CHAPTER-5: DISCUSSION

Having excluded the impossible,
whatever remains and unlikely it may be,
that must be the truth.
- Arthur Conan Doyle

5.1 Introduction
This chapter discusses the only most important findings of this study. It provides a detailed discussion on the reliability and validity of Gujarati version of Central Sensitization Inventory and Fear-Avoidance Beliefs Questionnaire. It also discusses the combined and individual effects of McKenzie Exercise Program and Conventional Physiotherapy Program on CNLBP with CS or without CS. In this chapter, an endeavor has been made to discuss the results obtained from the data analyses which are given in Chapter-4. The results have been discussed in the light of hypotheses formulated for the study, theoretical models available on the subject, and the studies already conducted in this regard.

5.2 Cross-Cultural Adaptation Of CSI-G Questionnaire Study
The aim of cross-cultural adaptation of a questionnaire is to achieve equivalence between the original and adapted questionnaire in another language. It is a process of preparing a questionnaire for use in another setting (225).

5.2.1 Discussion of CSI-G Questionnaire Study
The aim of this study was to translate and cross-culturally adapt the CSI into Gujarati and to check content validity, face validity, internal consistency, test-retest reliability, agreement and minimum detectable change (MDC) of CSI-G in CLBP patients. As a first step in analyzing the psychometric validation of the CSI-G, the questionnaire was translated from English into Gujarati and finalized in a consensus meeting including Gujarati-speaking researchers from Surat. In our opinion, the translation into Gujarati was appropriate, since
the data collection did not reveal any confusion or problems mentioned by the participants.

The test-retest reliability showed excellent Cronbach’s α value (0.914) and ICC value (ICC = 0.971) for CLBP patients, which confirms that the CSI-G is a psychometrically robust questionnaire. This study indicates that the CSI-G is a reliable and usable instrument in Gujarati culture. This is in accordance with coefficients described earlier in other studies (238, 245, 246). This is also in conformity with the findings of Mayer et al (247), in which Pearson’s correlation (r =0.82) was used. Pearson’s correlation is a commonly used measure in test-retest reliability assessment, however, it is correct to use the ICC due to its sensitivity to any bias between or among measurement times (248).

Mayer et al (247) used only healthy controls and 5-days of the time interval for test-retest analyses in their study, so it is possible that the consistency of filling out the CSI twice was more compared to CLBP patients. In the present study, a 7-days interval was chosen, thereby reducing the likelihood of remembering the responses given during the first assessment considering the high number of the items and also answers from the first assessment were held back.

The SEM and MDC provide researchers and clinicians with some direction for true changes in the measurement, which is not due to random measurement error. The result showed an MDC of 5.092 points for CSI-G (Scale range 0-100). Scores at or above this MDC value are likely to be due to patient improvement instead of measurement error. Estimated minimal meaningful changes should be greater than the MDC value.

No relevant information could be made out of Part-B of CSI-G as most of the patients found it difficult to understand the labels of diagnosed diseases mentioned in this section. Whoever scored high on Part-A of CSI-G were able to say “yes” to one or more diagnoses of Part-B suggesting this could be an extra sign of CS.
The convergent validity of the CSI-G was supported by the pattern of correlations with the RMDQ-G (r=0.527**, p<0.000), FABQ-G (r=0.455**, p<0.000) and PPT-TA (r=0.172*, p<0.045) in our study. The divergent validity is seen by negative correlation with trunk extensors endurance (r=-0.171*, p<0.045) and trunk flexors endurance (r=-0.273**, p<0.002).

In our study, we found a 6-factor solution from factor analysis of CSI-G. The internal consistency of factors 1, 2, 3 and 4 was good, with Cronbach’s alphas of respectively 0.912, 0.773, 0.782, and 0.728. The Cronbach’s alpha for factor 5 could not be calculated as it has loaded only one item (Item-24) and factor 6 was considered poor with a value of 0.348.

Mayer T G et al (247) found a 4-factors solution for the factor analysis of their original English version of CSI that accounted for 53.4% of the variance in the dataset. The factors were labelled for meaningfulness, and the variance is provided here: (a) Factor 1 – Physical Symptoms (30.9%), (b) Factor 2 – Emotional Distress (7.2%), (c) Factor 3 – Headache/Jaw Symptoms (10.1%), and (d) Factor 4 – Urological Symptoms (5.2%).

Kregel J et al (246) also found a 4-factor solution in their study of Dutch translation of CSI where factor 1 consists of items 2, 6, 8, 9, 17, and 25, and is named “General disability and physical symptoms”; items 4, 7, 10, 13, 18, 19, and 20 load on factor 2 which was named “Higher central sensitivity”; factor 3 consists of items 11, 14, and 21, and is named “Urological and dermatological symptoms”; and Factor 4 consists of items 3, 12, 13, 15, 16, and 17, which is named “Emotional distress”. Items 1, 5, 22, 23, and 24 did not load on any of the factors (i.e. factor loading <0.40) and were dropped from the subsequent confirmatory factor analyses. Pitance L et al (245) found a 5-factor solution for the factor analysis of French translation of CSI. Cuesta-Vargas A I et al (249) found a one-factor solution to be the best fit for the Spanish version of the CSI.
5.2.2 Conclusion of CSI-G Questionnaire Study

Our results suggest that the CSI-G has been successfully translated and cross-culturally adapted from English to Gujarati. The preliminary evidence generated by the psychometric testing showed that the CSI-G demonstrates psychometric properties similar to the English version. This study provides us with the evidence that the CSI-G is a reliable and valid measure to assess CS in Gujarati-speaking CLBP patients. The CSI-G total scores were significantly positively correlated with FABQ-G, PPT-IS, PPT-TA, and RMDQ-G, but were negatively correlated with trunk flexors and extensors endurance scores. The results of factor analyses of 25 items of CSI-G produced a six-factor solution, which accounted for 69.85% of the total variance in the principal component analysis with varimax rotation. Responsiveness of the CSI-G should be evaluated in further studies.

5.3 Cross-Cultural Adaptation of FABQ-G Questionnaire Study

The aim of cross-cultural adaptation of a questionnaire is to achieve equivalence between the original and adapted questionnaire in another language. It is a process of preparing a questionnaire for use in another setting (225, 226).

5.3.1 Discussion of FABQ-G Questionnaire Study

This study describes for the first time the psychometric properties of a cross-cultural translation of the FABQ into Gujarati. In general, all the patients clearly understood the translated version. As a first step in analyzing the psychometric validation of the FABQ-G, the questionnaire was translated from English into Gujarati and finalized in a consensus meeting including Gujarati-speaking researchers from Surat. In our opinion, the translation into Gujarati was appropriate, since the data collection did not reveal any confusion or problems mentioned by the participants. Test-retest reliability was excellent when the FABQ-G was administered twice with a gap of 48-hours in a CLBP sample. The test-retest reliability showed excellent ICC value for CLBP patients (FABQ-G =0.915; FABQ-G-W 0.864 and FABQ-G-PA 0.818), which confirms that the FABQ-G is a psychometrically robust questionnaire. The pain intensity score had a high correlation with FABQ-W (r=0.819; p<0.01),
and with the FABQ-PA (r=0.852; p<0.01) for subjects with CLBP showing good convergent validity with FABQ-G. Item-8 of FABQ was omitted in Gujarati translation as compensation claims for CLBP is not applicable in India.

The close correlations among the items showed that the FABQ-G-W and FABQ-G-PA subscales were internally consistent and similar to the original. Our findings are similar with the Swiss-German (FABQ-W:0.89 & FABQ-PA:0.82)\(^{(250)}\), German (FABQ-Work1:0.89; FABQ-Work2:0.94; & FABQ-PA:0.64)\(^{(251)}\), Portuguese (FABQ-W:0.80 and FABQ-PA:0.90)\(^{(252)}\), Norwegian (FABQ-W:0.90 & FABQ-PA:0.79)\(^{(253)}\), Greek (FABQ-Work1:0.86; FABQ-Work2:0.90; & FABQ-PA:0.72)\(^{(254)}\), Chinese (0.90)\(^{(255)}\) and Spanish result (0.93)\(^{(256)}\).

Test-retest reliability similar to the original scale was indicated by the highly significant correlation between the results obtained at baseline and after 48 hours for the measure as a whole and both subscales. Once again, our findings are similar with the Swiss-German (FABQ-W:0.91 & FABQ-PA:0.83)\(^{(250)}\), German (0.87)\(^{(251)}\), French (FABQ-W:0.88 & FABQ-PA:0.72)\(^{(257)}\), Portuguese (FABQ-W:0.91 & FABQ-PA:0.84)\(^{(252)}\), Norwegian (FABQ-W:0.82 and FABQ-PA:0.66)\(^{(253)}\), Greek (FABQ-Work1:0.93; FABQ-Work2: 0.94; & FABQ-PA:0.85)\(^{(254)}\), Chinese (0.81)\(^{(255)}\) and Spanish results (0.97)\(^{(256)}\).

The FABQ-G was highly acceptable, easily understood, and was found suitable for self-administration. It required approximately 5-6 minutes filling up. Hence it seems to be appropriate in routine clinical practice. Avoidance behavior led by FABs in patients with CLBP leads to the development of chronic disability. In reality, fear-avoidance behavior was shown to be a significant risk factor for chronicity. Hence, encouraging patients to change their beliefs and behaviors has become more crucial in managing CLBP, especially in the early stage. It is important to focus on educating patients regarding pain along with gradual exposure to activities to help reduce pain-related fear; rather than allowing patients believing the imaging reports leading to the development of fear-avoidance behavior. The FABQ helps
clinicians to detect patient’s FABs and helps to establish an effective management plan to prevent CLBP.

This study has few limitations that should be pointed out. First, it was a cross-sectional design, and any significant correlations should not be confused with causal effects; it is possible that pain-related fear leads to increased activity avoidance and disability, but the reverse also may be possible. Longitudinal data may be superior because they could provide a far better understanding of the impact of baseline characteristics, management issues and expectations on FABs. Second, the associations between self-reported beliefs and physical tests were not taken into consideration. In future studies, this may be explored. Third, our study was limited to only CLBP, and it is doubtful whether our result can be generalized to acute or subacute LBP and other complaints of the musculoskeletal system. Hence, this may well be further investigated in future studies.

The exploratory factor analysis (EFA) was used to examine the structure of the FABQ-GR (German version) instead of a confirmatory factor analysis model since the number of possible factors expected was not predetermined from the literature and either a two or a three-factor model was anticipated \(^{(221, 251)}\). Principal component analysis (PCA) modeling identified three distinct factors with salient loadings of the items.

A serious concern in factorial models is the adequacy of sampling, resulting in desired samples consisting of 300 and more subjects \(^{(232)}\). Although in this study, only 128 subjects participated, the factors identified which had more than 0.4 factor loadings above Eigenvalues>0.6 (Table-4.10), confirming a reliable model regardless of sample size \(^{(258)}\). Therefore, it can be argued that the 3-factor model, as established in this study, is statistically sound and acceptable for use.

The convergent validity of the FABQ was supported by the pattern of correlations with the RMDQ-G \((r=0.514, p<0.000)\) and CSI-G \((r=0.455,\)
p<0.000) in our study. The divergent validity is seen by negative correlation with trunk flexors endurance (r= -0.266, p<0.002).

5.3.2 Conclusion of FABQ-G Questionnaire Study
Our results suggest that the FABQ-G has been successfully translated and cross-culturally adapted from English to Gujarati. The preliminary evidence generated by the psychometric testing showed that the FABQ-G shows psychometric properties similar to the English version. This study provides us with the evidence that the FABQ-G is a reliable and valid measure to assess ‘fear avoidance beliefs’ in Gujarati-speaking CLBP patients and results of FABQ-G can be compared to international studies using other translated versions. The reasonable validity and reliability of the 3-factor FABQ-G shown in this study make it appropriate for clinical use with Gujarati CLBP patients.

5.4 Comparison of ‘McKenzie Exercise Program’ and ‘Conventional Physiotherapy Program’ in CNSLBP with or without Central Sensitization
The study was done on 128 subjects, 64 in each group. The mean age and BMI of the subjects in control group were 41.12±7.76 years and 24.72±2.76 Kg/m² respectively, while in the experimental group were 41.33±7.27 years and 24.88±2.97 Kg/m² respectively. The gender distribution in control group was 44% males and 53.8% females; while in the experimental group were 56% males and 46.2% females. Also, the groups were similar at baseline for all outcome measures with p-value > 0.05 (Table-4.11).

The main objective of the study was to determine the efficacy of ‘McKenzie exercise program’ over ‘conventional physiotherapy program’ by using outcome measures NPRS for pain, CSI-G for central sensitization, PPT-IS&PPT-TA for pressure pain threshold, RMDQ-G for disability, FABQ-G for fear-avoidance beliefs and GROC for satisfaction from treatment.

Primary objectives were to find the presence of CS in CNSLBP patients in terms of, those who display higher CS scores on CSI-G; and those who
display lower pressure pain thresholds (PPT) by pressure algometry and to identify the proportion of patients with CNSLBP experiencing central sensitization in terms of severity classification given by Neblett et al (244) by using CSI-G. Also literature was reviewed for description of presence of CS in chronic low back pain patients in previous studies. The secondary objectives were to find the relationship of CS with fear avoidance beliefs and disability.

The result of study which was done to test the central sensitization in CNSLBP population along with an objective to review the literature to examine the extent of sub-grouping and targeted treatment if anything previously revealed that there were subgroups of patients based on the severity of CSI scores according to Neblett et al (244). In the present study, almost 90.6% and 75% patients in experimental group and control group respectively had mild to extreme level of CS severity (Table-4.12). When the pressure pain threshold (PPT) is examined in both the experimental and control group mean scores were low; and which is near to 5.03 Kg/cm\(^2\) and 5.47 Kg/cm\(^2\) respectively also indicated the presence of CS in CNSLBP.

The tenability of the hypotheses observed for all the outcome measures of the study are as follows:

### 5.4.1 Central sensitization

The present study relates to the problem of CNSLBP in subjects and investigates the research question: **Is McKenzie exercise program more effective for reduction of central sensitization in CNSLBP patients in comparison to available conventional physiotherapy program?**

Table-4.13, Table-4.14, and Graph-4.7 show the recovery patterns of central sensitization scores of both the groups from baseline to 4\(^{th}\) week and from 4\(^{th}\) week to 8\(^{th}\) week. The subjects in experimental group receiving McKenzie exercise program (blue line) showed better recovery at 4\(^{th}\) week and 8\(^{th}\) week compared to conventional physiotherapy program (red line). The control group also recovered on central sensitization score, but it was significantly less than the experimental group. This central sensitization score was measured by
validated Gujarati version of central sensitization inventory (CSI-G). The original CSI was developed and validated by Mayer Tom G. et al \(^{(247)}\) on fibromyalgia, chronic widespread pain, regional CLBP, and a normative control group of patients. The psychometric strength of CSI to detect the CS related symptoms was excellent in above-mentioned patient groups. Hence in our study, we translated and validated the CSI in the Gujarati language to use with Gujarati population. In our study, in experimental group 78.1% patients have detected with central sensitization of varying severity and in control group, it was 64.1% patients, who had symptoms of CS. As CSI is inexpensive, it can very well be used to detect the presence of CS in chronic low back pain cases and patients can be sent towards more appropriate non-pharmacological treatments like manual therapy (e.g. McKenzie therapy) and pharmacological treatments like use of dual reuptake inhibitors which targets descending central pathways by enhancing serotonin and nor-epinephrine levels, resulting in decreased CS-related pain\(^{(259)}\).

In our study, we were successful to establish the existence of CS among CNSLBP patients to varying degrees by means of CSI-G scores and low-pressure pain threshold among CLBP patients who are having CSI-G scores above 40. Similarly, Giesecke T et al. \(^{(24)}\) have reported that patients with CLBP having CS experienced significantly more pain and showed more extensive, common patterns of neuronal activation in pain-related cortical areas. This may explain why some CLBP patients are having disproportionate pain irrespective of their actual pathology has already healed. The reason is probably the occurrence of augmented central pain processing in patients with CLBP.

There is not enough literature available regarding the use of this CSI, especially in the chronic low back pain cases. In future when more studies are conducted with this CS inventory, we might get a deeper insight into the functioning of CSI.

On the basis of above discussion, it can be stated that \textbf{H1: McKenzie exercise program is more effective for reduction of central sensitization}
scores on CSI-G in CNSLBP patients in comparison to available conventional physiotherapy program.

5.4.2 Pain
The present study relates to the problem of CNSLBP in subjects and investigates the research question: Is McKenzie exercise program more effective for reduction of pain in CNSLBP patients in comparison to available conventional physiotherapy program?

Table-4.13, Table-4.14, and Graph-4.8 show the recovery patterns of NPRS scores of both the groups from baseline to 4\textsuperscript{th} week and from 4\textsuperscript{th} week to 8\textsuperscript{th} week. The subjects in experimental group receiving McKenzie exercise program (blue line) showed better recovery at 4\textsuperscript{th} week and 8\textsuperscript{th} week compared to conventional physiotherapy program (red line). It is pertinent to note that recovery from pain was better during the 4\textsuperscript{th} week to 8\textsuperscript{th} week in the experimental group than with from baseline to 4\textsuperscript{th} week. Although control group also recovered on pain score; but it was significantly less than the experimental group.

Schnebel, Watkins, and Dillin \(^{(260)}\) suggested that the positive results associated with McKenzie approach might be related to activation of the gate control mechanisms or relaxation and/or decompression of neural tissues. DeRosa and Porterfield \(^{(261)}\) believed that the application of controlled forces to the spine through active exercise or manual techniques might temporarily reduce pain levels by altering the fluid dynamics of injured tissue. DeRosa and Porterfield \(^{(261)}\) proposed that the stimulation of arterial, venous and lymphatic drainage or mechanoreceptors stimulation with subsequent increased afferent input to the central nervous system might result in pain modulation and inhibition of hypertonic muscles.

In a study by Petersen T et al \(^{(115)}\) concluded that at the end of two months treatment there was no significant difference in pain scores of McKenzie group and intensive strength training group; but pain scores were consistently lower with McKenzie group, which indicates that McKenzie treatment method
has potential to treat chronic back pain. Petersen T et al (115) had accepted that the high dropout rate of patients is a drawback of their study.

Mbada et al. (262) concluded that pain is the major problem of long-term LBP and it results in deconditioning of the musculoskeletal system leading to stiffness, loss of motion, cartilage degeneration, muscular inhibition, fear-avoidance behavior, and muscle atrophy (263). Like a vicious cycle, the deconditioning syndrome may also precipitate and perpetuate pain which results in recurrent or acute-on-chronic LBP. Pain leads to muscle guarding of all movements in the affected region, disuse leads to muscular atrophy, which in turn results in weakness (263). The weakness, therefore, may be secondary to inhibition caused by the noxious stimuli caused by pain (263). The movement component of McKenzie exercise program as used in this study may have resulted in reconditioning of the patients by making them expand the limits to their physical functioning, and enhance their pain control ability.

On the basis of above discussion, it can be stated that H1: McKenzie exercise program is more effective for reduction of pain in CNSLBP patients in comparison to available conventional physiotherapy program.

5.4.3 Pressure Pain Threshold (Segmental and Extra-segmental)
The present study relates to the problem of CNSLBP in subjects and investigates the research question: Is McKenzie exercise program more effective for increasing pressure pain threshold over infraspinatus (extra-segmental) and tibialis anterior (segmental) in CNSLBP patients in comparison to available conventional physiotherapy program?

Table-4.13, Table-4.14, Graph-4.9 (PPT-IS) and Graph-4.10 (PPT-TA) show the recovery patterns of pressure pain threshold scores of both the groups from baseline to 4th week and from 4th week to 8th week. The subjects in experimental group receiving McKenzie exercise program (blue line) showed better recovery at 4th week and 8th week compared to conventional physiotherapy program (red line). The control group also recovered on central
sensitization score, but it was significantly less than the experimental group. Here, it is pertinent to note that recovery pattern of PPT was better during the 4th week to 8th week in the experimental group than with from baseline to 4th week for both PPT-IS and PPT-TA. This indicates that PPT recovers slowly over a period of two months to reach their normal or near normal level of sensitivity in CNSLBP patients.

Imamura M et al (264) showed that individuals with CLBP have lower PPT values than healthy individuals in almost all assessed structures and they proposed an approach that can differentiate patients with CLBP whose CS in the painful area should be further examined. However, Meeus M et al (174) did not find lower PPT values in CLBP patients in their study (n=21CLBP patients). This could be due to small sample size off CLBP patients. Imamura M, Alfieri FM, Filippo TR, and Battistella LR (265) in their study showed that most PPT values are correlated to the VAS and the Roland Morris Disability Questionnaire for LBP.

Şenay Özdolap, Selda Sarikaya, and Füruzan Köktürk (266) in their study showed that patients with CLBP have significantly lower PPT values at every individual site compared with healthy controls and their result suggests that widespread pain should be taken into account in the evaluation of patients with CLBP.

O'Neill S, Manniche C, Graven-Nielsen T, and Arendt-Nielsen L (173) in their study with a group of patients with CLBP (n=12) with intervertebral disc herniation demonstrated that PPT was lower in the anterior tibialis muscle compared to controls (n=12) and hence concluded that these patients should be investigated for generalized deep-tissue hyperalgesia suggesting presence of CS.

Farasyn A and Meeusen R (267) investigated the PPTs with respect to the Erector spinae and the hip muscles in 87 patients with subacute non-specific LBP. They found that the mean PPT values of the Erector spinae and the hip
at all examined points of the LBP group were a significantly lower in comparison to the PPT values of the healthy group.

There was a paucity of literature which directly shows the effect of physiotherapy or manual therapy methods to deal with reduced PPT. In this study, an attempt is made to demonstrate the effect of McKenzie exercise program to deal with CS in terms of changes in PPT.

On the basis of above discussion, it can be stated that H1: McKenzie exercise program is more effective for increasing both PPT-IS and PPT-TA scores in CNSLBP patients in comparison to available conventional physiotherapy program.

5.4.4 Roland Morris Disability Questionnaire for Low Back Pain

The present study relates to the problem of CNSLBP in subjects and investigates the research question: *Is McKenzie exercise program more effective for reduction of disability in terms of RMDQ-G in CNSLBP patients in comparison to available conventional physiotherapy program?*

Table-4.13, Table-4.14, and Graph-4.11 show the recovery patterns of RMDQ-G scores of both the groups from baseline to 4\textsuperscript{th} week and from 4\textsuperscript{th} week to 8\textsuperscript{th} week. The subjects in experimental group receiving McKenzie exercise program (blue line) showed better recovery at 4\textsuperscript{th} week and 8\textsuperscript{th} week compared to conventional physiotherapy program (red line). The control group also recovered on central sensitization score, but it was significantly less than the experimental group. It is pertinent to note that recovery from disability was better during the 4\textsuperscript{th} week to 8\textsuperscript{th} week in the experimental group than with from baseline to 4\textsuperscript{th} week.

The Roland-Morris Disability Questionnaire (\cite{219, 220}) is most sensitive to patients with mild to moderate disability due to acute, sub-acute or chronic low back pain. There are different questionnaires available, which differ from each other in the number of statements: 24-, 18- and 11-item questionnaire. The
score ranges from 0 (no disability) to 11, 18 or 24 (maximum disability) depending on the questionnaire that is used.

Miller E.R. (127) in their RCT compared a specific spine stabilization program with the McKenzie approach for CLBP patients and found that McKenzie group improved only in short form McGill Questionnaire and stabilization group improved on pain scores and straight leg raise range. In between group comparison, the functional status questionnaire (FSQ) revealed no statistical difference. But in our study pain scores, RMDQ-G scores (disability) were better with McKenzie exercise program. The difference in results can be attributed to small sample size and very wide age range (19-87 years) of patients in Miller’s study could be termed as confounding factors.

Paatelma M et al. (268) examined the effects of orthopedic manual therapy (OMT) and McKenzie method compared with one counseling session with a physiotherapist with “advice-only to stay active” for treating LBP/leg pain and disability. Paatelma M et al. (268) concluded that the OMT and McKenzie methods seemed to be only slightly more effective than was one session of assessment and advice-only. This conclusion was based on one year follow up and it is natural that at one-year follow-up the difference between treatments groups is expected to be minimal. However, our study is significantly favoring McKenzie exercise at 1-month and 2-month follow-up i.e. at the short term.

On the basis of above discussion, it can be stated that H1: McKenzie exercise program is more effective for reducing disability scores on RMDQ-G questionnaire in CNSLBP patients in comparison to available conventional physiotherapy program.

5.4.5 Fear-avoidance Beliefs Questionnaire-Gujarati for Low Back Pain
The present study relates to the problem of CNSLBP in subjects and investigates the research question: Is McKenzie exercise program more effective for reduction of fear-avoidance beliefs in terms of FABQ-G in
CNSLBP patients in comparison to available conventional physiotherapy program?

Table-4.13, Table-4.14, and Graph-4.12 show the recovery patterns of FABQ-G scores of both the groups from baseline to 4th week and from 4th week to 8th week. The subjects in experimental group receiving McKenzie exercise program (blue line) showed better recovery at 4th week and 8th week compared to conventional physiotherapy program (red line). The control group also recovered on central sensitization score, but it was significantly less than the experimental group. It is pertinent to note that recovery from disability was better during the 4th week to 8th week in the experimental group than with from baseline to 4th week.

Al-Obaidi SM, Al-Sayegh NA, Ben Nakhi H, and Al-Mandeel M (269) in their study showed that McKenzie intervention reduced pain and related fear and disability beliefs and improved physical performances in individuals with CLBP. George SZ, Bialosky J E, and Donald D A (270) predicted that higher the fear avoidance beliefs about work and absence of centralization phenomenon leads to higher level of disability in acute low back pain patients after 6-months. Mbada CE, Ayanniyi O and Ogunlade SO (271) found in their study that McKenzie Protocol alone, or in combination with static or dynamic back extensors endurance exercise reduces Fear avoidance beliefs (FAB) in patients with LBP.

On the basis of above discussion, it can be stated that H1: McKenzie exercise program is more effective for reducing fear-avoidance beliefs on the FABQ-G questionnaire in CNSLBP patients in comparison to available conventional physiotherapy program.

5.4.6 Trunk Flexors and Extensor Endurance
The present study relates to the problem of CNSLBP in subjects and investigates the research question: Is McKenzie exercise program more effective for improving ‘trunk flexors endurance’ and ‘trunk extensors
endurance’ scores in CNSLBP patients in comparison to available conventional physiotherapy program?

Table-4.13, Table-4.14, Graph-4.15 and Graph-4.16 show the recovery patterns of ‘trunk flexors endurance’ and ‘trunk extensors endurance’ scores of both the groups from baseline to 4th week and from 4th week to 8th week. The subjects in experimental group receiving McKenzie exercise program (blue line) showed less recovery at 4th week and 8th week compared to conventional physiotherapy program (red line). The experimental group also recovered on flexors and extensors endurance score, but it was significantly less than the control group. It is pertinent to note that recovery for flexors and extensors endurance was better during the 4th week to 8th week in the control group than with from baseline to 4th week.

Browder DA et al (272) in their multicenter RCT examined the effectiveness of an extension-oriented treatment approach (n=26) or a strengthening exercise program (n=22) in a subgroup of LBP whose pain was centralizing with extension movements. Their study showed that the extension-oriented treatment approach is more effective than the strengthening exercise program for reducing disability and pain. The weakness of this study may be small sample size and they did not take an outcome measure which accounts for trunk strength.

In our study, we measured trunk flexors and extensors endurance and found that it improves better in the control group, which is in accordance with ‘Specific adaptation to imposed demands principle’.

On the basis of above discussion, it can be stated that H1: McKenzie exercise program is less effective for improving ‘trunk flexors endurance’ and ‘trunk extensors endurance’ scores in CNSLBP patients in comparison to available conventional physiotherapy program.
5.4.7 Global Rating of Change Scale

The present study relates to the problem of CNSLBP in subjects and investigates the research question: *Is McKenzie exercise program more effective for demonstrating the global rate of change score in CNSLBP patients in comparison to available conventional physiotherapy program?*

In our study, the experimental group showed more positive changes in GROC scores than the experimental group (Table-4.18). GROC is a 15-point scale is used as described by Jaeschke R, Singer J, and Guyatt GH (273), and this scale requires the patient to rate the degree of change in his or her condition or to rate their own perception of improved function from the beginning of treatment to the present. The midpoint of the scale is no change (0). Ratings from -1 to -7 represent varying degrees of a worsening of the patient’s condition, whereas rating from +1 to +7 represent varying degrees of improvement.

At the end of 8th-week evaluation, the experimental group had significantly ($t=12.05$, $p<0.000$) greater improvements based on the GROC measure (mean ± SD, +6.63±0.58) as compared to the control group (+4.5±1.21). A cut-off score of +4 indicates significant improvement on GROC score in both the groups but experimental group fared significantly better.

In a study by Halliday MH et al (274) subjects reported a little better sense of perceived recovery with the McKenzie method than with the motor control method. Machado LAC et al (275) concluded in their study of acute LBP treated with McKenzie method does not produce appreciable additional short-term improvements in *global perceived effect*. But our study showed better outcome on GROC when treated with McKenzie exercise program.

On the basis of above discussion, it can be stated that **H1: McKenzie exercise program is more effective for improving the global rating of**
change scores in CNSLBP patients in comparison to available conventional physiotherapy program.

5.4.8 Efficacy of McKenzie Exercise Program

The minimum detectable change for CSI-G was 5.09 points on a total of 100 points scale. Considering this, a calculation of the percentage of patients benefitted for 5, 10, 15 and 20 points as the difference on a scale of a total of 100 points for CSI-G (Table-4.20). The number needed to treat (NNT- for benefit) calculation revealed that for a small difference (5 points) 30 patients would be treated to produce an effect in one patient for McKenzie exercise program and that for a large difference (20 points), it was only 2 patients. The efficacy of McKenzie program was also more than 82% for any of the difference ranging from 5-20 points. The study result also revealed that CSI-G had a moderate positive correlation with fear-avoidance beliefs and disability scores, which indicates that the CSI-G questionnaire would reflect the convergence of the symptoms of CNSLBP patients along with these scales (235).

5.4.9 How does McKenzie exercise program work to reduce CS?

Hypothetically exercise may activate the endogenous analgesia in the process of managing central sensitization (276). Hence the clinicians prefer the contingent approach in treating patients with OA and central sensitization. Even though the pain does not cease and the patient adheres to the predetermined exercise modalities may interpret pain increases as non-threatening (277). A pilot RCT by Sterling M et al (278) concluded that lateral glide applied to the cervical spine as manual therapy may be effective in reducing sensory hyperexcitability (nociceptive flexion reflex). However, the short-term analgesic effects of manual therapy limit its use for desensitizing the CNS. But increasing the frequency manual therapy sessions may result in long-term activation of descending anti-nociceptive pathways. In our study, McKenzie exercise is a patient-operated manual therapy which may explain its effects on CS on the line of activation of descending anti-nociceptive pathways. Bialosky J. E. et al(279) in their study demonstrated that inhibition of
Aδ fiber–mediated pain perception was similar for all the subgroups of LBP patients. However, inhibition of temporal summation was observed only in participants receiving manipulative therapy.

Jo Nijs et al (280) in their professional article described central sensitization as the development of more excitatory synapses. Such brain mechanisms are identical to those seen in learning and memory. To treat this altered brain mechanisms in pain problem they suggested *cognition-targeted exercise therapy*; the goal is to replace the old and maladaptive movement-related pain memories (systematic desensitization). The graded approaches of McKenzie exercise program may work as a systemic technique. Moreover, the anti-CS effect is by influencing neurotrophic factors. A habitual and regular exercise, in contrast to temporary exercise, increases Brain-derived neurotrophic factor (BDNF) in blood levels (281). A study in humans with osteoarthritis, a chronic pain disorder characterized by central sensitization, provides preliminary evidence that manual joint mobilization provides widespread analgesia (282). Hence, the reduction in pain and disability in the McKenzie group of CNSLBP patients might have been enhanced.

Nijs J. et al (276) in their narrative review stated that exercise activates endogenous analgesia in healthy subjects. The increased pain threshold following exercise is due to the liberation of endogenous opioids and activation of supraspinal nociceptive inhibitory mechanisms directed by the brain. But, many musculoskeletal conditions have shown the disturbed functioning of endogenous analgesia system in response to exercise in chronic pain patients. Generally, muscle contractions activate generalized endogenous analgesia in healthy, pain-free subjects and patients with rheumatoid arthritis or osteoarthritis, but in fibromyalgia patients, it results in increased pain sensitivity. Hence, it may be prudent not to exercise at high intensity but rather at a mild or low intensity which is comfortable to CS patients.

Smith Ashley et al (283) in their study showed increases in PPT at exercising (leg) and non-exercising (neck) body parts in subjects with whiplash
associated disorders and pain-free controls after the isometric exercise condition, but not after the aerobic bicycling exercise. This may explain how the repetitive isometric hold of lower back in flexion or extension is useful in reducing CS in our study.

It is well known that strength training is important for protecting and stabilizing joints and other body tissues, it is also well known that exercise has analgesic effects, particularly isometric exercise. With isometric contraction, the significant decrease in sensitivity to noxious stimulus occurs after low-intensity contractions (25–50% MVC) held for a longer duration \(^{(284)}\). This may be the reason that in our study control group also showed improvement in CS and PPT scores after treatment. It is recommended that strength training should be progressed slowly in a very graded manner.

### 5.4.10 Precautions in applying Manual Therapy and Therapeutic exercise

It is observed that manual therapy and therapeutic exercise, in general, exert hypoalgesia by activating descending inhibitory pain mechanisms \(^{(285, 286)}\). But in subjects with central sensitization, the reverse may also occur; exercise \(^{(287)}\) and potentially manual therapy may induce hyperalgesia if not well controlled. In reality, aggressive exercise or manual therapy in an ‘acute on chronic’ stage of CNSLBP may be detrimental if excessive or forceful movements trigger sensitize peripheral nociceptors and cause increased or prolonged pain. This flare response may happen through mechanisms of neurogenic inflammation where inflammatory mediators such as Substance P and calcitonin gene-related peptide (CGRP) are released into the periphery and promote pain and chronic inflammation \(^{(288)}\). Further, patients of CNSLBP with CS may experience greater exercise-induced hypoalgesia with lower intensity exercise. Physiotherapists must be skilled enough at discriminating and interpreting patient symptoms during treatment programs through consecutive reassessment.
5.4.11 Clinical Application

The present study may have important clinical implications because it provides preliminary support for using McKenzie exercise program that may work well with conventional physiotherapy program. Specifically, the present study strongly suggests that clinicians who aim to reduce CS, pain, reduce disability and fear avoidance beliefs during the treatment of non-specific chronic low back pain should consider McKenzie exercise program along with conventional physiotherapy program.

Central sensitization inventory - Gujarati version and Fear-avoidance beliefs questionnaire - Gujarati version is recommended in future research to detect the presence of CS and fear avoidance beliefs in musculoskeletal pain patients. As the usage of these questionnaires increases in musculoskeletal pain research in future may lead to its further refinement.

5.5 LIMITATIONS

Every research work is subjected to certain limitations and this study is also not different. Though the present study supported the hypotheses formulated in the Chapter-2, still there are some limitations observed in the study, which should be highlighted to help the researchers planning similar studies in future. Despite our best efforts, the present study has the following limitations:

(a) Data collection by an independent observer was not used.
(b) Patients may have answered questionnaires to please the researcher.
(c) Gender wise patient’s distribution in both groups was not equal. A greater number of females were assigned to the study compared with males in both the treatment groups. This gender imbalance may have biased the outcomes.
(d) The sample of the study covers only subjects from Surat, the southern part of Gujarat. For the sake of generalization of results, it would be more appropriate if the sample includes subjects from various parts of the country.
(e) As the elderly participants were not present in the sample, thus, the results cannot be generalized.
(f) One limitation of our study was not blinding the therapists and patients to the treatment allocation and this could be considered as a limitation of the study because of the risk of a possible preference bias due to differing in expertise.

(g) Moreover, we did not include a non-treatment or placebo control group in our study, which also can be considered as a limitation. The rationale for not including a non-treatment group in our study is based on a Cochrane review that investigated the effect of exercise therapy in patients with CLBP \(^\text{(79)}\) which concluded that exercise therapy is at least 10 points (on a scale of 0–100 points) more effective than no treatment.

(h) Although we used precisely translated and validated questionnaires we suspect that the population from Gujarat may have a different understanding of pain concepts and to what degree this would influence our study is not clear.

5.6 FURTHER RECOMMENDATIONS

(a) The long-term benefits of this treatment protocol could be established.

(b) This study can be done with other sub-populations of chronic low back pain.

(c) McKenzie exercise program along with trunk flexors and extensors endurance exercises can be evaluated by comparing with conventional physiotherapy program.

(d) The future study may include heterogeneous samples from larger populations and different zones of the country.

(e) Elderly subjects could be included in future research, for generalization of outcome.

(f) It is further suggested that only two groups should form the future study, one receiving McKenzie exercise program (experimental group) and the other only placebo (control group).

(g) The algometer used in the present study was manually operated. Using digital algometer could be an important improvement for recording PPT and minimizing the human error.

(h) A long-term follow-up (more than one year) study can be done in order to illustrate which treatment approach is more effective in long-term.