CHAPTER – 3

3.1: Literature for Spinal manipulation:

3.1.1, Standaert CJ (2011) et al conducted a study on “Comparative effectiveness of exercise, acupuncture, and spinal manipulation for low back pain” at University of Washington, USA to compare the structured exercise program, SMT, or acupuncture in patients with chronic LBP. The studies identified indicate that structured exercise and SMT appear to offer equivalent benefits in terms of pain and functional improvement. There is insufficient evidence to comment on the relative benefit and cost effectiveness of acupuncture compared with either structured exercise or SMT or structured exercise, SMT, or acupuncture for specific subgroups of individuals with chronic LBP.181

3.1.2, Konitzer LN (2011) et al conducted a study on “Investigation of abdominal muscle thickness changes after spinal manipulation in patients who meet a clinical prediction rule for lumbar stabilization” at Womack Army Medical Center, Fort Bragg, USA to investigate changes in abdominal muscle thickness with ultrasound imaging, after SMT, in patients with low back pain (LBP). 19 patients with LBP were undergone NPRS and ODI data were also collected. The results provide preliminary evidence that TrA and IO muscle resting and contracted thicknesses do not change post-SMT in patients with LBP in the LSE subgroup. In addition, while reductions in pain and disability were noted, they were not clinically meaningful.182

3.1.3, Bronfort G (2011) et al conducted a study on “Supervised exercise, spinal manipulation, and home exercise for chronic low back pain: a randomized clinical trial” at Northwestern Health Sciences University, Bloomington to assess the relative efficacy of supervised exercise, spinal manipulation, and home exercise for the treatment of CLBP. Supervised trunk exercise were most satisfied with care and improve trunk muscle endurance and strength, but they did not significantly differ from those receiving chiropractic spinal manipulation or home exercise in terms of pain and other patient-rated individual outcomes, in both the short- and long-term. For CLBP, supervised exercise was significantly better than spinal manipulation and home exercise in terms of satisfaction with treatment and trunk muscle endurance and strength.183
3.1.4, Clark BC (2011) et al conducted a study on “Neurophysiologic effects of spinal manipulation in patients with chronic low back pain” at Ohio University, USA to determine whether SM alters the amplitude of the MEP or the short-latency stretch reflex of the erector spinae muscles, and whether these physiologic responses depend on whether SM causes an audible joint sound. SM did not alter the erector spinae MEP amplitude in patients with LBP or in asymptomatic controls. Similarly, SM did not alter the erector spinae stretch reflex amplitude in patients with LBP or in asymptomatic controls. Findings suggest that a single SM treatment does not systematically alter corticospinal or stretch reflex excitability of the erector spinae muscles.\(^{184}\)

3.1.5, Rubinstein SM (2011) et al conducted a study on “Spinal manipulative therapy for chronic low-back pain: an update of a Cochrane review” at VU University Medical Center, The Netherlands to assess the effects of spinal manipulative therapy (SMT) for chronic low-back pain. Study included 26 RCTs. There is a high-quality evidence that SMT has a small, significant, but not clinically relevant, short-term effect on pain relief and functional status in comparison with other interventions. There is varying quality of evidence that SMT has a significant short-term effect on pain relief and functional status when added to another intervention. High-quality evidence suggests that there is no difference between SMT and other interventions for reducing pain and improving function in patients with chronic low-back pain.\(^{185}\)

3.1.6, Bicalho E (2010) et al conducted a study on “Immediate effects of a high-velocity spine manipulation in paraspinal muscles activity of nonspecific chronic low-back pain subjects.” at The Pontifical Catholic University of Paraná, Brazil to analyze the immediate effects of high-velocity spine manipulation on paraspinal activity during flexion-extension trunk movements. 40 nonspecific CLBP patients were randomized into two groups, manipulation (n = 20) and control (n = 20). While the manipulation group received high-velocity spine manipulation at the L4-L5 level, the control group remained lying in the same position. EMG surface signals from the right and left paraspinal muscles (L5-S1 level) were acquired during trunk flexion-extension cycles. The results suggest that a high-velocity spinal manipulation is able to acutely reduce abnormal EMG activity during the full-flexion static phase and activation during the extension phase.\(^{186}\)
3.1.7, Richard A (2010) et al conducted a study on “Inflammatory response following a short-term course of chiropractic treatment in subjects with and without chronic low back pain” at Université du Québec à Montréal, Canada to observe the responses of inflammatory markers (IL-6 and CRP) after a series of 9 chiropractic spinal manipulations. 21 participants were assigned. Treatment group received 9 chiropractic interventions. Mediators of inflammation were modified by the intervention received in the treatment group, and the effect size demonstrated a tendency toward the control group. Total of 9 chiropractic spinal manipulations caused the mediators of inflammation to present a normalization response in individuals suffering from chronic LBP.\textsuperscript{187}

3.1.8, Ianuzzi A (2010) et al conducted a study on “Validation of the cat as a model for the human lumbar spine during simulated high-velocity, low-amplitude spinal manipulation” at Stony Brook University, USA to determine the relationship between human and cat lumbar spines during HVLA-SM. Cat lumbar spine were mechanically tested and joint kinematics and FJC strain were measured optically. Human FJC strain and kinematics data were taken from a prior study. Joint kinematics in cat spines was greater in magnitude compared with humans. Human spines, site-specific HVLA-SM produced regional cat FJC strains at distant motion segments. Regression relationships demonstrated that species, HVLA-SM site, and interactions thereof were significantly and moderately well correlated for HVLA-SM that generated tensile strain in the FJC.\textsuperscript{188}

3.1.9, Bialosky JE (2010) et al conducted a study on “The relationship of the audible pop to hypoalgesia associated with high-velocity, low-amplitude thrust manipulation: a secondary analysis of an experimental study in pain-free participants” at University of Florida, USA to observe the influence of the Audible Pop (AP) on hypoalgesia associated with HVLA manipulation. 40 participants underwent thermal pain sensitivity testing. Participants received HVLA manipulation to their low back. Repeated-measure ANOVAs were used to observe changes in pain sensitivity before and immediately after HVLA manipulation. The study suggests hypoalgesia is associated with HVLA manipulation and occurs independently of a perceived AP. Inhibition of lower extremity temporal summation may be larger in individuals in whom an AP is perceived, but further study is necessary to confirm this finding.\textsuperscript{189}
3.1.10, Cecchi F (2010) et al conducted a study on “Spinal manipulation compared with back school and with individually delivered physiotherapy for the treatment of chronic low back pain: a randomized trial with one-year follow-up” at Fondazione Don Carlo Gnocchi, Italy to compare spinal manipulation, back school and individual physiotherapy in the treatment of CLBP. (n = 210) RMDQ and Pain Rating Scale were assessed. Spinal manipulation was associated with higher functional improvement and long-term pain relief than back school or individual physiotherapy. Pain recurrences and drug intake also reduced compared to back school or individual physiotherapy. Spinal manipulation provided better short and long-term functional improvement, and more pain relief in the follow-up than either back school or individual physiotherapy.  

3.1.11, Bialosky JE (2009) et al conducted a study on “Spinal manipulative therapy has an immediate effect on thermal pain sensitivity in people with low back pain: a randomized controlled trial” at University of Florida, USA to assess the immediate effects of SMT on thermal pain perception in people with LBP. 36 people were included. Result indicated significant hypoalgesia in SMT group, but not in those low back extension exercises. Psychological factors did not significantly correlate with changes in temporal summation in participants who received SMT. Inhibition of A-delta fiber-mediated pain perception was similar for all groups. However, inhibition of temporal summation was observed only in participants receiving SMT, suggesting a modulation of dorsal horn excitability that was observed primarily in the lumbar innervated area.  

3.1.12, Hondras MA (2009) et al conducted a study on “A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with sub acute or chronic low back pain” at The Center for Chiropractic Research, USA to compare the effects of 2 biomechanically distinct forms of SM and minimal conservative medical care. 105 women and 135 men without significant co morbidities. There were no significant differences between LVVA-SM and HVLA-SM at any of the end points. Biomechanically distinct forms of SM did not lead to different outcomes in older LBP patients and both SM procedures were associated with small yet clinically important changes in functional status by the end of treatment for this relatively healthy older population.
3.1.13, Chou R (2007) conducted a study on “Non pharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline” at the American Pain Society, USA to assess benefits and harms of non pharmacologic therapies for acute or chronic LBP. Systematic reviews and randomized trials of 1 or more of the preceding therapies for low back pain that reported pain outcomes, back-specific function, general health status, work disability, or patient satisfaction. Therapies with good evidence of moderate efficacy for chronic or sub acute low back pain are cognitive-behavioral therapy, exercise, spinal manipulation, and interdisciplinary rehabilitation. For acute low back pain, the only therapy with good evidence of efficacy is superficial heat.193

3.1.14, Fritz JM (2006) et al conducted a study on “Does the evidence for spinal manipulation translate into better outcomes in routine clinical care for patients with occupational low back pain? A case-control study” at University of Utah, USA by review on patients with low back pain of less than 16 days duration was examined and categorized as having received thrust manipulation, non thrust manipulation, or no manipulation. Thrust manipulation was received by 107 patients; 36 received non thrust manipulation and 72 received no manipulation. Patients receiving manipulation (thrust or non thrust) experienced greater reductions in pain and disability with treatment. Patients receiving thrust manipulation had fewer sessions, a shorter length of stay, and lower costs in physical therapy than patients receiving non thrust manipulation.194

3.1.15, David W (2006) et al conducted a study on “A biomechanical model for mechanically efficient cavitations production during spinal manipulation: pre thrust position and the neutral zone” at School of Health and Rehabilitation, Keele University, Staffordshire, UK. Biomechanical factors that facilitate mechanically efficient cavitation production during manipulation have been explored, and a revision of the conceptual and kinematic model has been proposed. Central to this model, mechanically efficient cavitation production during manipulation requires a pre thrust position, in which the target joint is ideally positioned into its own neutral zone motion region, thus maximizing the efficiency of the manipulation. Future research is needed to test this model.195
3.1.16, Steven Z (2006) et al conducted a study on “**Immediate effects of spinal manipulation on thermal pain sensitivity: an experimental study**” at University of Florida, USA on asymptomatic subjects (n = 60). Hypoalgesia from spinal manipulation was observed in lumbar innervated areas, but not control areas. Spinal manipulation hypoalgesia for A-delta fiber mediated pain perception did not differ from stationary bicycle and lumbar extension (p > 0.05). Spinal manipulation hypoalgesia for C-fiber mediated pain perception was greater than stationary bicycle riding, but not for lumbar extension (p = 0.105). Local dorsal horn mediated inhibition of C-fiber input is a potential hypoalgesic mechanism of spinal manipulation for asymptomatic subjects.\(^{196}\)

3.1.17, John D. Childsa (2006) et al conducted a study on “**A perspective for considering the risks and benefits of spinal manipulation in patients with low back pain**” at US Army-Baylor University, USA to determine patients who do not receive manipulation are at an increased risk for worsening disability compared to patients receiving an exercise intervention without manipulation. 139 patients with LBP were completed the exercise intervention without manipulation were eight times more likely to experience a worsening in disability than patients who received manipulation. Patient from experiencing a worsening in disability was 9.9 and with manipulation was 11.6. The results of this study offer an additional perspective for considering the risks and benefits of SM and help to inform the integration of current evidence for spinal manipulation.\(^{197}\)

3.1.18, Joshua A (2006) et al conducted a study on” **The Use of a Lumbar Spine Manipulation Technique by Physical Therapists in Patients Who Satisfy a Clinical Prediction Rule: A Case Series**” at USA to describe the outcomes of patients presenting to physical therapy with LBP who met the CPR and were treated with an alternative lumbar manipulation technique. Patients were treated for 2 visits with a side-lying lumbar manipulation technique. Patients who exhibited a 50% reduction or greater in disability. 12 patients who participated in this study, the mean reduction in disability were 57%. 11 of the 12 patients who satisfied the CPR and were treated with an alternative lumbar manipulation technique demonstrated a successful outcome in 2 visits. It is plausible that patients with LBP who satisfy the CPR may obtain a successful outcome with either manipulation technique directed at the lumbopelvic region.\(^{198}\)
3.1.19, Ianuzzi A (2005) conducted a study on “High loading rate during spinal manipulation produces unique facet joint capsule strain patterns compared with axial rotations” at Stony Brook University, USA to determine whether speed or loading site affected facet joint capsule (FJC) strain magnitudes or patterns. During SM, 7-mm displacement was applied to L3, L4, or L5 at 5 to 50 mm per second. Applied torque and vertebral rotation magnitudes were similar across speed and vertebral level. The similar patterns observed in vertebral motion and FJC strain across actuation sites during SM and physiological rotations suggest that site specificity of SM may have minimal clinical relevance. High loading rates during lumbar SM resulted in unique patterns in FJC strain, which may result in unique patterns of FJC mechanoreceptor response. 199

3.1.20, Leena Niemisto (2005) et al conducted a study on “A Randomized Trial of Combined Manipulation, Stabilizing Exercises, and Physician Consultation Compared to Physician Consultation Alone for Chronic Low Back Pain” at University of Tampere, Finland to examine the effectiveness of combined manipulative treatment, stabilizing exercises, and physician consultation compared with physician consultation alone for chronic low back pain. 204 CLBP patients were randomly assigned. The treatment included four sessions of manipulation and stabilizing exercises. Manipulative treatment with stabilizing exercises was more effective in reducing pain intensity and disability than the physician consultation alone. The study showed that short, specific treatment programs may alter the course of chronic low back pain. 200

3.1.21, Julie M Fritz (2005) et al conducted a study on “Pragmatic application of a clinical prediction rule in primary care to identify patients with low back pain with a good prognosis following a brief spinal manipulation intervention” at University of Utah, USA to examine the association between two factors (duration and distribution of symptoms). Patients with symptoms of <16 days duration and no symptoms distal to the knee were considered to have a good prognosis following manipulation. 141 patients participated. Mean pre- and post-treatment Oswestry scores were 41.9 and 24.1. 63 subjects had successful treatment outcomes. The results of this study demonstrate that two factors; symptom duration of less than 16 days, and no symptoms extending distal to the knee, were associated with a good outcome with spinal manipulation. 201
3.1.22, Willem JJ (2004) et al conducted a study on “Spinal manipulative therapy for low-back pain” at Leiden University Medical Centre, Netherlands to resolve the discrepancies related to the use of spinal manipulative therapy. The Cochrane Central, MEDLINE, EMBASE and CINAHL were searched. Comparison treatments were classified into sham, conventional general practitioner care, analgesics, physical therapy, exercises, back school, or a collection of therapies judged to be ineffective or even harmful. SM therapy had no statistically or clinically significant advantage over general practitioner care, analgesics, physical therapy, exercises, or back school. Results for patients with CLBP were similar. There is no evidence that spinal manipulative therapy is superior to other standard treatments for patients with acute or chronic low-back pain.\textsuperscript{202}

3.1.23, Martin Descarreaux (2004) et al conducted a study on “Efficacy of preventive spinal manipulation for chronic low-back pain and related disabilities: A Preliminary study” at Laval University, Canada to document the potential role of chiropractic spinal manipulation to reduce overall pain and disability levels associated with CLBP. 30 patients were separated into 2 groups. The 1\textsuperscript{st} group received 12 treatments in an intensive 1-month period and the 2\textsuperscript{nd} group received 12 treatments in an intensive 1-month period and also received maintenance SMT for 3 weeks. Intensive SMT is effective for the treatment of chronic low back pain. Future studies, however, are needed to confirm the finding in a larger group of patients with chronic low-back pain.\textsuperscript{203}

3.1.24, Jean-Yves Maigne (2003) et al conducted a study on “Mechanism of action of spinal manipulative therapy” at Place du Parvis de Notre-Dame, France stated that SM therapy acts on the various components of the vertebral motion segment. SMT distracts the facet joints, with faster separation when a cracking sound is heard. Intradiscal pressure may decrease briefly. Forceful stretching of the paraspinal muscles occurs, which induces relaxation via mechanisms that remain to be fully elucidated. SMT probably has an inherent analgesic effect independent from effects on the spinal lesion. These changes induced by SMT are beneficial in the treatment of spinal pain but short-lived. To explain a long-term therapeutic effect, one must postulate a reflex mechanism, for instance the disruption of a pain–spasm–pain cycle or improvement of a specific manipulation-sensitive lesion, whose existence has not been established to date.\textsuperscript{204}
3.1.25, Timothy Flynn (2002) et al conducted a study on “A Clinical Prediction Rule for Classifying Patients with Low Back Pain Who Demonstrate Short-Term Improvement With Spinal Manipulation” at U.S. Army-Baylor University, USA to develop a clinical prediction rule for identifying patients with LBP who improve with spinal manipulation. 71 patients participated. 32 had success with the manipulation. A clinical prediction rule with five variables (symptom duration, fear–avoidance beliefs, lumbar hypo mobility, hip internal rotation ROM, and no symptoms distal to the knee) was identified. The presence of four of five of these variables increased the probability of success with manipulation from 45% to 95%. It appears that patients with low back pain likely to respond to manipulation can be accurately identified before treatment. 205

3.1.26, Leung SL (2002) conducted a study on“Efficacy of conventional physiotherapy and manipulative physiotherapy in the treatment of low back pain: A randomized controlled trial.” at The Hong Kong Polytechnic University, Hong Kong on (n = 440) patients, where 227 in the CPT group and 213 in the PMT group. Patients in the MPT treatment had significantly lower LBP disability scores, lower current perceived health scores and lower mean pain intensity scores throughout the short term follow up. In the long term the benefits of MPT were less clear. MPT may provide more treatment benefit than CPT in the short term and the effect can be seen soon after the treatment was started. The beneficial effect of MPT is of short duration. Patients who were older, female, and had repeated attacks of LBP may benefit more from MPT than CPT. 206

3.1.27, Paul G (1992) conducted a study on “Spinal Manipulation for Low-Back Pain” at UCLA Schools of Medicine, California to review the use, complications, and efficacy of spinal manipulation as a treatment for low-back pain. 58 articles, including 25 controlled trials, were retrieved. Serious complications of lumbar manipulation, including paraplegia and death, have been reported. For patients with uncomplicated, acute low-back pain, the difference in probability of recovery at 3 weeks favoring treatment with spinal manipulation is 0.17. For patients with low-back pain and sciatic nerve irritation, the difference in probabilities of recovery at 4 weeks is 0.098. Spinal manipulation is of short-term benefit in some patients, particularly those with uncomplicated, acute low-back pain. Data are insufficient concerning the efficacy of SMT for CLBP. 207
3.2: Literature for Low Level Laser Therapy:

3.2.1, Glazov G (2010) et al conducted a study on “The influence of baseline characteristics on response to a laser acupuncture intervention: an exploratory analysis” at University of Western Australia, Australia to identify the response to laser acupuncture. 100 participants in a trial of laser and sham laser acupuncture were included. Adjusted analysis suggested a clinically important effect of laser compared to sham (p<0.05), at short term follow-up only. The findings of this study suggest which characteristics of patients with chronic low back pain are more likely to respond to laser acupuncture treatment, but require replication in other studies. The findings may not apply in other acupuncture interventions and treatment of different conditions.208

3.2.2, Charłusz M (2010) et al conducted a study on “Comparative analysis of analgesic efficacy of selected physiotherapy methods in low back pain patients” at Medical University, Lodz. 94 people (A: n=35) low energy laser therapy, (B: n=27) ultrasound sessions (C: n=32) vacuum therapy. Modified Latinen questionnaire, visual analogue scale, Schober test and the finger-to-floor test was used. The study showed higher analgesic efficacy of laser biostimulation in comparison to vacuum therapy combined with Ultra Reiz current in patients with low back pain. A more prominent increase in lumbosacral spine mobility was observed after vacuum therapy combined with Ultra Reiz current and ultrasound therapy.209

3.2.3, Ay S, Doğan SK (2010) et al conducted a study on “Is low-level laser therapy effective in acute or chronic low back pain?” at Ufuk University School of Medicine, Ankara, Turkey to compare the effectiveness of low-level laser therapy on pain and functional capacity in patients with acute and chronic low back pain. 40 patients with acute and 40 patients with chronic low back pain were included. After There were statistically significant improvements in pain severity, patients' and physician's global assessment, ROM, RDQ scores, and MODQ scores in all groups (p < 0.05). However, no significant differences were detected between four treatment groups. There were no differences between laser and placebo laser treatments on pain severity and functional capacity in patients with acute and chronic LBP.210
3.2.4, Morshed Hadi (2009) et al conducted a study on “Low Level Laser Therapy (LLLT) for Chronic Low Back Pain (LBP)” at Qazvin University of medical science, Qazvin – Iran, to determine the effect of LLLT on the intensity of chronic LBP. 30 patients, range of 30-60 years old were included. Continuous red light laser and pulse infrared with 890nm wavelength and 4-6 J/cm2 dose was irradiated on the vertebral bodies and spinouts processes. Treatment in laser placebo group was done with off laser. There was significant difference between two groups (P<0.05). Low level laser is irradiated on the mentioned area with appropriate dose, wavelength and exposure time, it will be a suitable and less aggressive method without side effect on the LBP.211

3.2.5, Yousefi-Nooraie R (2008) et al conducted a study on ” Low level laser therapy for nonspecific low-back pain” at Tehran University of Medical Sciences, Iran to assess the effects of LLLT in patients with non-specific LBP. Three small studies separately showed statistically significant but clinically unimportant pain relief for LLLT versus sham therapy for sub-acute and chronic low-back pain. One study showed that LLLT was more effective than sham at reducing disability in the short term. Three studies reported that LLLT plus exercise were not better than exercise, with or without sham in the short-term in reducing pain or disability. Two studies reported that LLLT was not more effective than exercise, with or without sham in reducing pain or disability in the short term. Two small trials independently found that the relapse rate in the LLLT group was significantly lower than in the control group at the six-month follow-up.212

3.2.6, Yousefi-Nooraie R (2007) et al conducted a study on” Low level laser therapy for nonspecific low-back pain” at Tehran University of Medical Sciences, Iran to assess the effects of LLLT in patients with non-specific low-back pain. There is some evidence of pain relief with LLLT, compared to sham therapy for sub acute and chronic low-back pain. There was no difference between LLLT and comparison groups for pain-related disability. There is insufficient evidence to determine the effectiveness of LLLT on antero-posterior lumbar range of motion compared to control group in short-term follow-up. The relapse rate in the LLLT group was significantly lower than in the control group at six months follow-up period according to the findings of two trials.213
3.2.7. Djavid GE (2007) et al conducted a study on “In chronic low back pain, low level laser therapy combined with exercise is more beneficial than exercise alone in the long term: a randomized trial” at Academic Center for Education, Iran. Pain severity: 10-cm VAS, lumbar ROM: Schober Test, disability: Oswestry Disability Index. There was also no greater effect of laser therapy plus exercise compared with exercise for any outcome at 6 weeks. However, in the laser therapy plus exercise group pain had reduced by 1.8 cm, lumbar range of movement increased by 0.9 cm on the Schober Test and by 15 deg of active flexion, and disability reduced by 9.4 points more than in the exercise group at 12 weeks. In chronic low back pain low level laser therapy combined with exercise is more beneficial than exercise alone in the long term.\textsuperscript{214}

3.2.8. Konstantinović L (2006) et al conducted a study on “Quality of life in patients with sub acute low back pain treated with physiotherapy rehabilitation” 60 patients suffering from sub acute low back pain were treated by low level laser therapy and the second group was treated by meloxicam. The mean Oswestry scores for group A have reduced from 25+/-2 to 16+/-3 and in group B from 24+/-2.5 to 22+/-2.5. For the 12-item health survey (SF-12) from 22.33+/-4.66 to 36.33+/-3.66 in group A and from 23.66+/-3.66 to 30.33+/-4.66 in group B. Intensity of pain in group A have been reduced from 82+/-6.50 to 46+/-5.50 and from 80+/-5.50 to 62+/-6.50 in group B. Results of this study showed that better results were achieved in group treated with complex rehabilitation methods in comparison with patients treated only with anti-inflammatory drugs.\textsuperscript{215}

3.2.9. Jan M Bjordal (2003) et al conducted a study on “A systematic review of low level laser therapy with location-specific doses for pain from chronic joint disorders” at University of Bergen, Norway investigated LLLT of the joint capsule can reduce pain in chronic joint disorders. 20 trials included patients with chronic joint disorders. The results showed a mean weighted difference in change of pain on VAS of 29.8 mm in favour of the active LLLT groups. Global health status improved for more patients in the active LLLT groups ( relative risk of 0.52; 95% CI 0.36 to 0.76). Low level laser therapy with the suggested dose range significantly reduces pain and improves health status in chronic joint disorders, but the heterogeneity in patient samples, treatment procedures and trial design calls for cautious interpretation of the results.\textsuperscript{216}
3.2.10, **Gur A, Karakoc M** (2003) et al conducted a study on “Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain” at Dicle University, Turkey to determine whether low power laser therapy (Gallium-Arsenide) is useful or not for the therapy of chronic low back pain (LBP). 75 patients (laser + exercise-25, laser alone-25, and exercise alone-25) with LBP. VAS, Schober test, RDQ and MODQ were used. Significant improvements were noted in all groups with respect to all outcome parameters, except lateral flexion (P < 0.05). Low power laser therapy seemed to be an effective method in reducing pain and functional disability in the therapy of chronic LBP.\(^1\)

3.2.11, **Basford JR** (1990) et al conducted a study on “Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain” at Mayo Clinic, Rochester, USA to assess the effectiveness of LLLT in the treatment of musculoskeletal low back pain. 63 subjects underwent irradiation for 90 seconds at eight symmetric points along the lumbo sacral spine three times a week for 4 weeks and level of function is assessed by the ODQ, and lumbar mobility. The treated group had improvement in two of the three outcome measures: perception of benefit and level of function. Lumbar mobility did not differ between the groups. Treatment with low-intensity laser irradiation produced a moderate reduction in pain and improvement in function in patients with musculoskeletal low back pain.\(^2\)

3.2.12, **Klein RG** (1990) et al conducted a study on” Low-energy laser treatment and exercise for chronic low back pain: double-blind controlled trial” at Sansum Medical Clinic, CA on 20 patients with chronic low back pain. Ten patients received low-energy gallium-arsenide laser treatment, and ten received placebo laser treatment. Visual analogue and disability pain scores showed significant (p less than .02) improvements in both groups, but no relative advantage was found for either group. Range of motion, isometric torque, and isodynamic velocity were also performed before and after treatment. There were significant improvements in objective parameters in both the laser and placebo groups, but no relative advantage accrued to either group. Under the conditions of this study, low-energy laser stimulation plus exercise did not provide a significant advantage over exercise alone.\(^3\)
3.2.13, Mika T, Orlow H (1990) et al conducted a study on “Infrared laser radiation in the treatment of low back pain syndrome” at Zakładu Medycyny Fizykalnej Centralnego Szpitala Klinicznego WAM. The effectiveness was estimated of infrared laser radiation in the treatment of low back pain syndrome. The patients received irradiation from a semiconductor laser. The results were evaluated in 82 patients using a questionnaire of pain, taking into account its intensity, frequency, taking of analgesics, and the motor activity of the patient. The results suggest a favorable effect of infrared laser radiation on pain.220
3.3: Literature for Conventional Exercise:

3.3.1, Chan CW (2011) et al conducted a study on “Aerobic exercise training in addition to conventional physiotherapy for chronic low back pain: a randomized controlled trial” at The Hong Kong Polytechnic University, Hong Kong to examine the effect of adding aerobic exercise to conventional physiotherapy treatment for patients with CLBP. Patients with chronic LBP (N=46) were recruited. Groups received conventional physiotherapy with additional individually tailored aerobic exercise prescribed only to the intervention group. Both groups demonstrated a significant reduction in pain (P<.001) and an improvement in disability (P<.001). The addition of aerobic training to conventional physiotherapy treatment did not enhance either short- or long-term improvement of pain and disability in patients with chronic LBP.221

3.3.2, Smeets RJ (2009) conducted a study on “Do lumbar stabilizing exercises reduce pain and disability in patients with recurrent low back pain?” at Maastricht University, The Netherlands. 71 patients with recurrent mechanical LBP were allocated. The graded exercise program and the walking program were applied. There was no clinically-important difference between the groups with respect to median change in pain: exercise group -12 (-34 to -3); walking group -12 (-22 to 0). For disability the between-group difference in median scores was 8. exercise group -10 (-20 to -2); walking group -2 (-12 to 2). Lumbar stabilizing exercises appear to have a similar effect on pain and disability for patients with recurrent low back pain as a daily walking program.222

3.3.3, Manuela L. Ferreira (2007) et al conducted a study on “Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: A randomized trial” at School of Physiotherapy, Brazil to compare effects of general exercise, motor control exercise and manipulative therapy on chronic back pain. 240 low back pain patients received general exercise included strengthening, stretching and aerobic exercises. Motor control exercise involved retraining specific trunk muscles using ultrasound feedback. SMT included joint mobilization and manipulation. Motor control exercise and spinal manipulative therapy produce slightly better short-term function and perceptions of effect than general exercise, but not better medium or long-term effects, in patients with chronic non-specific back pain.223
3.3.4, Van Tulder (2007) et al conducted a study on “Statistical Significance versus Clinical Importance: Trials on Exercise Therapy for Chronic Low Back Pain as Example” to assess the results of back pain. 43 trials of the Cochrane review on exercise therapy for low back pain were included. Eighteen trials reported positive conclusions in favor of exercise. Only six of the 43 studies showed both clinically important and statistically significant differences in favor of the exercise groups on function, and 4 on pain. It seems that many conclusions of studies of exercise therapy for chronic low back pain have been based on statistical significance of results rather than on clinical importance and, consequently, may have been too positive. Authors of trials should report not only statistical significance of results but also clinical importance.\textsuperscript{224}

3.3.5, Jill Hayden (2005) et al conducted a study on “Exercise therapy for treatment of non-specific low back pain” at Dalhousie University, Canada to evaluate the effectiveness of exercise therapy in chronic low-back pain. 61 RCTs - 6390 participants were evaluated. Mean improvement was 7.3 points for pain, 2.5 points for function at earliest follow-up. In studies investigating patients mean improvement was 13.3 points for pain, 6.9 for function. There is some evidence of effectiveness of graded-activity exercise program sub acute low-back pain in occupational settings. Exercise therapy appears to be slightly effective at decreasing pain and improving function in adults with chronic low-back pain. In acute low-back pain, exercise therapy is as effective as either no treatment or other conservative treatments.\textsuperscript{225}

3.3.6, Karen J (2005) et al conducted a study on “Comparing Yoga, Exercise, and a Self-Care Book for Chronic Low Back Pain - A Randomized, Controlled Trial” to determine whether yoga is more effective than conventional therapeutic exercise for patients with CLBP. 101 adults were included for 12-week sessions of yoga or conventional therapeutic exercise classes or a self-care book. Clinically significant change was considered to be 2.5 points on the functional status scale and 1.5 points on the bother someness scale. No significant differences in symptom bothersomeness were found between any 2 groups. Yoga was more effective than a self-care book for improving function and reducing chronic low back pain, and the benefits persisted for at least several months.\textsuperscript{226}
3.3.7, James Rainville (2004) et al conducted a study on “Exercise as a treatment for chronic low back pain” at The Spine Center, Boston, USA to review the safety and efficacy of exercise in treating CLBP. Literature suggests that exercise has either a neutral effect or may slightly reduce risk of future back injuries. The 1st goal of exercise is to improve or eliminate impairments in back flexibility and strength. The 2nd goal of exercise is to reduce the intensity of back pain. The 3rd goal of exercise is to reduce back pain–related disability through a process of desensitization of fears and concerns. Most studies have observed improvements in global pain ratings after exercise programs, and many have observed that exercise can lessen the behavioral, cognitive, affect and disability aspects of back pain syndromes.227

3.3.8, Aure (2003) et al conducted a study on “Manual Therapy and Exercise Therapy in Patients with Chronic Low Back Pain: A Randomized, Controlled Trial With 1-Year Follow-up” to compare the effect of manual therapy to exercise therapy in patients with CLBP. Total of 49 patients were randomized to either manual therapy (n = 27) or to exercise therapy (n = 22). Pain intensity, Spinal range of motion, functional disability, general health and return to work were recorded. After 2-month treatment period, 67% in the manual therapy and 27% in the exercise therapy group had returned to work (P < 0.01). Improvements were found in both intervention groups, but manual therapy showed significantly greater improvement than exercise therapy in patients with CLBP.228

3.3.9, John M. Mayer (2003) et al conducted a study on “Exercise Therapy for Low Back Pain - Chiropractors’ Patterns of Use and Perceptions of Educational Quality” at Syracuse University to describe chiropractors’ patterns of use and perceptions of educational quality regarding exercise therapy for low back pain. 450 U.S. chiropractors were asked to indicate which exercises they regularly used for the management of low back pain. The response rate was 35.1%. 76% of the respondents regularly used six or more exercises. Stretching/flexibility and abdominal strengthening exercises were regularly used by the highest percentage of respondents. Three of the 10 exercises received “good” or “excellent” ratings for perceived educational quality from greater than 50% of the respondents. In general, clinical use paralleled perceived educational quality and whether or not the respondents received training for a specified exercise.229
3.3.10, Van Tulder M (2000) et al conducted a study on “Exercise therapy for low back pain: a systematic review within the framework of the Cochrane collaboration back review group” at Free University, The Netherlands to evaluate the effectiveness of exercise therapy for LBP. There is strong evidence that exercise therapy is not more effective for acute LBP than other active treatments. There is conflicting evidence on the effectiveness of exercise therapy compared with inactive treatments for chronic LBP. Exercise therapy was more effective than usual care by the general practitioner and just as effective as conventional physiotherapy for chronic LBP. Exercises may be helpful for patients with chronic LBP to increase return to normal daily activities and work.\textsuperscript{230}

3.3.11, Jennifer Klaber Moffett (1999) et al conducted a study on “Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences” at University of Hull, Hull to evaluate effectiveness of an exercise program in patients with LBP. 187 patients aged 18-60 years were included. Strengthening exercises, Stretching exercises, Relaxation session, and brief education on back care. At 6 weeks the intervention group improved marginally more than the control group. At 6 months and 1 year, the intervention group showed significantly greater improvement in the disability questionnaire score. Outcome was not influenced by patients' preferences. The exercise class was more clinically effective than traditional general practitioner management, regardless of patient preference, and was cost effective.\textsuperscript{231}

3.3.12, Brox JI (1999) et al conducted a study on “Is exercise therapy and manipulation effective in low back pain” at Senter for ortopedi, Oslo to evaluate the effectiveness of exercises and manipulation on low back pain. On the basis of 11 studies, no additional benefits from exercises and manipulation were found in patients with acute complaints (0-4 weeks). One study found reduced disability and sick leave in the subacute stage (4-12 weeks) 7 studies evaluated manipulation; the effectiveness was no better than other treatments. Based on 7 studies in patients with chronic low back pain (> 12 weeks), there is strong evidence that exercises reduce disability and pain. 4 studies compared different exercise regimens, but found no evidence in favour of one particular method. The effectiveness of manipulation in patients with chronic pain is poorly documented.\textsuperscript{232}
3.3.13, Hilde (1998) et al conducted a study on “Effect of exercise in the treatment of chronic low back pain: a systematic review, emphasizing type and dose of exercise” to evaluate the efficacy of exercise in the treatment of chronic LBP. 6 trials evaluated the effect of exercise versus control treatment and 3 compared different exercise interventions. Internal validity scores varied from 7 to 26 points on a scale from 0 to 39 points. Length of exercise interventions varied from 2 weeks to 3 months, the total number of sessions from eight to 270, the repetition number per session from 60 to 300, and consisted either of flexion and/or extension exercises. No firm conclusions concerning efficacy of exercise in the treatment of chronic LBP can be drawn from the existing RCTs retrieved in the present review.233
3.4: Literature for Visual Analog Scale:

3.4.1, Matamalas (2010) et al conducted a study on “The Visual Analog Scale and a Five-Item Verbal Rating Scale Are Not Interchangeable for Back Pain Assessment in Lumbar Spine Disorders” to evaluate the degree of interchangeability of a 100-mm visual analog scale (VAS) and a 5-point verbal rating scale (VRS) for the assessment of pain intensity. 151 patients completed 100-mm VAS and a discrete 5-category VRS. Pain intensity on the VAS was rated using the same question than for the VRS. The order-consistency level was low with overlapping of pain records between the 2 scales, indicating that VAS and VRS are not interchangeable and, therefore, a results obtained with the use of each scale cannot be compared.234

3.4.2, Boonstra (2008) et al conducted a study on “Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain” at University of Groningen, The Netherlands to determine the reliability and concurrent validity of a VAS for disability as a single item instrument measuring disability in chronic pain patients. In reliability study values varied from 0.60 to 0.77; and in the validity study values of VAS disability scores with SF-36 scores varied from 0.16 to 0.51, with RMDQ scores from 0.38 to 0.43 and with VAS pain scores from 0.76 to 0.84. The reliability of the VAS is moderate to good. Because of a weak correlation with other disability instruments and strong correlation with the VAS its validity is questionable.235

3.4.3, Zanoli G (2001) et al conducted a study on “Visual analog scales for interpretation of back and leg pain intensity in patients operated for degenerative lumbar spine disorders.” at Lund University Hospital, Sweden to describe the use of recording VAS for pain intensity in patients operated on for lumbar spine problems. 755 patients, mean age 50 years Diagnosed herniated nucleus pulposus (45%), central stenosis (19%), lateral stenosis (14%), isthmic spondylolisthesis (9%), and degenerative disc disease (9%). Moderate correlation between different types of pain outcomes and with patient satisfaction was present. Measuring pain intensity with VAS is a useful tool in describing spine patients. In the search for a standard in the evaluation of pain as an outcome, the differences between the various methods should be taken into account.236
3.4.4, McGorry RW (2000) et al conducted a study on “The relation between pain intensity, disability, and the episodic nature of chronic and recurrent low back pain.” at Liberty Mutual Research Center for Safety and Health, Hopkinton, USA to study the intensity and episodic nature of low back pain is related to disability and medication use. 94 participants with self-reported chronic or recurrent low back pain over a 6-month period. Pain intensity can affect disability, but the episodic nature of low back pain also affects the ability to function in both work and personal life. Intermittent increases in pain can markedly alter disability. Chronic low back pain should not be treated as a static phenomenon. 237

3.4.5, Michael Ogon (1996) et al conducted a study on “Chronic low back pain measurement with visual analogue scales in different settings” University of Innsbruck, Austria. 78 chronic low back pain patients report their pain intensity on horizontally-oriented VAS. Statistical analysis showed normal distribution of data in the horizontal VAS, but no homogeneous distribution on the vertical VAS. No correlation was found between current and usual pain. There was no significant difference in the failure rate between the vertical and horizontal VAS. Owing to a negative influence in distribution of rates and an increase in the failure rate, complex questions should be avoided. A short written introduction to the scale is sufficient, and oral explanations are not essential. 238

3.4.6, Carol Hagino (1996) et al conducted a study on “Agreement between 2 pain visual analogue scales, by age and area of complaint in neck and low back pain subjects: the standard pen and paper VAS versus plastic mechanical slide rule VAS” at Canadian Memorial Chiropractic College, Toronto, Canada to determine the agreement between the standard pencil and paper pain VAS and a relatively newly designed plastic mechanical VAS in assessing cervical and lumbar pain intensity in cervical pain vs low back pain. The ICC analysis revealed an ICC of 0.86 for the group under 65 with neck pain, and an ICC of 0.87 for the group under 65 with low back pain. The results of this study suggest that for the most part, there is statistically significant and clinically acceptable agreement between the pencil and paper VAS (pVAS) and a mechanical VAS (mVAS). 239
3.4.7, Triano (1993) et al conducted a study on “A comparison of outcome measures for use with back pain patients: results of a feasibility study” at National College of Chiropractic, Lombard to compare the reliability, validity and change in patient clinical status over time with treatment for six potential outcome questionnaires. 186 participants on three separate occasions were participated. Differences were found in the mean value of the modified Zung with respect to both gender and time. Unexpected drop in patients' somatic perceptions in association with the process of clinical evaluation was found for the Modified Somatic Pain Questionnaire. Overall, the Oswestry and VAS were the most reliable and responsive to clinical change for musculoskeletal disorders.240

3.4.8, Price DD (1983) et al conducted a study on “The validation of visual analogue scales as ratio scale measures for chronic and experimental pain” 6 noxious thermal stimuli applied for 5 sec to the forearm by a contact thermode. The power functions were predictive of estimated ratios of sensation or affect produced by pairs of standard temperatures (e.g. 47 and 49 degrees C), thereby providing direct evidence for ratio scaling properties of VAS. Vas sensory intensity responses to experimental pain, VAS sensory intensity responses to different levels of chronic pain, and direct temperature matches to 3 levels of chronic pain were all internally consistent, thereby demonstrating the valid use of VAS for the measurement of and comparison between chronic pain and experimental heat pain.241

3.4.9, Carlsson AM (1983) et al conducted a study on “Assessment of chronic pain, Aspects of the reliability and validity of the visual analogue scale.” In clinical practice the percentage of pain relief, assessed by VAS, is often considered as a measure of the efficacy of treatment. The validity of VAS estimates performed by patients with chronic pain may be unsatisfactory. Two types of VAS, an absolute and a comparative scale, were compared with respect to factors influencing the reliability and validity of pain estimates. The patients appear to differ considerably in their ability to use the VAS reliably. When assessing efficacy of treatment attention should therefore be paid to several complementary indices of pain relief as well as to the individual's tendency to bias his estimates.242
3.5: Literature for Modified Modified Schober Method:

3.5.1, MTousignant, L Poulin (2005) et al conducted a study on “The Modified–Modified Schober Test for range of motion assessment of lumbar flexion in patients with low back pain: A study of criterion validity, intra- and inter-rater reliability and minimum metrically detectable change” at University of Ottawa, Canada to estimate the psychometric properties of the Modified–Modified Schober Test (MMST). 31 subjects with LBP, measurements with MMST and X-ray were taken in same position. MMST demonstrated moderate validity ($r=0.67; 95\% CI 0.44–0.84$), excellent reliability (intra: ICC=$0.95; 95\% CI 0.89–0.97$; inter: ICC=$0.91; 95\% CI 0.83–0.96$) and a MMDC of 1 cm. The MMST showed moderate validity but excellent reliability and MMDC.

3.5.2, Sandra A Miller (1992) et al conducted a study on “Reliability Problems Associated with the Modified Schober Technique for True Lumbar Flexion Measurement” 50 normal subjects were included using a blind inter rater protocol. Systematic error can be affects inter-rater reliability ($r=0.71$). Moreover, skin landmarks are inconsistently present, being completely absent in 26% of cases. Skin tends to distract even over completely immobile bony structures (eg, the sacrum), whereas, on average, only 3.5 of the 6 spinal segments (T12-S1) are included in the Schober technique for purported measurement of "lumbar spine flexion." The utility of this method is questioned on both scientific and clinical grounds.

3.5.3, Gill K (1988) et al conducted a study on “Repeatability of four clinical methods for assessment of lumbar spinal motion” at Southwestern Orthopaedic Institute, Texas, USA. The common fingertip-to-floor distance; the modified Schober; the two-inclinometer method, and a photometric technique. Ten normal subjects ages 24 to 34 years old, were examined in full flexion, full extension, and the erect position, both standing and sitting. Repeatability was poor for the fingertip-to-floor method in all postures and for the two-inclinometer method in full flexion. Although other methods for various postures had good repeatability, the modified Schober method of determining lumbar spinal motion was the most repeatable and is recommended for a routine, noninvasive, clinical evaluation of lumbar spinal motion.
3.5.4, Ray G (1986) et al conducted a study on “Reliability and Validity of Four Instruments for Measuring Lumbar Spine and Pelvic Positions” at University of Pittsburgh, USA studied the between-therapist reliability and the validity of four instruments in measuring lumbar spine curvature and pelvic tilt. Tape, Gravity goniometer, Parallelogram goniometer, Standard goniometer were used to measure the pelvic angle and lumbar curvature during stance, trunk flexion, and trunk extension. No single instrument to be the most reliable or valid. Between-therapist reliability ranged from .64 to .93 (PC) and from .60 to .92 (ICC). The validities of the instruments compared with measurements from roentgenograms generally were low, ranging from -.13 to .76 (PC) and -.73 to -.05 (ICC).  

3.5.5, Merritt JL (1986) et al conducted a study on “Measurement of trunk flexibility in normal subjects: reproducibility of three clinical methods” Three objective techniques fingertip-to-floor, modified Schober and Moll tests, and the Loebl inclinometer method were used to test 25 normal subjects. Fingertip-to-floor, 83% and 76.4%; flexion (Schober), 6.3% and 6.6%; right lateral flexion (Moll), 11.9% and 8.9%; left lateral flexion (Moll), 10.2% and 9.5%; extension (Moll), 9.5% and 7.3%; lumbar flexion (Loebl), 9.6% and 13.4%; and lumbar extension (Loebl), 65.4% and 50.7%. Reproducibility of the "fingertip-to-floor" test and the Loebl extension test was poor, all other tests studied had good reproducibility.  

3.5.6, G. Kelley Fitzgerald (1983) et al conducted a study on “Objective Assessment with Establishment of Normal Values for Lumbar Spinal Range of Motion” at Sacred Heart Hospital, Milwaukee, USA to present an assessment method, in conjunction with age-related normal values, for lumbar spinal range of motion. Lumbar flexion, lumbar extension, and right and left lateral flexion were measured on 172 subjects by a combination of goniometry and spinal distraction techniques. Normal values are given for six age groups; each group had a range of 10 years. The results demonstrate that a significant decrease in lumbar spinal range of motion is expected with increasing age. The inter observer reliability based on 17 subjects was substantial for the four measurements taken; coefficients ranged from +.76 to +1.0. The information may prove useful to the clinician as an improved method for assessing the lumbar spine.
3.6: Literature for Roland and Morris Disability Scale:

3.6.1, Umile Giuseppe Longo (2010) et al conducted a study on “Rating scales for low back pain” at Bio medico University, Italy to assess the functional status of patients with low back pain with functional questionnaire. 28 scoring systems are currently available for the evaluation of LBP. Each of them evaluates low back pain using specific variables. Although many scoring systems have been used to evaluate the back function, we are still far from a single outcome evaluation system that is reliable, valid and sensitive to clinically relevant changes, taken into account both patients’ and physicians’ perspective. Further studies are required to evaluate the reliability, validity and sensitivity of the low back pain scoring systems used in the common clinical practice.249

3.6.2, Kitti Jirarattanaphochai (2005) et al conducted a study on “Reliability of the Roland - Morris Disability Questionnaire (Thai version) for the Evaluation of Low Back Pain Patients” at Khon Kaen University, Khon Kaen to determine the reliability of the Thai version of the RMDQ in LBP patients. 120 LBP patients were tested. The Cronbach’s alpha coefficient of the scale was 0.83. The Cronbach’s alpha coefficient of each question in the Thai version of the Roland - Morris disability questionnaire exceeded 0.7. The Cronbach’s alpha coefficient tested in acute or chronic low back pain patients whether they have back pain only or back pain with radiculopathy which also exceeded 0.7. The Thai version of the Roland - Morris disability questionnaire is a reliable tool for assessing functional disability of low back pain in Thai patients.250

3.6.3, Sandra Brouwer (2004) et al conducted a study on “Reliability and stability of the Roland Morris Disability Questionnaire Intra Class Correlation and limits of agreement” to analyze test- retest reliability and stability of the Dutch language version of the RMDQ in a sample of patients (n=30) suffering from CLBP. ICC was used as a measure for reliability. An ICC of 0.75 or more was considered as an acceptable reliability. The Dutch RMDQ showed good reliability, with an ICC of 0.91. Calculating limits of agreement to quantify the stability, a large amount of natural variation (± 5.4) was found relative to the total scoring range of 0 to 24. The Dutch RMDQ proves to be a reliable instrument to measure functional status in CLBP patients. However, the natural variation should be taken into account when using it clinically.251
3.6.4, M. Grotle (2003) et al conducted a study on “Cross-cultural adaptation of the Norwegian versions of the Roland-Morris disability questionnaire and the Oswestry disability index” at University of Oslo, Norway to evaluate reliability and construct validity of the Norwegian versions of the RMD Questionnaire and the modified ODI. 105 patients were included in the study. Repeatability of the RMDQ was 4 points, coefficient of variation 15% and ICC 0.89, and of the modified ODI 11, 12% and 0.88. Internal consistency was 0.94 for both questionnaires. The questionnaires correlated physical functioning scale of SF-36, pain, mental scales of the SF-36. The reliability and construct validity of the Norwegian versions of the RMDQ and the modified ODI are acceptable for assessing functional status of Norwegian speaking patients with low back pain.252

3.6.5, Ayse A (2001) et al conducted a study on “Turkish translation of the Roland-Morris Disability Questionnaire” at University of Ankara, Turkey to validate the Turkish version of the RMDQ for use in low back pain. 81 patients with LBP were assessed by RMDQ. Internal consistency of the RMDQ is found to be adequate (> 0.85) Internal construct validity of the scale is good. Associations with pain confirm external construct validity. There is little evidence of Differential Item Functioning. (DIF). The RMDQ is a robust unidimensional ordinal measure, largely free of DIF, which works well in the Turkish population.253

3.6.6, L. Nusbaum (2001) et al conducted a study on “Translation, adaptation and validation of the Roland-Morris questionnaire - Brazil Roland-Morris” Universidade Federal de São Paulo, São Paulo, Brasil to translate the Roland-Morris Questionnaire into Brazilian-Portuguese and adapt and validate it. 30 CLBP patients consecutively selected from the spine disorders outpatient clinic. Brazil-RM, a 6-point pain scale, and its numerical pain rating scale (PS) and a visual analog scale (VAS) were administered. The mean time of questionnaire administration was 4 min and 53 s. The SCC and ICC were 0.88 (P<0.01) and 0.94, respectively, for the test-retest reliability and 0.86 (P<0.01) and 0.95, respectively, for inter observer reliability. The correlation coefficient was 0.80 (P<0.01) between the PS and Brazil-RM score and 0.79 (P<0.01) between the VAS and Brazil-RM score. The Brazil-RM was successfully adapted for application to Brazilian patients, with satisfactory reliability and cross-sectional construct validity.254
3.6.7, Stratford PW (2000) et al conducted a study on “Development and initial validation of the back pain functional scale” at McMaster University, Ontario, Canada to examine the measurement properties of the Back Pain Functional Scale and RMQ. 77 patients with LBP were included. Reliability, cross-sectional validity, and longitudinal validity coefficients were calculated. Test-retest reliability estimates of 0.81 and 0.88 were obtained for the RMQ and BPFS. The measures demonstrated similar levels of cross-sectional validity. Correlations of 0.56 and 0.65 were noted between a prognostic rating of change and the RMQ and BPFS. The BPFS appears to have sound measurement properties, and a formal head-to-head comparison study with the RMQ is warranted.

3.6.8, Paul W Straford (1996) et al conducted a study on “Defining the Minimum Level of Detectable Change for the Roland-Morris Questionnaire” at McMaster University, Canada to determine the minimum level of detectable change when the RMQ is applied to individual patients. 60 outpatients with LBP were administered RMDQ. Conditional standard errors of measurement (CSEMs) were computed. Minimum levels of detectable change at the 90% confidence level varied from 4 to 5 RMQ points. The magnitude of CSEMs is sufficiently small to detect change in patients with initial scores in the central portion of the scale (4-20 RMQ points). However, the magnitude is too large to detect improvement in patients with scores of less than 4 and deterioration in patients who have scores greater than 20.

3.6.9, Petros J. Boscainos et al conducted a study on “Greek Versions of the Oswestry and Roland-Morris Disability Questionnaires” at Athens University, Athens, Greece. The two questionnaires RMDQ & ODI were translated for use with the Greek population. The Greek versions of the Oswestry Disability Index and the Roland-Morris Disability Questionnaire were tested in 697 patients with low back pain. Internal consistency reliability for the Greek translation of the Oswestry Disability Index and the Roland-Morris Disability Questionnaire reached a Cronbach’s alpha coefficient of 0.833 and 0.885 respectively. Face validity and content validity were ensured. Concurrent validity was assessed using a six-point pain scale as a criterion. The correlation of both scales was significant. The Greek translation of these disability questionnaires provided reliable and valid instruments for the evaluation of Greek speaking patients with low back pain.
3.7: Literature for Physical Health Questionnaire-9 (PHQ-9):

3.7.1, Fischer HF (2011) et al conducted a study on “How to compare scores from different depression scales: equating the Patient Health Questionnaire (PHQ) and the ICD-10-Symptom Rating (ISR) using Item Response Theory” at Charité - Universitätsmedizin Berlin, Germany. Two different depression scales [Patient Health Questionnaire (PHQ-9) and ICD-10-Symptom Rating (ISR)] obtained in clinical settings from a consecutive sample. Analysis showed that the predicted scores provided by the conversion tables are similar to the observed scores in a validation sample. The PHQ-9 and ISR depression scales measure depression severity across a broad range with similar precision. While the PHQ-9 shows advantages in measuring low or high depression severity, the ISR is more parsimonious and also suitable for clinical purposes.258

3.7.2, Phillips LJ (2011) conducted a study on “Measuring Symptoms of Depression: Comparing the Cornell Scale for Depression in Dementia – CSSD and the Patient Health Questionnaire-9-Observation Version” to extend available psychometric data on PHQ-9-OV by comparing it with the CSDD. The sample (N = 54) was 87% women with mean age of 84.5, mean CSDD score of 3.96, and mean PHQ-9-OV score of 4.22. Neither scale was significantly correlated with depression diagnosis nor antidepressant agent use. Both measures demonstrated adequate reliability. The PHQ-9-OV item scoring and established cut-off points designate a lower threshold than the CSDD to detect clinically significant depressive symptoms.259

3.7.3, Manea L (2011) et al conducted a study on “Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis” to select the optimal cut-off for detecting depression with PHQ-9. We identified 18 validation studies (n = 7180) conducted in various clinical settings. Eleven studies provided details about the diagnostic properties of the questionnaire at more than one cut-off score (including 10), four studies reported a cut-off score of 10, and three studies reported cut-off scores other than 10. The PHQ-9 was found to have acceptable diagnostic properties for detecting major depressive disorder for cut-off scores between 8 and 11.260
3.7.4, Hyphantis T (2011) et al conducted a study on “Diagnostic accuracy, internal consistency, and convergent validity of the Greek version of the patient health questionnaire 9 in diagnosing depression in rheumatologic disorders” at University of Ioannina Medical School, Greece to estimate its diagnostic accuracy, internal consistency, reliability, and convergent validity in diagnosing major depressive disorder (MDD) in Greek patients with rheumatologic disorders. The PHQ-9 showed a sensitivity of 81.2% and a specificity of 86.8%. The area under the curve was 0.91. The PHQ-9 presented unidimensional structure with good scale reliability ($\alpha = 0.82$). At a cutoff of 10, the PHQ-9 is an accurate, reliable, and valid measure for screening for MDD among Greek rheumatologic patients.\textsuperscript{261}

3.7.5, Cuidong Bian (2011) et al conducted a study on “Reliability and validity of patient health questionnaire: Depressive syndrome module for outpatients” at Tongji University, Shanghai China to evaluate the reliability, validity and detection rate of the Depressive Syndrome module of the PHQ-9 in general hospital outpatients. 600 outpatients were evaluated using the PHQ-9. The internal reliability, test-retest reliability and validity were examined. Cronbach’s $\alpha$ coefficient of PHQ-9 was 0.857 and the test-retest reliability was 0.947. The correlation coefficient of the nine items with the total score of the scale was 0.588 - 0.784. The sensitivity, specificity of PHQ-9 and Kappa value was 91, 97% and 0.884, respectively. The detection rate was 16.3% (95% CI: 13.4 - 19.3%). The Chinese version PHQ-9 was shown to have good reliability and validity for screening of depressive syndrome in general hospital outpatients.\textsuperscript{262}

3.7.6, Liu SI (2010) et al conducted a study on “Validation of Patient Health Questionnaire for depression screening among primary care patients in Taiwan” at Mackay Memorial Hospital, Taipei, Taiwan to determine the reliability and validity of a Chinese version of the Patient Health Questionnaire (PHQ-9). A total of 1954 primary care patients completed the PHQ-9. The PHQ-9 had a good internal consistency ($\alpha = .80$) and test-retest reliability (intraclass correlation coefficient = 0.87). A principal component factor analysis yielded 1-factor structure, which accounted for a total of 42.0% of the variance. The PHQ-9 and its 2 subscales, PHQ-2 and PHQ-1, seem reliable and valid for detecting MDD among Chinese primary care patients.\textsuperscript{263}
3.7.7, Chen S (2010) et al conducted a study on “Reliability and validity of the PHQ-9 for screening late-life depression in Chinese primary care” at Zhejiang University, Hangzhou, China to examine the reliability and validation of the 9-item Patient Health Questionnaire for late-life depression in Chinese primary care. The optimal cut-off score of PHQ-9 ≥ 9 revealed a sensitivity of 0.86, specificity of 0.77, and positive likelihood ratio of 5.73. The area under the curve (AUC) in this study was 0.92 (SD = 0.02, 95% CI 0.88-0.96). The PHQ-2 also revealed good sensitivity (0.84) and specificity (0.90) at the cut-off point ≥ 3. The PHQ-9 performs well and has acceptable psychometric properties for screening of patients with late-life depression in Chinese primary care settings.²⁶⁴

3.7.8, Kroenke K (2010) et al conducted a study on “The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review” at Indiana University, Indianapolis. Evidence regarding the characteristics of the Patient Health Questionnaire (PHQ)-9 depression, generalized anxiety disorder (GAD)-7 anxiety and PHQ-15 somatic symptom scales are synthesized. The PHQ-9 and its abbreviated eight-item (PHQ-8) and two-item (PHQ-2) versions have good sensitivity and specificity for detecting depressive disorders. GAD-7 and its abbreviated two-item (GAD-2) version have good characteristics for detecting generalized anxiety, panic, social anxiety and post-traumatic stress disorder. The PHQ-9, GAD-7 and PHQ-15 are brief well-validated measures for detecting and monitoring depression, anxiety and somatization.²⁶⁵

3.7.9, Zuithoff (2010) et al conducted a study on “The Patient Health Questionnaire-9 for detection of major depressive disorder in primary care: consequences of current thresholds in a cross sectional study” to determine the reliability, construct validity and accuracy of the PHQ-9 and PHQ-2 to detect major depressive disorder in primary care. The PHQ-9 showed a high degree of internal consistency (ICC = 0.88) and test-retest reliability (correlation = 0.94). With respect to construct validity, it showed a clear association with functional status measurements, sick days and number of consultations. Sensitivities at the recommended thresholds were 0.49 for the PHQ-9 at a score of 10 and 0.28 for a categorical algorithm. The PHQ-9 and the PHQ-2 are useful instruments to detect major depressive disorder in primary care, provided a high score is followed by an additional diagnostic work-up.²⁶⁶
3.7.10, **Poongothai S** (2009) et al conducted a study on “Reliability and validity of a modified PHQ-9 item inventory (PHQ-12) as a screening instrument for assessing depression in Asian Indians” at Madras Diabetes Research Foundation, India to evaluate the validity and reliability of the modified Patient Health Questionnaire (PHQ) 12 item as a screening tool for assessing depression compared to PHQ-9. Two questionnaires (modified PHQ-12 item and PHQ-9 item) were administered to the subjects to compare their effectiveness in detecting depression. The mean age of the study was 38.6 +/- 11.6 years and 48% were males. Pearson's correlation coefficient between the modified PHQ-12 and the PHQ-9 item was 0.913. The modified PHQ-12 item is a valid and reliable instrument for large scale population based screening of depression in Asian Indians. 

3.7.11, **Damush TM** (2008) et al conducted a study on “Self-management practices among primary care patients with musculoskeletal pain and depression” at Center of Excellence on Implementation of Evidence-Based Practices, Indianapolis, USA to assess the effect of clinical depression on pain self-management practices. Musculoskeletal pain (low back pain present >or=3 months), Brief Pain Inventory severity score >or=5. Depression was defined as a PHQ-9 score >or=10. Depressed patients exercised less per week than did non depressed patients. On analysis, depression severity substantially decreased the use of exercise as a pain self-management strategy. Understanding the differences between preferential strategies of pain patients with and without depression may be useful in tailoring pain self-management programs.

3.7.12, **Manote Lotrakul** (2008) et al conducted a study on “Reliability and validity of the Thai version of the PHQ-9” at Department of Psychiatry, Mahidol University, Bangkok, Thailand to examine the reliability and validity of a Thai version Patient Health Questionnaire (PHQ-9) as a screening tool for major depression in primary care patients. The mean age of the participants was 45.0 years (SD = 14.3) and 73.7% of them were females. The mean PHQ-9 score was 4.93 (SD = 3.75). The Thai version of the PHQ-9 had satisfactory internal consistency (Cronbach's alpha = 0.79) and showed moderate convergent validity with the HAM-D (r = 0.56; P < 0.001). The Thai version of the PHQ-9 has acceptable psychometric properties for screening for major depression in general practice with a recommended cut-off score of nine or greater.
3.7.13, Adewuya AO (2006) et al conducted a study on “Validity of the patient health questionnaire (PHQ-9) as a screening tool for depression amongst Nigerian university students” at Obafemi Awolowo University, Nigeria to validate the PHQ-9 as a screening tool for depression amongst Nigerian university students. (n=512) completed the PHQ-9 and the Beck’s Depressive Inventory (BDI). The internal consistency of PHQ-9 was 0.85. The PHQ-9 had good concurrent validity with the BDI (r=0.67, P<0.001). It also had a good (r=0.894, P<0.001) one month test-retest reliability. The PHQ-9 has good psychometric properties amongst Nigerian university students. Because of its validity, reliability, brevity and ease of administration, the PHQ-9 will be a valuable tool for estimating depression amongst college students in Nigerian community.270

3.7.14, Alexandra Martin (2006) et al conducted a study on “Validity of the Brief Patient Health Questionnaire Mood Scale (PHQ-9) in the general population” Philipps-University Marburg, Germany to assess the validity of the PHQ-9. 2066 subjects, 14–93 years filled the PHQ-9 for diagnosis and other measures. The two depression groups had higher Brief-BDI and GHQ-12 scores, and reported lower health status (EuroQOL) and health-related quality of life (SF-36) than did the DS_ group. Strong associations between PHQ-9 depression severity and convergent variables were found. The results support the construct validity of the PHQ depression scale, which seems to be a useful tool to recognize not only major depression but also sub threshold depressive disorder in the general population.271

3.7.15, Kurt Kroenke (2001) et al conducted a study on “The PHQ-9: Validity of a Brief Depression Severity Measure” at Institute for Health Care, Indianapolis, to examine the validity of a brief, new measure of depression severity. The Patient Health Questionnaire (PHQ) is a self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. As PHQ-9 depression severity increased, there was a substantial decrease in functional status on all 6 SF-20 subscales. Also, symptom-related difficulty, sick days, and health care utilization increased. In addition to making criteria-based diagnosees of depressive disorders, the PHQ-9 is also a reliable and valid measure of depression severity. These characteristics plus its brevity make the PHQ-9 a useful clinical and research tool.272
3.8: Literature for Health Related Quality of Life-4 (HRQOL-4):

3.8.1, Han-Yang Chen (2011) et al conducted a study on “Health-Related Quality of Life among Adults with Multiple Chronic Conditions in the United States” to examine the association between the chronic conditions and HRQOL outcomes among adults. People with 3 or more chronic conditions had the highest risk of reporting fair or poor health compared with respondents with no chronic conditions. People with cardiovascular conditions or diabetes had higher risk of reporting poor HRQOL outcomes than those with other chronic conditions. Strategies that help clinicians to manage their patients’ chronic conditions may contribute to improve HRQOL among adults.273

3.8.2, Ummuhan Bas Aslan (2010) et al conducted a study on “Reliability and validity of the Turkish version of the CDC HRQOL-4 scale in patients with chronic low back pain” to investigate reliability and validity of Turkish version of Healthy Days Measures assessing health related quality of life in CLBP. Cronbach’s alpha of CDC HRQOL-4-items in CLBP patients was 0.69. The number of physically and mentally unhealthy days, and activity limitation days was found to be higher in the CLBP patients than the healthy controls (p<0.05). The CLBP patients with fair or poor health reported more PUD, MUD, and ALD than the CLBP patients with excellent, very good, or good health (p<0.05). The results of this study indicate that the Turkish version of the CDC HRQOL-4 is a short, reliable and valid tool to assess HRQOL in CLBP patients.274

3.8.3, Ugur Cavlak (2009) et al conducted a study on “A new tool measuring health-related quality of life (HRQOL): The effects of musculoskeletal pain in a group of older Turkish people” at Pamukkale Universitesi, Denizli, Turkey to show the effects of musculoskeletal pain on HRQOL and to look at gender differences in this field in elderly people. The HRQOL-4 survey tool was used to measure HRQOL of the subjects. VAS was used to determine pain intensity. 72.1% reported musculoskeletal pain. The prevalence of pain was higher among women (85.5%) than men (61.8%). Majority of the subjects with musculoskeletal pain reported fair–poor self-rated health, those without pain reported excellent–very good–good health. They concluded that musculoskeletal pain interfered negatively with HRQOL, increasing the number of unhealthy days and decreasing physical and mental performance in the elderly participants.275
3.8.4, David G Moriarty (2009) et al conducted a study on “The Centers for Disease Control and Prevention's Healthy Days Measures – Population tracking of perceived physical and mental health over time” at Division of Adult and Community Health, Georgia, USA to promote the health and quality of life of United States residents. A core set of measures (CDC HRQOL- 4) asks about self-rated general health and the number of recent days when a person was physically unhealthy, mentally unhealthy, or limited in usual activities. The full set of 14 Healthy Days Measures (the CDC HRQOL-14) has shown good measurement properties in several populations, languages, and settings. The brief standard CDC HRQOL-4 is now often used in surveys, surveillance systems, prevention research, and population health report cards.276

3.8.5, Thomas R (2007) et al conducted a study on “A Primer on Health-Related Quality of Life in Chronic Pain Medicine” to identify the most commonly applied HRQOL measurement instruments. This primer provides an overview of the concept of HRQOL as a clinical measurement and the specific means by which to measure health-related quality of life across various cultures in adults, as well as in children and adolescents, suffering from chronic pain conditions. They concluded that the ability and impetus to routinely assess adult and pediatric health-related quality of life in chronic pain medicine. A valid preference-based, utility measure of health-related quality of life is a requirement for performing a cost-effective analysis and undertaking formal decision analysis modeling.277

3.8.6, Kruger J (2007) et al conducted a study on “Health-related quality of life, BMI and physical activity among US adults (/>=18 years): National Physical Activity and Weight Loss Survey, 2002.” at CDC, Atlanta, USA to examine the association between HRQOL and physical activity. Prevalence was calculated by body mass index (BMI) category and PA level. Logistic regression evaluated BMI as an effect modifier of the relationship between HRQOL and PA. Inactive adults reported more fair to poor HRQOL than active adults, regardless of BMI category. BMI did not modify the association between PA and any of the four HRQOL indicators. Prevalence of low HRQOL is inversely related to PA participation, and the relationship is not altered by BMI status. Regardless of their weight status, adults should be encouraged to engage in PA.278
3.8.7, Toet J (2006) et al conducted a study on “Validation of the Dutch version of the CDC core healthy days measures in a community sample” at Department of Epidemiology, Utrecht, The Netherlands, investigated the reliability and validity of health related quality of life, the Dutch version of the four item 'CDC HRQOL-4. Randomly sampled 659 respondents completed the questionnaire. 58% women; mean age 41 years; 15% of non-Dutch origin. Cronbach's alpha of three of the four CDC HRQOL-4-items was 0.77. The four items of the CDC HRQOL-4 showed higher correlations with their corresponding domains of the other instruments. Comparison of respondents with or without a chronic condition, depression, visit to the GP and use of prescription drugs produced evidence for an excellent construct validity of the CDC HRQOL-4.279

3.8.8, Jeffrey M. Lackner (2006) et al conducted a study on “Measuring Health-Related Quality of Life in Patients with Irritable Bowel Syndrome (IBS): Can Less Be More” to assess the ability of health-related quality of life of patients with irritable bowel syndrome (IBS). 109 Patients with IBS averaged 15 of 30 days with poor physical or mental health. Overall unhealthy days among patients with IBS varied directly with IBS symptom severity, abuse, pain, and psychological distress. The CDC HRQOL-4 is a psychometrically sound, rapid, and efficient instrument whose HRQOL profile reflects the symptom burden of moderate-to severe IBS, is sensitive to treatment effects associated with cognitive behavior therapy, and is not a proxy for personality variables identified as potential confounders of HRQOL.280

3.8.9, SS Tavafian (2005) et al conducted a study on “Quality of Life in Women with Different Intensity of Low Back Pain” at Tehran University of Medical Sciences, Iran to assess quality of life in patients suffering from different density of chronic low back pain. 101 patients with chronic low back pain, females, and married aged 18 years or over and underwent rheumatologic clinical examination. Data were collected by using SF-36. Patients were divided into 2 groups: severe pain group and mild pain group. The results showed that there were significant differences between quality of life scores among people with different intensity of low back pain in all dimensions but the role emotional and social functioning scales. The findings from this study confirm that quality of life in patients with low back pain depending on its intensity may vary.281
3.8.10, Brown DW (2004) et al conducted a study on “Associations between physical activity dose and health-related quality of life.” at CDC, Atlanta, USA, to examine the relationships between frequency, duration, and intensity of PA and HRQOL among 175,850 adults. Participation in no moderate PA was associated with an increased likelihood of having 14 or more unhealthy days. Similar associations were observed for participation in vigorous PA. Persons achieving recommended levels of PA were more likely to report fewer unhealthy days compared with inactive and insufficiently active persons; however, participation in daily moderate or vigorous PA and participation in very short or extended periods of PA was associated with poorer HRQOL.\(^{282}\)

3.8.11, Dominick KL (2002) et al conducted a study on “Relationship of health-related quality of life to health care utilization and mortality among older adults” at Durham VA Medical Center, Durham, North Carolina, USA to investigate the ability of a four-item Health-Related Quality of Life (HRQOL) scale to predict short-term (30-day) and long-term (1-year) physician visits, hospitalization, and mortality among older adults. Subjects included 84065 individuals aged 65 and older who completed a CDC-HRQOL-4. These results signify that all four dimensions of HRQOL represented by the BRFSS Core HRQOL Module are important predictors of both short-term and long-term adverse health events among older adults. This brief scale may be particularly useful for assessing the health of older adults in clinical settings and large-scale epidemiological studies.\(^{283}\)

3.8.12, Ounpuu S (2001) et al conducted a study on “Validity of the US Behavioral Risk Factor Surveillance System's health related quality of life survey tool in a group of older Canadians” at Mcmaster University, Ontario, USA to assess HRQOL-4 validity in different groups. 926 men and women (age > or = 65 years) completed health exam and questionnaire. Results indicated that physical and mental health and physical activity limitation were each related to self-perceived health. Compared with subjects who reported excellent health, those with poor self-rated health reported a more than 17-fold increase in the number of unhealthy days in the previous 30. Psychosocial factors were most consistently associated with mental health, responses to health and health behaviour questions were more associated with items related to physical health.\(^{284}\)