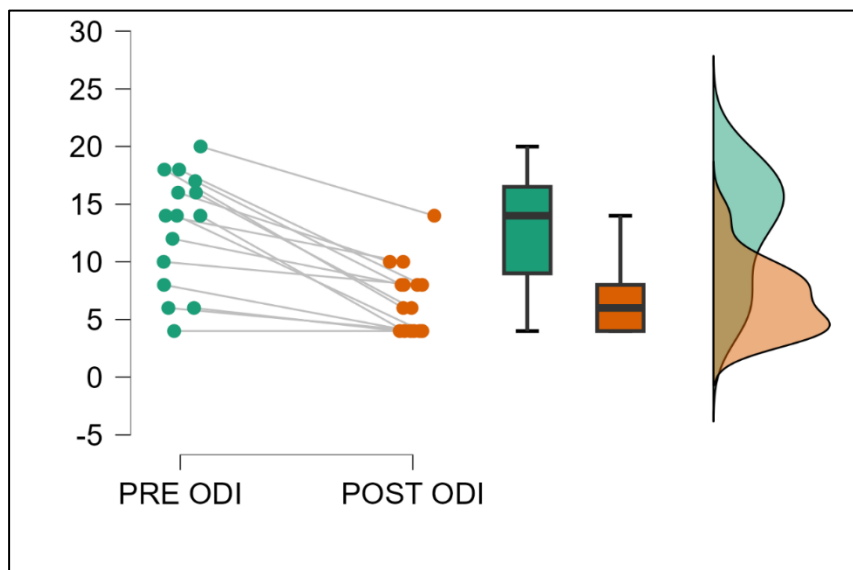
Table- 2.1- Descriptive data of mean and standard deviation for GROUP B

Raincloud Plots

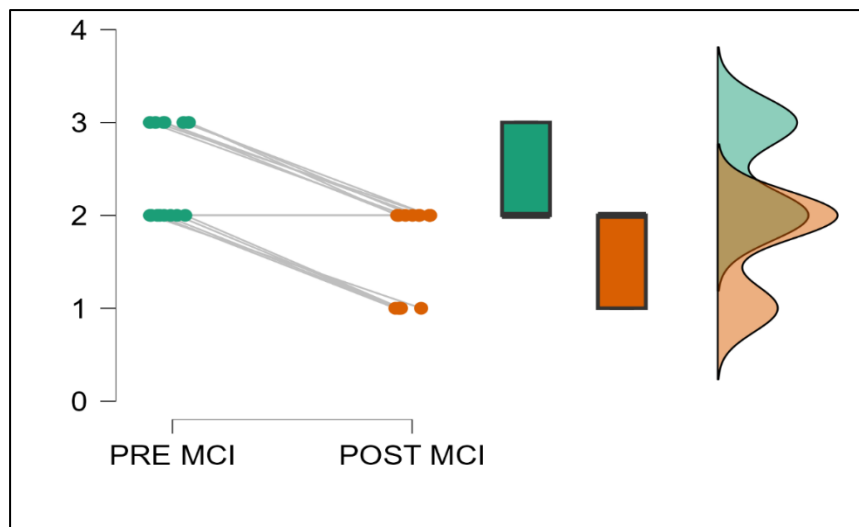
PRE NPRS – POST NPRS



PRE ODI – POST ODI



PRE MVCI – POST MVCI



Test of Normality (Shapiro-Wilk)

			W	p
PRE-NPRS	-	POST-NPRS	0.798	0.003
PRE ODI	-	POST ODI	0.911	0.139
PRE MVCI	-	POST MVCI	0.499	< .001

Note. Significant results suggest a deviation from normality.

Performing repeated measures anova

NPRS

Repeated Measures ANOVA

Within Subjects Effects

Cases	Sum of Squares	df	Mean Square	F	p
NPRS Score	38.880	4	9.720	154.636	< .001
Residuals	3.520	56	0.063		

Note. Type III Sum of Squares

Between Subjects Effects

Cases	Sum of Squares	df	Mean Square
Residuals	30.080	14	2.149

Note. Type III Sum of Squares

Table-3.1- Within & between group effect of NPRS

Post Hoc Tests

Post Hoc Comparisons - NPRS Score

		Mean Difference	SE	t	Cohen's d	p _{holm}
0 Week	4 Week	1.800	0.092	19.662	2.598	< .001
	6 Week	1.800	0.092	19.662	2.598	< .001
	8 Week	1.800	0.092	19.662	2.598	< .001
	12 Week	1.800	0.092	19.662	2.598	< .001
4 Week	6 Week	-3.331×10 ⁻¹⁶	0.092	-3.638×10 ⁻¹⁵	-8.882×10 ⁻¹⁶	1.000
	8 Week	-1.110×10 ⁻¹⁵	0.092	-1.213×10 ⁻¹⁴	-1.332×10 ⁻¹⁵	1.000
	12 Week	-1.110×10 ⁻¹⁶	0.092	-1.213×10 ⁻¹⁵	0.000	1.000
6 Week	8 Week	-7.772×10 ⁻¹⁶	0.092	-8.489×10 ⁻¹⁵	-4.441×10 ⁻¹⁶	1.000
	12 Week	2.220×10 ⁻¹⁶	0.092	2.425×10 ⁻¹⁵	8.882×10 ⁻¹⁶	1.000
8 Week	12 Week	9.992×10 ⁻¹⁶	0.092	1.091×10 ⁻¹⁴	1.332×10 ⁻¹⁵	1.000

Note. P-value adjusted for comparing a family of 10

Table-3.2- Post hoc comparison of NPRS

ODI

Repeated Measures ANOVA

Within Subjects Effects

Cases	Sum of Squares	df	Mean Square	F	p
ODI Score	562.522	4	140.631	58.898	< .001
Residuals	133.710	56	2.388		

Note. Type III Sum of Squares

Between Subjects Effects

Cases	Sum of Squares	df	Mean Square
Residuals	521.787	14	37.271

Note. Type III Sum of Squares

Table-4.1- Within & between group effect of ODI

Post Hoc Tests

Post Hoc Comparisons - ODI Score

		Mean Difference	SE	t	Cohen's d	p _{holm}
0 Week	4 Week	6.847	0.564	12.135	2.237	< .001
	6 Week	6.847	0.564	12.135	2.237	< .001
	8 Weeks	6.847	0.564	12.135	2.237	< .001
	12 Weeks	6.847	0.564	12.135	2.237	< .001
4 Week	6 Week	1.776×10 ⁻¹⁵	0.564	3.148×10 ⁻¹⁵	4.441×10 ⁻¹⁶	1.000
	8 Weeks	-4.441×10 ⁻¹⁶	0.564	-7.871×10 ⁻¹⁶	-8.882×10 ⁻¹⁶	1.000
	12 Weeks	2.220×10 ⁻¹⁵	0.564	3.935×10 ⁻¹⁵	4.441×10 ⁻¹⁶	1.000
6 Week	8 Weeks	-2.220×10 ⁻¹⁵	0.564	-3.935×10 ⁻¹⁵	-1.332×10 ⁻¹⁵	1.000
	12 Weeks	4.441×10 ⁻¹⁶	0.564	7.871×10 ⁻¹⁶	0.000	1.000
8 Weeks	12 Weeks	2.665×10 ⁻¹⁵	0.564	4.722×10 ⁻¹⁵	1.332×10 ⁻¹⁵	1.000

Note. P-value adjusted for comparing a family of 10

Table-4.2- Post hoc comparison of ODI

MVCI

Repeated Measures ANOVA

Within Subjects Effects

Cases	Sum of Squares	df	Mean Square	F	p
MCI	41.813	4	10.453	127.628	< .001
Residuals	4.587	56	0.082		

Note. Type III Sum of Squares

Between Subjects Effects

Cases	Sum of Squares	df	Mean Square
Residuals	13.547	14	0.968

Note. Type III Sum of Squares

Table-5.1- Within & between group effect of MVCI

Post Hoc Tests

Post Hoc Comparisons - MVCI

	Mean Difference	SE	t	Cohen's d	p _{holm}
0 Week 4 Week	1.867	0.105	17.863	3.668	< .001
6 Week	1.867	0.105	17.863	3.668	< .001
8 Week	1.867	0.105	17.863	3.668	< .001
12 Week	1.867	0.105	17.863	3.668	< .001
4 Week 6 Week	1.665×10 ⁻¹⁶	0.105	1.594×10 ⁻¹⁵	2.220×10 ⁻¹⁶	1.000
8 Week	3.886×10 ⁻¹⁶	0.105	3.718×10 ⁻¹⁵	6.661×10 ⁻¹⁶	1.000
12 Week	1.110×10 ⁻¹⁶	0.105	1.062×10 ⁻¹⁵	0.000	1.000
6 Week 8 Week	2.220×10 ⁻¹⁶	0.105	2.125×10 ⁻¹⁵	4.441×10 ⁻¹⁶	1.000
12 Week	-5.551×10 ⁻¹⁷	0.105	-5.312×10 ⁻¹⁶	-2.220×10 ⁻¹⁶	1.000
8 Week 12 Week	-2.776×10 ⁻¹⁶	0.105	-2.656×10 ⁻¹⁵	-6.661×10 ⁻¹⁶	1.000

Note. P-value adjusted for comparing a family of 10

Table-5.2- Post hoc comparison of MVCI

Table- 6.1- Follow up - Percentage Changes & comparison

Treatment group

Time	0 TO 4TH WEEKS	4TH TO 6TH WEEKS	6TH TO 8TH WEEKS	8TH TO 12TH WEEKS
NPRS	-58.11%	0.00%	0.00%	0.00%
ODI	-48.46%	0.00%	0.00%	0.00%
MVCI	-75.56%	0.00%	0.00%	0.00%

Control Group

Time	0 TO 4TH WEEKS	4TH TO 6TH WEEKS	6TH TO 8TH WEEKS	8TH TO 12TH WEEKS
NPRS	-45.33%	0.00%	26.67%	38.89%
ODI	-43.11%	0.00%	0.00%	0.00%
MVCI	-32.22%	0.00%	0.00%	0.00%

Comparison

Time Period	NPRS	ODI	MVCI
0 to 4th Weeks	Treatment: -58.11%	Treatment: -48.46%	Treatment: -75.56%
	Control: -45.33%	Control: -43.11%	Control: -32.22%
4th to 6th Weeks	Treatment: 0.00%	Treatment: 0.00%	Treatment: 0.00%
	Control: 0.00%	Control: 0.00%	Control: 0.00%
6th to 8th Weeks	Treatment: 0.00%	Treatment: 0.00%	Treatment: 0.00%
	Control: 26.67%	Control: 0.00%	Control: 0.00%
8th to 12th Weeks	Treatment: 0.00%	Treatment: 0.00%	Treatment: 0.00%
	Control: 38.89%	Control: 0.00%	Control: 0.00%

Key Differences:

- The treatment group experiences a significantly larger initial improvement in all metrics compared to the control group.
- While both groups stabilize from the 4th to 6th weeks, the treatment group maintains this level of improvement till 12 weeks, whereas the control group starts to deteriorate after 6 weeks.

Conclusion of data-

Overall, the data suggests a positive initial response to the treatment group as compare to control group, with improvements in non-specific low back pain, disability and movement impairment.

DISCUSSION AND CONCLUSION

DISCUSSION

The purpose of the study is to assess the efficacy of movement control training to reduce pain and disability in people with movement control impairment. MVCI is direction-specific impairment, it can be provoked either by flexion, extension, rotation or multidirectional movements and in this study, we got flexion and extension related movement control impairment patients. 30 subjects had been divided into two groups, 15 subjects in each group, were Experimental group (Group A) underwent individual specific movement control training and control group (Group B) underwent conventional physiotherapy and the outcome measures are NPRS, ODI, MVCI test. After completing the 4-weeks training phase in experimental group there is reduction in pain, disability and impairment.

The results of the study revealed that group A, who received movement control training for four weeks, experienced significant reduction in pain, disability & impairment than group B that received conventional physiotherapy. This gives support to the alternative hypothesis that movement control training helps in reducing pain and disability in non-specific low back pain and movement impairment as measured by NPRS and ODI. There was a significant change in self-reported function between the groups in favour of movement control training at the three months follow-up.

A study done by Hannu Antero Luomajokia et.al (2018) reveal that Movement control exercise for people with NSLBP and MVCI appears to be more effective in improving disability(1). Another study done by Sara Salamat et.al (2017) concluded that patient with movement control impairment received 4 weeks of movement control exercise and there is reduction in Pain and disability(7).

Osama Neyaz et.al (2019) conducted a study and they concluded that Both yoga and the Conventional therapy exercise group have shown significant improvement in back pain intensity and back-related dysfunction within both the groups(5).

SARA MUMTAZ et.al (2021) conducted a study and they concluded that conventional physiotherapy treatment is improving pain and functional ability in patients of nonspecific low backache(6).

Results of this study coincide with result of above study stating that both group A and B i.e., movement control training group and Conventional physiotherapy group showed improvement in pain, disability and impairment in within group analysis i.e. pre and post, but Significant Improvement was seen in pain, disability and impairment with movement control training as compare to control group when done between group analysis. Follow up comparison of three months shows that the treatment group experiences a significantly larger initial improvement in all metrics NPRS, ODI, MVCI compared to the control group. While both groups stabilize from the 4th to 6th weeks, the treatment group maintains this level of improvement, whereas the control group starts to deteriorate after 6 weeks.

Limitations of the study-

A limitation of the study is that we did not evaluate the impact of psychosocial risk factors.

Another limitation was small sample size, because of that we did not get rotational impairment patient.

Future scope-

Large sample size can be taken and Psychosocial risk assessment can be added in future studies to evaluate any psychosocial risk factors on patients.

CONCLUSION

In this study, movement control training was investigated for its impact on reducing pain and disability in non-specific low back pain and movement control impairment condition. The patient- specific functional complaints and disabilities improved significantly after the implementation of the individual based specific exercise programme. Group A experiencing greater benefits then group B. These findings suggest that movement control training can effectively alleviate non-specific LBP and disability among movement control impairment condition and also have long term effect.

REFERENCES

REFERENCES

1. Luomajoki HA, Beltran MB, Careddu S, Bauer CM. Effectiveness of movement control exercise on patients with non-specific low back pain and movement control impairment: a systematic review and meta-analysis. *Musculoskeletal Science and Practice*. 2018 Aug 1;36: 1-1.DOI-
<https://doi.org/10.1016/j.msksp.2018.03.008>.
2. Lehtola V, Luomajoki H, Leinonen V, Gibbons S, Airaksinen O. Sub-classification based specific movement control exercises are superior to general exercise in sub-acute low back pain when both are combined with manual therapy: A randomized controlled trial. *BMC musculoskeletal disorders*. 2016 Dec;17: 1-9.DOI- <https://doi.org/10.1186/s12891-016-0986-y>.
3. Saner J, Kool J, De Bie RA, Sieben JM, Luomajoki H. Movement control exercise versus general exercise to reduce disability in patients with low back pain and movement control impairment. A randomised controlled trial. *BMC musculoskeletal disorders*. 2011 Dec;12: 1-8.DOI-
<https://doi.org/10.1186/1471-2474-12-207>.
4. D'souza CE, Shinde S, Bhore P. Effect of Movement Control Spinal Exercise Programme on Pain and Mobility in Individual with Non-Specific Low Back Pain. *Journal of Pharmaceutical Research International*. 2021 Nov 11;33(49A): 292-8.DOI-
<https://doi.org/10.9734/jpri/2021/v33i49A33332>
5. MUMTAZ S, JAVED A, MUSTANSAR A, GUL N, SALEEM M, LATIF W, LAIQUE T. Effect of Core Stability Exercises with Conventional Physiotherapy in Reducing Pain among Patients with Non-Specific Low Back Pain: RCT.DOI-<http://dx.doi.org/10.53350/pjmhs2115103063>

6. Salamat S, Talebian S, Bagheri H, Maroufi N, Shaterzadeh MJ, Kalbasi G, O'Sullivan K. Effect of movement control and stabilization exercises in people with extension related non-specific low back pain-a pilot study. *Journal of bodywork and movement therapies*. 2017 Oct 1;21(4): 860-5.DOI- <https://doi.org/10.1016/j.jbmt.2017.02.005>
7. Ghorbanpour A, Azghani MR, Taghipour M, Salahzadeh Z, Ghaderi F, Oskoue AE. Effects of McGill stabilization exercises and conventional physiotherapy on pain, functional disability and active back range of motion in patients with chronic non-specific low back pain. *Journal of physical therapy science*. 2018;30(4): 481-5.DOI- <https://doi.org/10.1589/jpts.30.481>
8. Bello AI, Quartey JN, Lartey M. Efficacy of behavioural graded activity compared with conventional exercise therapy in chronic nonspecific low back pain: implication for direct health care cost. *Ghana Medical Journal*. 2015;49(3): 173-80.DOI- <https://doi.org/10.4314%2Fgmj.v49i3.8>
9. Luomajoki H, Kool J, De Bruin ED, Airaksinen O. Movement control tests of the low back; evaluation of the difference between patients with low back pain and healthy controls. *BMC musculoskeletal disorders*. 2008 Dec;9: 1-2.DOI- <https://doi.org/10.1186/1471-2474-9-170>
10. Chiarotto A, Maxwell LJ, Terwee CB, Wells GA, Tugwell P, Ostelo RW. Roland-Morris Disability Questionnaire and Oswestry Disability Index: which has better measurement properties for measuring physical functioning in nonspecific low back pain? Systematic review and meta-analysis. *Physical therapy*. 2016 Oct 1;96(10): 1620-37.DOI- <https://doi.org/10.2522/ptj.20150420>
11. Luomajoki H, Kool J, De Bruin ED, Airaksinen O. Reliability of movement control tests in the lumbar spine. *BMC musculoskeletal disorders*. 2007 Dec;8(1): 1-1.DOI- <https://doi.org/10.1186/1471-2474-8-90>

12. Luomajoki H: Movement Control Impairment as a subgroup of nonspecific low back pain. Book Movement Control Impairment as a subgroup of non-specific low back pain City: Eastern Finland University Library/Sales of Publications; 2010, 70, 22.10.2010
13. Brennan GP, Fritz JM, Hunter SJ, Thackeray A, Delitto A, Erhard RE. Identifying subgroups of patients with acute/subacute “nonspecific” low back pain: results of a randomized clinical trial. DOI-
<https://doi.org/10.1097/01.brs.0000202807.72292.a8>
14. Kahl C, Cleland JA. Visual analogue scale, numeric pain rating scale and the McGill pain Questionnaire: an overview of psychometric properties. Phys Ther Rev. 2005 Jun 1;10(2):123–8. DOI-
<http://dx.doi.org/10.1179/108331905X55776>
15. Boonstra AM, Stewart RE, Köke AJA, Oosterwijk RFA, Swaan JL, Schreurs KMG, et al. Cut-Off Points for Mild, Moderate, and Severe Pain on the Numeric Rating Scale for Pain in Patients with Chronic Musculoskeletal Pain: Variability and Influence of Sex and Catastrophizing. Front Psychol. 2016; 7:1466. DOI-
<https://doi.org/10.3389/fpsyg.2016.01466>

ANNEXURES

ANNEXURE – 1
CONCENT FORM

CONSENT FORM

Title of the study-

EFFICACY OF MOVEMENT CONTROL TRAINING ON REDUCING PAIN AND
DISABILITY IN PEOPLE WITH NON-SPECIFIC LOW BACK PAIN & MOVEMENT
CONTROL IMPAIRMENT – A RANDOMISED CONTROLLED TRIAL

I have been informed by Miss. Aishwarya Choudhary; pursuing MPT (Ortho) conducting the study under the guidance of Prof. Dr. Joseph Oliver Raj (Dean, ABSMARI).

I have understood about movement control training procedure and its potential benefits on non-specific low back pain & movement control impairment as explained by Miss Aishwarya Choudhary and is as mentioned in her study. I have no objection regarding to be a part of this study. I also understand that the study does not have any negative implication on my health. I understand that the information produced by the study will become a part of the institute's record and will be utilized, as per confidentiality regulations of the institute. I am also aware that the data might be used for medical literature and teaching purposes, but all the personal details will be kept confidential.

I am well informed to ask as many questions as I can to Miss. Aishwarya Choudhary, either during the study or later.

I understand that my assent is voluntary and I reserve the right to withdraw or discontinue the participation from the study at any point of time during the study.

I voluntarily agree to and give my consent to be a part of the above-mentioned study.

- I have explained to MR/MISS/MRS _____, subjects of the study about the purpose of the research and the benefits of the treatment.

(Investigator)

(Date)

I confirm that Miss. Aishwarya Choudhary (investigator) has explained to me in the language I can understand the purpose of the study and the procedure. Therefore, I voluntarily agree to and give my consent to be a part of the above-mentioned study and I will be accountable for the decisions.

(Signature)

(Date)

ANNEXURE – 2

ETHICAL COMMITTEE CLEARANCE CERTIFICATE



ABSMARI ETHICS COMMITTEE

ABHINAV BINDRA SPORTS MEDICINE AND RESEARCH INSTITUTE,
BHUBANESWAR, ODISHA

Prof. (Dr.) E. Venkata Rao
Chairperson

Mr. Chinmaya Kumar Patra
Member Secretary

Ref. No. ABSMARI/IEC/2023/046

Date: 12/08/2023

APPROVAL LETTER APPENDIX- VIII

To,

AISHWARYA CHOUDHARY
ABSMARI
273, PAHAL, BHUBANEWAR-752101

Protocol Title: Efficacy of Movement Control Training on Reducing Pain and Disability in People with Non-Specific Low Back Pain & Movement Control Impairment – A Randomised Controlled Trial

Protocol ID.: ABS-IEC-2023-PHY-005

Subject: Approval for the conduct of the above referenced study

Dear Mr./Mrs./Dr **AISHWARYA CHOUDHARY**

With reference to your Submission letter dated 12/08/2023 the ABSMARI IEC has of the Ethics reviewed and discussed your application for conduct of clinical trial on dated 12/08/2023 (Sat Day).

The following documents were reviewed and discussed

S.N.	Documents	Document (Version/Date)
1	IEC Application Form	08-08-2023
2	Informed Consent Form	08-08-2023
3	Undertaking form PI	08-08-2023
4	CRF	08-08-2023
5	COI from the Investigators	08-08-2023

The following members were present at meeting held on 12-08-2023

S.N.	Name of the Member	Designation & Qualification	Representation as per NDCT 2019	Gender (M/F)	Affiliation with the Institution (Y/N)
1	Prof. Dr. E. Venkata Rao	Professor (MBBS, MD, Dept. of Community Med.) IMS & Sum Hospital, BBSR	Chair Person	M	N
2	Dr. Satyajit Mohanty	Director-Medcare Hospital, BBSR	Basic Medical Scientist	M	N
3	Dr. Ashok Singh Chouhan	PhD. Pharmacology, Assoc. Prof. Dept. of Pharmacology, Hi-Tech Medical College & Hospital, BBSR	Basic Medical Scientist	M	N

1

MEMBERS
Dr. Smaraki Mohanty, Clinician
Dr. Satyajit Mohanty, Basic Medical Scientist
Dr. Ashok Singh Chouhan Basic Medical Scientist
Mr. Shib Shankar Mohanty Legal Expert
Ms. Annie Hans, Social Scientist
Ms. Subhashree Samal, Lay Person
Mr. Deepak Ku. Pradhan, Scientific Member
IEC-SECRETARIAT
Mr. Gouranga Ku. Padhy Mr. Susant Ku. Raychudamani



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ABSMARI ETHICS COMMITTEE

ABHINAV BINDRA SPORTS MEDICINE AND RESEARCH INSTITUTE,
BHUBANESWAR, ODISHA

Prof. (Dr.) E. Venkata Rao
Chairperson

Mr. Chinmaya Kumar Patra
Member Secretary

Ref. No. ABSMARI/IEC/2023/046

Date: 12/08/2023

MEMBERS

Dr. Smaraki Mohanty,
Clinician

Dr. Satyajit Mohanty,
Basic Medical Scientist

Dr. Ashok Singh Chouhan
Basic Medical Scientist

Mr. Shih Shankar Mohanty
Legal Expert

Ms. Annie Hans,
Social Scientist

Ms. Subhashree Samal,
Lay Person

Mr. Deepak Ku. Pradhan,
Scientific Member

IEC-SECRETARIAT

Mr. Gouranga Ku. Padhy
Mr. Susant Ku. Raychudamani

S.N.	Name of the Member	Designation & Qualification	Representation as per NDCT 2019	Gender (M/F)	Affiliation with the Institution (Y/N)
4	Dr. Smaraki Mohanty	Asst. Prof-IMS & Sum Hospital/MBBS, MD (Community Med)	Clinician	F	N
5	Mr. Chinmaya Kumar Patra	Principal-ABSMARI, MPT	Member Secretary	M	Y
6	Mr. Shiba Sankar Mohanty	Junior Counsel-Lt. Ramachandra Sarangi's Chamber / BA LLB	Legal Expert	M	N
7	Ms. Annie Hans	Disability Inclusive Development Co-Ordinator in Humanity and Inclusion (India/Nepal/Srilanka). /MA in Social Work	Social Scientist	F	N
8	Ms. Subhashree Samal	Ref. Reader-Pol Sc.	Lay Person	F	N
9	Mr. Deepak Kumar Pradhan	Asst. Prof-ABSMARI, MPT	Scientific Member	M	Y

This is to confirm that only members who are independent of the Investigator and the Sponsor of the trial have voted/ provided opinion on the trial.

This Committee approves the documents and the conduct for the trial in the presented form with necessary recommendation.

The ABSMARI IEC must be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and requests to be provided a copy of the final report.

The ABSMARI IEC follows procedures that are in compliance with the requirements of ICH (International Conference on Harmonization) guidance related to GCP (Good Clinical Practice) and applicable Indian regulations.

Yours sincerely

Mr. Chinmaya Kumar Patra
Member Secretary
ABSMARI ETHICS COMMITTEE

ABSMARI Ethics Committee
Pahal, Bhubaneswar



2

Utkal Signature, Plot No.-273,
Ground Floor, Pahal, Bhubaneswar-752101

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ANNEXURE –3

ASSESSMENT FORM

DEMOGRAPHIC DATA-

Name-

Age-

Gender-

Address-

Phone number-

Height-

Weight-

Date of assessment –

HISTORY-

- Any medical condition
- Any musculoskeletal condition
- Any recent injury within 6 months

ON EXAMINATION-

GROUP =

TEST	PRE-INTERVENTION SCORE	POST INTERVENTION SCORE
NPRS		
ODI		
MVCI		

FOLLOW UPS =

TEST	4 WEEKS	6 WEEKS	8 WEEKS	12 WEEKS
NPRS				
ODI				
MVCI				

ANNEXURE – 4

MASTER CHART

MYCE GRP														
SL.NO	SUBJECT NAME	AGE	WEIGHT(kg)	HEIGHT(cm)	MI(kg/m ²)	PRE-NPRS	POST-NPRS	DIFF.	PRE	POST	DIFF.	PRE	POST	DIFF.
1	RAJESHWARI MISHRA	29	62	155	25.8	4	2	2	14	6	8	3	1	2
2	SWEETY GUPTA	31	53	153	22.6	4	2	2	16	8	8	2	1	1
3	MRUNAL BHOSLE	26	55	157	22.3	3	1	2	18	6	12	3	1	2
4	BISWAMAYEE SAHOO	30	58	153	24.8	3	2	1	18	6	12	3	1	2
5	SUMIT K. PATI	32	75	176	24.2	4	2	2	4	2	2	2	0	2
6	BHABANI K. SHANKAR	30	72	174	23.8	3	2	1	6	5	1	2	0	2
7	ANSUMAN MISHRA	30	70	183	20.9	5	3	2	6	4	2	3	0	3
8	RONIT ROY	26	65	156	26.7	4	2	2	16	8	8	3	1	2
9	SHRADHANJALI SAHOO	27	70	163	26.3	4	2	2	8	4	4	3	0	3
10	DHUPCHAYA DUTTA	26	54	155	22.5	3	1	2	14	6	8	2	1	1
11	KARISHMA ASHER	30	62	165	22.8	4	3	1	18	9	9	2	1	1
12	MANSI CHOUDHARY	32	50	157	20.3	5	2	3	17.7	10	7.7	3	1	2
13	ANUPRIYA JHA	25	54	155	22.5	5	3	2	18	9	9	2	0	2
14	MEGHA PRIYADARSHINI	28	50	153	21.4	4	3	1	14	6	8	2	0	2
15	PRIYAL PATRA	24	53	157	21.5	5	3	2	14	10	4	2	1	1
	AVERAGE	28.4	60.2	160.8	23.22667	4	2.2	1.8	13.4467	6.6	6.8467	2.46667	0.6	1.86667
	Stdyt	2.498	8.453233	3.525905	1.376095	0.755323	0.676123	0.560612	4.96486	2.35433	3.4552	0.5164	0.50709	0.63394
CONTROL GRP														
SL.NO	NAME	AGE	WEIGHT(kg)	HEIGHT(cm)	MI(kg/m ²)	PRE-NPRS	POST-NPRS	DIFF.	PRE	POST	DIFF.	PRE	POST	DIFF.
1	BADRINATH DAS	28	75	171	25.6	4	2	2	16	6	10	3	2	1
2	MANMOHAN NAYAK	35	72	173	24.1	5	2	3	14	4	10	3	2	1
3	MEERA RANI	32	69	166	25	4	2	2	20	14	6	2	1	1
4	KABITA NATH	34	65	163	24.5	3	1	2	18	8	10	2	1	1
5	SHREEJA DASH	35	70	167	25.1	3	1	2	17	8	9	3	2	1
6	POONYA PATTHAIK	30	72	178	22.7	3	2	1	14	4	10	2	1	1
7	MADHURI MOHARANA	28	59	155	24.6	4	1	3	12	8	4	3	2	1
8	RAJKUMAR MOHANTY	27	74	173	24.7	4	2	2	4	4	0	2	1	1
9	IVAN KUWAR	28	78	176	25.2	4	1	3	14	10	4	2	1	1
10	RAKESH PATNAIK	30	75	167	26.9	3	1	2	8	4	4	2	2	0
11	LIMA MISHRA	29	66	154	27.8	4	2	2	6	4	2	3	2	1
12	MUSKAN JAIN	27	58	163	21.8	5	2	3	6	4	2	2	2	0
13	SUBHAM SAHOO	25	75	168	26.6	3	2	1	10	8	2	3	2	1
14	ANIL NAYAK	34	72	169	25.2	5	2	3	18	6	12	2	2	0
15	JITENDRA KUMAR DASH	36	80	176	25.8	4	1	3	16	10	6	3	2	1
	AVERAGE	30.533	70.66667	167.3333	25.04	3.866667	1.6	2.266667	12.8667	6.8	6.0667	2.46667	1.66667	0.8
	Stdyt	3.5227	6.365831	7.116045	1.509872	0.743223	0.507093	0.703732	4.93809	3.00476	3.826	0.5164	0.48795	0.41404

ANNEXURE – 5

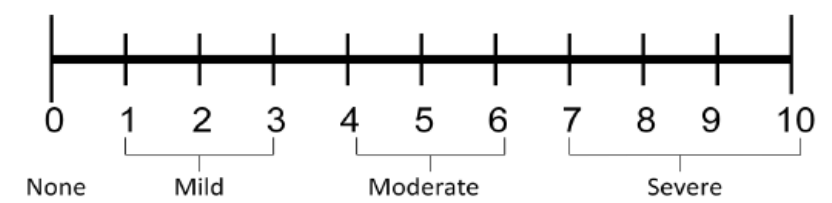
The Numeric Pain Rating Scale Instructions

General Information:

- The patient is asked to make three pain ratings, corresponding to current, best and worst pain experienced over the past 24 hours.
- The average of the 3 ratings was used to represent the patient's level of pain over the previous 24 hours.

Patient Instructions (adopted from (McCaffery, Beebe et al. 1989):

"Please indicate the intensity of current, best, and worst pain levels over the past 24 hours on a scale of 0 (no pain) to 10 (worst pain imaginable)"



ANNEXURE – 6

OSWESTRY LOW BACK DISABILITY QUESTIONNAIRE

Instructions: this questionnaire has been designed to give us information as to how your back pain has affected your ability to manage everyday life. Please answer every section and mark in each section only the ONE box which applies to you at this time. We realize you may consider 2 of the statements in any section may relate to you, but please mark the box which most closely describes your current condition.

1. PAIN INTENSITY

- ☐ I can tolerate the pain I have without having to use pain killers
- ☐ The pain is bad but I manage without taking pain killers
- ☐ Pain killers give complete relief from pain
- ☐ Pain killers give moderate relief from pain
- ☐ Pain killers give very little relief from pain
- ☐ Pain killers have no effect on the pain and I do not use them

2. PERSONAL CARE (e.g. Washing, Dressing)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self care
- ☐ I don't get dressed, I was with difficulty and stay in bed

3. LIFTING

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, i.e. on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

4. WALKING

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me walking more than one mile
- ☐ Pain prevents me walking more than ½ mile
- ☐ Pain prevents me walking more than ¼ mile
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time and have to crawl to the toilet

5. SITTING

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favorite chair as long as I like
- ☐ Pain prevents me from sitting more than one hour
- ☐ Pain prevents me from sitting more than ½ hour
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

6. STANDING

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than one hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

7. SLEEPING

- ☐ Pain does not prevent me from sleeping well
- ☐ I can sleep well only by using medication
- ☐ Even when I take medication, I have less than 6 hrs sleep
- ☐ Even when I take medication, I have less than 4 hrs sleep
- ☐ Even when I take medication, I have less than 2 hrs sleep
- ☐ Pain prevents me from sleeping at all

8. SOCIAL LIFE

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, i.e. dancing, etc.
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

9. TRAVELLING

- ☐ I can travel anywhere without extra pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad, but I manage journeys over 2 hours
- ☐ Pain restricts me to journeys of less than 1 hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from traveling except to the doctor or hospital

10. EMPLOYMENT/ HOME MAKING

- ☐ My normal homemaking/ job activities do not cause pain.
- ☐ My normal homemaking/ job activities increase my pain, but I can still perform all that is required of me.
- ☐ I can perform most of my homemaking/ job duties, but pain prevents me from performing more physically stressful activities (e.g. lifting, vacuuming)
- ☐ Pain prevents me from doing anything but light duties.
- ☐ Pain prevents me from doing even light duties.
- ☐ Pain prevents me from performing any job or homemaking chores.