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Impact of Early Initiation of Exercise on Acute Low Back Pain and Disability

Author
Marcos, Maria Felicia Hidalgo

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Impact of Early Initiation of Exercise on Acute Low Back Pain and Disability

A dissertation submitted in partial satisfaction

of the requirement for the degree of Doctor of Nursing Practice

by

Maria Felicia Hidalgo Marcos

2020

ABSTRACT OF THE DISSERTATION

Impact of Early Initiation of Exercise
on Acute Low Back Pain and Disability

by

Maria Felicia Hidalgo Marcos
Doctor of Nursing Practice
University of California, Los Angeles, 2020
Professor Mary Ann Shinnick, Co-Chair
Professor Mary Woo, Co-Chair

Background: Low back pain (LBP) is the leading cause of chronic pain and disability worldwide and was the third major contributor to health care spending in the United States. Early initiation of exercise is known to be beneficial in chronic LBP but there is limited evidence on the benefits of similar activity prescription in acute LBP. **Aim:** This evidence-based project was an exploratory study that evaluated the utility of implementing a patient education tool promoting Early Exercise for Acute Low Back Pain (EE) and the use of instruments to measure pain (Numeric Pain Rating Scale [NPRS]) and disability (Roland Morris Disability Questionnaire [RMDQ]) at baseline and again at 4-weeks post-presentation. **Methods:** This pilot study was a single group, quasi-experimental design conducted at an urgent care clinic in Southern California. The intervention (EE patient education tool) was offered to adult patients aged 30-60 years with acute (<4 weeks), non-specific LBP. Baseline data on participants was

collected using the EE Demographic and Baseline Questionnaires, NPRS, and RMDQ. Follow-up data was collected using the online EE Follow-Up Questionnaire, NPRS, and RMDQ 4-weeks post-presentation. Analysis of the data was evaluated with a one-tailed t-test. **Results:** Due to the concurrent COVID-19 pandemic, only two subjects completed all components of the project. At initial visit, average NPRS was 8.6 (out of 10) and average RMDQ was 15 (out of 24). At 4-week follow-up, participants reported an NPRS of zero. On a one-tailed t-test, there was statistical difference between pre- and post-intervention pain levels ($p = 0.04$) on these two participants. Follow-up measurement of disability showed one participant with complete resolution (RMDQ score of zero) while the other participant had a follow-up score of 7 for an average follow-up RMDQ score of 3.5. **Conclusions:** This pilot project, while time and subject limited, demonstrated a large effect size, utility and feasibility of the EE intervention in the urgent care setting. A power analysis indicates that a two-tailed ANCOVA, with 3 covariates, and assuming a large (0.40) effect size, would require at least 111 subjects in a future study.

The dissertation of Maria Felicia Hidalgo Marcos is approved.

Sarah E. Choi

Nancy A. Pike

Mary Ann Shinnick, Committee Co-Chair

Mary A. Woo, Committee Co-Chair

University of California, Los Angeles

2020

DEDICATION

To my parents -

Thank you for showing me the values of hard work and dedication.

I am grateful every day for the opportunities you have given me to succeed

and for the constant love and support in everything I do.

This is for you.

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BIOGRAPHICAL SKETCH

Education

2018 – present, Doctor of Nursing Practice Candidate (degree in progress),
University of California, Los Angeles

2005 – 2009, Master of Science, Nursing and Certificate, Family Nurse Practitioner,
Western University of Health Sciences

1995 – 1999, Bachelor of Science, Biology, University of California, Los Angeles

Professional Positions

2014 – present, Nurse Practitioner, Hoag Medical Group, Urgent Care

2010 – 2014, Nurse Practitioner, Memorial Care Medical Group, Internal Medicine

2006 – 2010, Registered Nurse, St. Joseph Hospital, Emergency Department

Professional Affiliations

2020 – present, American Association of Nurse Practitioners

2008 – present, California Association for Nurse Practitioners

2007 – present, Sigma Theta Tau, International Nursing Honor Society

The lower back, or lumbar spine, is defined as the area involving the lumbar vertebrae, intervertebral discs, connective tissues, and muscles which together provide structural support for the body and create movement to spine, pelvic girdle, and lower extremities. Low back pain (LBP) typically occurs when there is dysfunction or trauma to any of the structures of the lumbar spine and is the most common area of pain associated with the back. LBP is experienced below the costal angles and above the gluteal fold, can occur without a specific trigger, and is defined by pain that lasts for at least one day (Casazza, 2012). While structural defects such as scoliosis, degenerative (or arthritic), or spinal cord (nerve) problems can contribute to LBP, more than 85% of LBP cases evaluated in the primary care setting are considered "non-specific," or without any underlying cause (Chou & Huffman, 2007). Most cases of LBP are typically associated with flaws in the control of specific movements and the corresponding muscles used to create that movement (Bialy, Adamczyk, Marczykowski, Majchrzak, & Gnat, 2019). Spinal instability and movement flaws can lead to increased muscle irritation and inflammation which can trigger pain receptors over time (McGill, 2016).

Acute LBP can last up to four weeks, sub-acute LBP can persist 4 to 12 weeks, and chronic LBP extends beyond 12 weeks (Chou & Huffman, 2007; Qaseem, Wilt, McLean, & Forciea, 2017). Guidelines suggest that a majority of patients with acute LBP will improve on their own within the first 4 weeks of symptoms without any medical intervention (Chou et al., 2018; Maher, Underwood, & Buchbinder, 2017). While all age ranges are affected by LBP, individuals over the age of 40 are more likely to experience episodes of LBP and are more likely to be female (Hoy et al., 2012; Maher et al., 2017). Anecdotally, in the researcher's urgent care clinic population, the most common persons diagnosed with LBP tend to be over the age of 30 years and are typically male. In addition to age and sex as risk factors for LBP, body mass index,

activity level, job-related activities, mental health, and smoking status also contribute to the incidence of LBP (Peng, Perez, & Pettee Gabriel, 2018; Taylor, Goode, George, & Cook, 2014). Higher levels of disability and pain intensity as well as previous episodes of LBP were associated with increased health care utilization (Ferreira et al., 2010; Garcia, Cook, & Rhon, 2019).

LBP is the foremost cause of chronic pain and disability worldwide (James et al., 2018; Maher et al., 2017; Mokdad et al., 2018). Approximately 30% of the adult population in the United States has experienced acute LBP (< 4 weeks after initial pain onset) in the last 3 months (Herndon, Zoberi & Gardner, 2015). With approximately 30% of LBP patients seeking care, it is one of the leading reasons for outpatient medical visits (St. Sauver et al., 2013). LBP is the third major contributor to health care spending in the United States at $100 billion and had the fastest rate of spending increases for medical diagnoses in 2013 (Dieleman et al., 2016). While surgical interventions are a costly expenditure associated with only 1.2% of LBP patients, the remaining non-surgical LBP patients were associated with more spending related to care that did not follow clinical guidelines such as early imaging that was not indicated and without a trial of physical therapy (Kim et al., 2019).

Current clinical guidelines for acute LBP treatment in the United States recommend conservative management of symptoms with non-pharmacologic treatments such as heat, acupuncture, massage, spinal manipulation, and pharmacologic treatments such as non-steroidal anti-inflammatories (NSAIDs) and skeletal muscle relaxants (SMRs) (Qaseem et al., 2017). While not an “official” or evidence-based recommendation, exercise is prescribed by almost two-thirds of US physicians for initial treatment of acute LBP without worsening in pain and disability (Chou et al., 2018; Webster, Courtney, Huang, Matz, & Christiani, 2006). Although

exercise is possibly an efficacious intervention to improve spinal and trunk stabilization and to reduce recurrent episodes of LBP it is not a recommended treatment for acute LBP in the Unites States (Chou et al., 2018; Oliveira et al., 2018; Qaseem et al., 2017). Current guidelines in the United States suggest use of exercise for subacute (> 6 weeks but < 3 months from initial pain onset) and persistent or chronic LBP (pain lasting > 3 months) (Qaseem et al., 2017). In contrast, international guidelines recommend the use or promotion of exercise as a first-line treatment in acute LBP episodes (Chou et al., 2018) despite the limited evidence on the benefits of this activity prescription in acute LBP (Chou & Huffman, 2007; Fritz et al, 2015; Olivera et al., 2018).

There is some evidence that the initiation of an exercise-based program can reduce the severity, recurrence, and chronicity of LBP (Shiri, Coggon, & Falah-Hassani, 2018) but its use to treat pain or minimize disability during acute LBP is equivocal (Hayden, van Tulder, Malmivaara, & Koes, 2005; Machado, Kamper, Herbert, Maher, & McAuley, 2009; van Tulder, Malmivaara, Esmail, & Koes, 2000). Exercise has been associated with general (not specifically lower back) pain relief by reducing the phosphorylation of *N*-Methyl-D-aspartate receptors on nerve cells and increasing serotonin and opioid levels in central inhibitory pathways (Lima, Abner, & Sluka, 2017). Many clinicians believe that motor control exercises (MCEs) may be the most promising type of exercise for treatment of LBP. Motor control exercises improve muscle coordination, control, and movement associated with the trunk and spine responsible for maintaining stability through static and dynamic functional movements (Macedo et al., 2012). These types of exercise treatments include strengthening exercises or movements to improve core and lumbar stability such as the curl-up, side plank, and bird dog (also known as the "McGill Big 3"), and are widely used by physical therapists in the treatment of acute, sub-acute

and chronic LBP and in the prevention of recurrent LBP episodes (Ahmed, Shakil-Ur-Rehman, & Sibtain, 2014; Foster et al., 2018; McGill, 2010). However, there is no strong evidence supporting efficacy, timing and the specific types of exercises such as the "McGill Big 3" which are commonly used physical therapy treatment. Moreover, their association with reducing early pain and disability associated with acute LBP episodes remains unclear (Aluko, DeSouza, & Peacock, 2013; Chou & Huffman, 2007; Macedo et al., 2016).

Problem Statement

Promoting evidence-based, non-pharmacologic interventions for patients with acute LBP (as defined by onset of symptoms within 4 weeks) may be helpful at mitigating early pain symptoms and disability associated with acute LBP. Current US guidelines compiled from moderate quality evidence have shown improved short-term relief of disability associated acute LBP disability (but not with pain relief) compared to placebo with the use of NSAIDs, SMRs, and superficial heat (Qaseem et al, 2017). Patient education on these types of interventions, typically given by health care providers during an urgent care visit, consists of self-care modalities such as staying active but often does not include specific exercises to attempt or when to initiate them. It has been suggested that initiation of exercise for acute LBP can safely begin 1-2 weeks within the first two weeks of acute symptoms after major red-flag concerns are ruled out by thorough medical evaluation (Chou et al., 2018; Maher et al., 2017). However, the efficacy of the early initiation of exercise during the first two weeks of acute LBP and which specific types of exercise to recommend have not been adequately studied despite the widespread early use of exercises such as the "McGill Big 3" by physical therapists who treat LBP. Therefore, the Doctor of Nursing Practice (DNP) scholarly project was an exploratory study to: 1. evaluate the feasibility of the project at an urgent care clinic; 2. pilot the intervention (patient education tool)

designed to promote specific early exercises for acute LBP patients and data collection instruments specific to measuring the impact of these exercises on acute LBP and related disability; 3. to allow calculation of intervention effect size and power analysis for a future intervention study to determine efficacy of an exercise intervention in acute LBP; and 4. enable refinement and identification of important confounding variables for the condition which would be important to consider for a future LBP study.

PICOT Question

In otherwise healthy adults (30-60 years old) presenting to the urgent care clinic for acute, non-specific LBP, what is the feasibility and potential efficacy of adding a patient education tool, that promotes the early initiation of exercise, to usual care and what is the impact on a patient's subjective level of pain and disability related to acute LBP at a 4-week follow-up as compared to baseline?

The Iowa Model for Research Utilization

The Iowa Model of Research-Based Practice to Promote Quality Care is a research utilization model and framework developed to guide clinicians in driving patient care through evidence-based practice (Titler et al, 2001). This framework was recently revised and validated by the Iowa Model Collaborative to account for changes in evidence-based practice, nursing science, and in healthcare (Buckwalter et al., 2017). The steps of the revised Iowa Model are identifying triggering issues and opportunities; stating the question or purpose; identifying if the topic is a priority (decision point #1); forming a team; assembling appraising and synthesizing a body of evidence; identifying if there is sufficient evidence (decision point #2); designing and piloting the practice change; identifying if the change is appropriate for adoption (decision point #3); and finally, disseminating the results (Buckwalter et al., 2017). Utilization of the revised

Iowa Model provided a solid, evidence-based framework for the development and implementation of an acute LBP patient education tool to enhance patient engagement in their own self-care (Doody & Doody, 2011). Each step of the revised Iowa Model acted as a theoretical mile-posts when developing and refining the research question and gathering of evidence. While this was an exploratory project, the design of the study and the data collection tools as well as the selection of the outcome measurements were reviewed with an expert panel of providers that frequently cared for LBP pain patients in primary care and the urgent care settings. For future studies, a team of urgent care providers and staff will be recruited to further refine the study and assist in participant recruitment, data collection, reviewing the findings and discussing if and how practice change would occur, and ultimately, disseminating the results with the rest of the urgent care group. The Iowa Model was utilized to guide the creation and evaluation of the patient education tool promoting the early initiation of exercise in acute LBP care and management in the urgent care setting. Ultimately, if the outcomes of the scholarly project are met then the utility of the designed intervention and data collection instruments can be verified.

Review of the Literature

A preliminary literature review was performed to identify evidence-based guidelines and recommendations for non-pharmacologic treatment of acute LBP. Utilizing the search parameters of *acute low back pain*, a literature review performed identified 3,656 articles on PubMed as well as 8,500 articles on the CINAHL (Cumulative Index to Nursing and Allied Health Literature) database. This search was further narrowed utilizing an article filter for practice guidelines and restricting the time frame to only include articles from the last 5 years which resulted in five articles on PubMed and nine articles on CINAHL. Of the resulting 14

articles, seven were identified as actually having guideline recommendations for the management of LBP. After reviewing current international and national guidelines, the literature review revealed a large gap in quality research and evidence on movement-based treatments of acute LBP. Therefore, another literature review was performed to explore the utility of exercise in the management and treatment of acute LBP and the search parameters of *acute low back pain* and *exercise* were used on PubMed and the CINAHL databases. This search resulted in 442 articles on PubMed and 944 articles on CINAHL. By restricting the search to only include recent publications within the past 10 years, the results were narrowed to 186 articles on PubMed and 377 articles on CINAHL. Articles were further restricted to clinical trials that were available in English and from peer-reviewed journals which resulted in 33 articles on PubMed and 39 articles on CINAHL. The resulting 72 articles were reviewed and studies were excluded that were duplicate articles, that focused on chronic LBP and not acute, did not have exercise (or a movement-based modality) as the intervention of the study, had populations that were outside of the age range being evaluated in the project, had very specific populations that could not be generalizable (e.g., pregnant women), or did not have pain or disability as a primary outcome. These additional search criteria resulted in five databased articles: two articles were study protocols or pilot studies and the remaining three that were used for this project were randomized controlled trials that examined the impact of a movement-based treatment on acute LBP. Additional articles included in PubMed's "Similar Articles" were identified during the literature review and an additional two randomized controlled trial studies were found relating to the early intervention or timing of exercise, physical therapy in acute LBP resulting in a total of five articles that were used for this project.

The articles appraised were randomized controlled trials evaluating the effects of a movement-based treatment (i.e., physical therapy, spinal manipulation, spinal loading, or strengthening exercises) or the timing of the intervention on patients with acute pain and disability related to LBP. The articles explored the efficacy of specific types of movements such as spinal loading or spinal manipulation or stretching (i.e., the McKenzie and Strain-Counterstrain Methods) and lumbar (or trunk) strengthening (i.e., core or trunk strengthening exercises and specific movement control exercises [SMCE]) as well as determining the effect of timing or initiation of a movement-based treatment on acute LBP and disability (see Table of Evidence). The articles reviewed were to determine if current treatments commonly used and recommended by clinicians in their practice, such as trunk or spinal stabilizing exercises, and the timing of prescribing a movement-based treatment are effective, despite not being included in current acute LBP guidelines.

Synthesis of Evidence

All studies reviewed and included in the Review of Literature and Table of Evidence were randomized controlled trials studying the concepts of initiating an early movement-based treatment modality and specifics types of movements or exercises in the treatment of acute LBP. However, all of the reviewed studies had limitations and threats to external, internal, statistical and construct validity.

External validity threats were evident in four of the studies as they were conducted outside of the United States (one in Finland, two in Australia/New Zealand, and one in England) and in countries that all have widespread public health care systems or socialized medicine programs (Lehtola, Luomajoki, Leinonen, Gibbons, & Airaksinen, 2016; Lewis, Souvlis, & Sterling, 2011; Machado, Maher, Herbert, Clare, & McAuley, 2010; Wand et al., 2004). Having

a single-payor system may affect the care seeking behaviors of patients suffering from acute LBP in that they may choose not to be evaluated for their symptoms due to longer waits to see a primary care provider. One of the studies in Australia was conducted at the outpatient physical therapy department of a rural hospital while the others were conducted in metropolitan areas. The samples evaluated in the reviewed studies are unlikely to be consistent with the target population of the scholarly project which was conducted in Orange County, California, a primarily suburban area of the greater Los Angeles area, and most of the patients at the DNP data collection site had private or Medicare insurance coverage.

Internal validity issues were evident in all of the studies due to patient recruitment, selection and retention issues. Almost all the studies had a large pool of potential participants (Fritz et al., 2015; Lehtola et al., 2016; Machado et al., 2010; Wand et al., 2004); however, after respective inclusion/exclusion criteria the range of eligible subjects enrolled in the studies range from as low as 12.7% to as high as 88.1%. Randomization of subjects also appeared to be problematic in all of the studies resulting in unequal group sizes and/or non-equivalent distribution of important confounding factors, such as the experimental groups in two studies with more subjects on adjunctive medications (Lewis et al., 2011; Machado et al., 2010) and dissimilar gender distributions between the control and experimental groups ranging from 7-11% in four of the studies (Fritz et al., 2015; Lehtola et al., 2016; Lewis et al., 2011; Wand et al., 2004). In the studies reviewed, participants and, when included, their therapists could not be blinded to the treatment they were randomized to which can potentially impact the internal validity of the results. While the populations of each trial were homogenous, with all participants having acute LBP and being referred by their primary care provider for further treatment with physical therapy, subjects that chose to proceed with physical therapy may be more inclined to

be adherent to any recommendations or interventions prescribed as well as with follow-up which is consistent with the overall retention rate of 93% or more subjects in three of the studies (Fritz et al., 2015; Lewis et al., 2011; Machado et al., 2010). Internal validity could also have been affected by skill level of the clinician providing any of the treatment modalities.

Construct validity is key to the value of research findings and is dependent on the quality of the variables and the study design. All of the studies reviewed in the Table of Evidence had very strong research designs (randomized clinical trial). Two of the studies were single-blinded and were able to collect outcomes data by a blinded assessor which can provide some strength to the respective studies (Fritz et al., 2015; Wand et al., 2004). However, there were significant methodology flaws identified with each study. None of the studies had objective measures for their outcomes (all primary outcome data were via subjective questionnaires). Only two of the studies addressed confounding factors such as medication effect on the reduction in pain and disability seen on their findings as well as the natural course of acute LBP and its spontaneous resolution within 4 weeks (Fritz et al., 2015; Lewis et al., 2011). The studies used instruments for the measure of disability that are well-documented, but variable, in their levels of validity and reliability (Oswestry Disability Index [ODI] or the Roland Morris Disability Questionnaire [RMDQ]). Four of the studies (Fritz et al., 2015; Lewis et al., 2011; Machado et al., 2010; Wand et al., 2004) measured pain using the Numeric Pain Rating Scale (NPRS) or the Visual Analog Scale (VAS), both of which are standard practice measurement tools in all clinical settings for multiple types of pain intensity despite low quality evidence supporting the validity and test-retest reliability of both tools (Chiarotto et al., 2018; Chiarotto, 2019). None of the studies established reliability of the use of their data collection instruments.

Reasonable conclusions rely on statistical validity. In four of the studies, the power analyses used to determine sample sizes for the desired effect were not based on LBP but on their primary outcome of disability. Furthermore, these same studies did not perform any multivariate analyses, limiting the understanding of the interventions and important confounding variables (Fritz et al., 2015; Lehtola et al. , 2016; Lewis et al., 2011; Wand et al., 2004).

The literature review and synthesis of the material did not reveal clear evidence that early initiation of a movement-based intervention involving the trunk or spinal strengthening in acute LBP episodes is effective in pain management or disability. None of the studies that measured pain were able to show statistically significant improvements in pain intensity with relation to any of the movement interventions or with timing of the intervention. Also, the exact timing of when to initiate exercise in these patients to achieve the greatest benefit in improving acute pain and disability remains unclear. Thus, the current common practice in the United States to prescribe exercise as part of the initial treatment for acute LBP without reliable evidence is questionable. Therefore, the DNP scholarly project was to evaluate the feasibility and effect of a patient education, movement-based intervention in the urgent care clinic setting. With the emphasis on strengthening and core stabilizing activities specifically, the "McGill Big 3."as a treatment for acute LBP, the project was to determine its effects on acute pain and disability over a short-term follow-up period of 4 weeks and to evaluate whether common current clinical exercise recommendations are appropriate.

Methods

Design and Sample

The scholarly project was a pilot study to determine utility of an early exercise intervention. It used a single group, quasi-experimental design conducted at an outpatient urgent

care clinic that is part of a larger primary care medical group in Southern California. It was also done to provide an effect size estimation and power analysis to identify a larger, future intervention study. Inclusion criteria were adult patients between the ages of 30 and 60 years old with acute (< 4 weeks), non-specific LBP. While the literature indicates that individuals over the age of 40 are more likely to experience LBP, the age range of the project was extended to include patients in their 30s due to the higher incidence of LBP patients served at the urgent care clinic at which the project was carried out. A chart review revealed that patients seeking care in the urgent care for LBP ranged from 25 to 75 years old; thus, an age range of 30 to 60 years old was utilized to capture a large group of potential participants while excluding those that were more likely to have LBP associated with any of the exclusion history or red flag symptoms. Any patients with a history spinal trauma, injury, fracture, and/or surgery; radicular symptoms; previous history of chronic LBP (pain >3 months); history of cancer or malignancy; or with history or physical exam findings consistent with acute infection, trauma/injury, genitourinary etiology (i.e., urinary tract infection, pyelonephritis, renal/ureteral calculi with or without hydronephrosis, etc.), or neuro- sensory or muscular deficits (i.e., cauda equina syndrome, spinal malignancy, infection, stenosis or injury) were excluded from the study.

Recruitment of participants was obtained from a convenience sample of patients seen by the researcher (an employed nurse practitioner [NP]) at the designated urgent care clinic who are diagnosed with acute, non-specific LBP. Diagnosis of non-specific, acute LBP was based on patient history, clinical presentation, physical exam findings, and diagnostic testing (if indicated). The onset of the patient's lower back pain determined chronicity of pain (i.e., acute, sub-acute, or chronic). Defining the location of the patient's back pain (i.e., thoracic, lumbar, or sacral), if there was any radiation of pain, the quality and severity of pain, aggravating and

relieving factors, and the timing of lower back pain identified potential patients with acute LBP. Each subject's medical and medication history was reviewed as well as ascertaining any history of any associated injuries ruled out, potential disease processes such as previous surgery, malignancy, or spinal trauma, or fractures which would exclude the patient from the study. Finally, a thorough physical assessment and review of systems was performed, not only musculoskeletal system (with specific emphasis on the spine) but also other associated symptoms from neurologic, cardiovascular, respiratory, abdominal, or genitourinary systems. A thorough assessment can identify red flag symptoms that may warrant further diagnostic testing to rule out cauda equina syndrome, ankylosing spondylitis, or infection which would exclude these patients from the study. The musculoskeletal and neurologic exams revealed if there was any pain associated with infection, structural abnormalities, and neurosensory deficits which would also exclude patients from the study.

Data Collection Instruments and Intervention

Early Exercise (EE) Demographic Questionnaire. The EE Demographic Questionnaire is a 6-item questionnaire created by the nurse practitioner investigator and includes basic demographic data such as gender, age, body mass index, ethnicity, co-morbidities and medications. It also includes data related to the participants' LBP such as onset/duration of pain, previous history of LBP, and social history such as smoking. This paper-and-pencil questionnaire was given to participants prior to receiving the intervention at the initial (Appendix A). This data collection questionnaire was validated using content validity methodology. Three subject matter experts (SME's) were utilized as judges. They included one primary care physician (board certified in family medicine and sports medicine) and two board certified family nurse practitioners currently practicing in the urgent care setting. All SMEs have had extensive

experience in evaluating and treating LBP patients in their respective specialties. All items on the EE Demographic Questionnaire showed high agreement among the raters (with a content validity index [CVI] = 1.00).

Early Exercise Baseline Questionnaire. The EE Baseline Questionnaire is a 4-item, check box, fill-in style questionnaire created by the nurse practitioner investigator and includes data including chronicity and current level of pain, using the Numeric Pain Rating Scale (NPRS) on an 11-point Likert scale, pharmacologic and/or non-pharmacologic treatments attempted before seeking care, activity level prior to onset of pain, and the types of exercise the participant engages in. This paper-and-pencil questionnaire was given to participants prior to receiving the intervention at the initial visit (Appendix B). Content validity was obtained by the same SME panel aforementioned. All items on the Early Exercise Baseline Questionnaire showed high agreement among the raters (with a content validity index [CVI] = 1.00).

Early Exercise Intervention. The EE for Acute Low Back Pain patient education teaching tool was developed by the nurse practitioner investigator for this study. The information on the teaching tool was based upon the investigator's review of evidence-based, non-pharmacologic treatment options as recommended on national guidelines for sub-acute and chronic LBP and randomized clinical trial publications using exercise as an intervention in acute LBP. The EE is primarily made up of pictures and instructions on movements based on the McGill Big Three: the curl-up, the side plank, and the bird dog (McGill, 2015). Instructions for the exercises include beginning the exercises once acute pain has subsided to a level that is tolerable and to perform the exercises daily. Each exercise should be performed with a descending pyramid repetition scheme to reduce potential fatigue and over-work by beginning with 5 repetitions, resting for 20-30 seconds, then performing 3 repetitions, resting again for

another 20-30 seconds, and finally completing one last repetition (McGill, 2010). Each movement should be held for 8-10 seconds and repeated for the recommended descending pyramid repetition scheme. In addition to the McGill Big 3, the EE encourages the early introduction of a walking program (5 to 10-minute bouts increasing in intensity and frequency as tolerated up to three times per day, every day). The EE also references other resources to review such as videos and textbooks on how to perform the exercises with the goal of reducing acute pain without aggravating it (Appendix C). The EE tool was given to patients and reviewed at the end of their visit and they were allowed to ask questions regarding any of the included information. Video links were provided on the handout to provide visual demonstrations of the exercises. Ultimately, the EE tool is a take-home handout that subjects can review on their own after initial visit with the expectation that they would attempt the exercises presented.

Finally, the EE tool includes a list of symptoms to trigger follow-up care or report to the ER such as worsening pain despite the recommended or prescribed treatments; persistent pain beyond 3-4 weeks; pain that radiates down the legs; numbness, tingling, or weakness of the legs; loss of bowel or urinary control; fever; or any falls or injuries involving the spine. The content of the tool is based on evidence-based national guidelines and recommendations that are not readily available to acute LBP patients and has been widely used by experts that manage and treat acute, sub-acute and chronic LBP (i.e., physical therapists, strength and conditioning coaches, urgent care providers, and sports medicine specialists) (Chou et al., 2018; Oliveira et al., 2018; Qaseem et al., 2017).

Numeric Pain Rating Scale (NPRS). The NPRS is a single-item measurement which quantifies a subject's pain intensity on a Likert scale of "0" through "10" with a zero being no pain at all to a ten being the worst pain possible. Use of the NPRS is standard practice for the

measurement of pain intensity for LBP despite low quality evidence supporting the validity and test-retest reliability (Chiarotto et al., 2018; Chiarotto et al., 2019). Because of this and its standard use in all clinical settings as the pain assessment method of choice, it was chosen for this study. Previous studies have shown that it is responsive for 2-point pain scale changes (Chapman et al., 2011; Childs, Piva, & Fritz, 2005). This measurement was included on the Early Exercise Baseline Questionnaire (Appendix B) which was administered before the intervention was given at the initial visit. The NPRS was also included on the Early Exercise Follow-Up Questionnaire (Appendix E) that was administered 4 weeks after the intervention.

Roland Morris Disability Questionnaire (RMDQ). The RMDQ is the most validated tool (content and construct validity) for measurement of level of disability associated with acute, sub-acute (Smeets, Koke, Lin, Ferreira, & Demoulin, 2011). The RMDQ is a self-reported outcome measure that lists 24 statements related to how a patient's activities of daily living such as walking, changing position, and resting are affected by low back pain (Roland & Morris, 1983; Appendix D). Scoring on this instrument reflects a person's level of disability related to LBP with each statement being scored as 1-point each and the most severe disability having full agreement on all 24 statements ("24/24") and no agreement on any statement equated to no disability ("0/24"). The RMDQ has a good test-retest reliability with a correlation coefficient of 0.91 (Smeets, et al., 2011) and is available in over 50 languages, some of which have also been validated in the respective language (Chiarotto et al., 2016). The RMDQ was administered before the intervention was given at the initial visit and was repeated 4 weeks later with the EE Follow-Up Questionnaire. The follow-up RMDQ was converted into an online or digital format using Google Forms (Google, 2020). A corresponding link was generated which was then sent to

participants via text and e-mail for them to access both the EE Follow-Up Questionnaire and RMDQ.

Early Exercise Follow-Up Questionnaire. The EE Follow-Up Questionnaire is an 8-item questionnaire created by the nurse practitioner investigator comprised of questions regarding chronicity and level of pain upon follow up, what pharmacologic and/or non-pharmacologic treatment modalities were utilized since the initial visit, if the patient utilized the recommended EE and when exercise was initiated (Appendix E). A final follow-up question evaluates if additional care was sought with a different provider or clinic between the proposed follow up intervals and what additional treatment was given (i.e., prescribed opioid pain medications, imaging studies, referrals to specialists, etc.). Content validity was obtained by the same SME panel aforementioned. All items on the EE Follow-Up Questionnaire showed high agreement among the raters (with a content validity index [CVI] = 1.00). The questionnaire was created into an online or digital format using Google Forms (Google, 2020). A corresponding link was generated which was then sent to participants via text and e-mail for them to access both the EE Follow-Up Questionnaire and RMDQ.

Reliability Testing of Instruments. All questionnaire data collection instruments had reliability established for this study through the use of inter-rater reliability. Two board certified family nurse practitioners currently practicing in the urgent care setting were utilized to review the same completed baseline and follow-up questionnaires (including the NPRS) as well the same completed RMDQ. A 100% level of agreement between two independent raters (who were blinded to the other rater's scores) was achieved determining reliability of each tool for use in this project.

Procedure

Institutional Review Board exemption was obtained by the University of California, Los Angeles. Institutional permission was obtained from the Hoag Urgent Care Executive Medical Director to perform the quality improvement project at Hoag Urgent Care clinic locations. Data collection was conducted by a single provider (the researcher) to maintain consistency in patient education, reassurance and prescribing practices.

All acute LBP patients were provided with *Usual Care* which includes history and physical exam as well as treatment recommendations (usual care does not routinely include exercise recommendations). Prescribed treatment modalities such as physical therapy referral and/or medications such as non-steroidal anti-inflammatory medications and/or smooth muscle relaxants, if indicated, were given as part of *Usual Care*. Additional self-care recommendations were provided for active rest, topical heat treatments, and reassurance – informing patients of the non-dangerous nature of acute low back pain such as muscle strain or spasm, that it may take a few days for acutely intense pain to improve, and it may take up to 4 to 6 weeks for acute episodes of LBP to resolve. Those who met the inclusion/exclusion criteria aforementioned were consented for the study.

Following a description of the study, consenting acute LBP patients received *Usual Care* plus the intervention of EE for Acute LBP intervention at the time of their clinic visit and completed three instruments: Acute Low Back Pain Early Exercise Demographic Questionnaire, Acute Low Back Pain Early Exercise Baseline Questionnaire (including the Numeric Pain Rating Scale [NPRS]), and the Roland Morris Disability Questionnaire (RMDQ).

Follow-up NPRS, RMDQ, and other variables of interest on the EE Follow-Up Questionnaire were collected via online survey 4 weeks after initial visit. A link to the survey

was texted or e-mailed to subjects at the 4-week post visit timepoint. Following completion of all of the assessments at each timepoint, each participant was mailed a $25 Amazon Gift Card as a "thank you" for their participation in the study.

Statistical Analysis

Statistical analyses were performed using a one-tailed t-test using Microsoft Excel software (Office 2016; Microsoft Corporation, Redmond, WA) to assess any change in pain or disability between baseline and the 4-week follow-up data. A power analysis (Faul, Erdfelder, Buchner, & Lang, 2009) was performed based on this trial data, and indicated that a two-tailed ANCOVA with 3 covariates (most likely covariates will be age, gender, and body mass index) would require a minimum of sample of 111 subjects for future studies in order to have the ability to detect a large effect size (0.40) with alpha of 0.05 and power of 0.80.

Results

This project was severely impacted by the overlapping influenza season and novel coronavirus (COVID-19) pandemic. During the patient recruitment period from January 26, 2020 through March 15, 2020, patient volumes fluctuated with the shift in care seeking behaviors from non-urgent musculoskeletal symptoms such as acute LBP to acute upper and lower respiratory illnesses. This resulted in only three patients presenting to the clinic that met inclusion/exclusion criteria for recruitment into this project with only two patients completing all components.

All three participants presented to urgent care clinic within the first week of onset of acute LBP symptoms and were given the EE intervention education tool. The mean age of the participants was 39, two of the participants were male, and the average BMI (body mass index) was 30.9 (BMI of the female participant was 26.5 and BMI's of the male participants was 28.9

and 37.5). All three participants had no significant prior medical history and did not smoke. All three participants exercised at least 4 days per week for at least 50 minutes and walked daily. At the initial visit, the average pain level on the NPRS was 8.6 out of 10 (range 8-10) and the average RMDQ score was 15 out of 24 (range 7-24) despite attempting use of at least an NSAID medication and heat. One of the participants did not complete the 4-week EE Follow-Up Questionnaire despite three attempts at contact up to 6 weeks after the initial visit. The two participants that completed the follow-up questionnaires, one male participant and one female participant, reported complete resolution of pain (zero out of 10) – the female participant after 3 weeks and the male participant after 5 weeks. On a one-tailed t-test, there was statistical difference between the pre- and post-intervention pain levels ($p = 0.04$) on these two participants. On the measurement of disability, the female participant had a complete resolution associated with acute LBP while the male participant continued to have an RMDQ of 7; however, it is also noted that the he had an initial RMDQ score of 24.

Both participants were also prescribed with smooth muscle relaxants and the female participant responded as medications "seemed to make more of a difference" for initial relief of acute LBP stating "prescribed muscles relaxer helped a lot initially. After pain got better I stuck with Advil, but only had to take a few times." Non-medication modalities such as rest, heat, ice, massage, chiropractic treatment, and the recommended exercises were demonstrated as what "seemed to make more of a difference" in improving pain and disability for the male participant. Both responding participants were able to initiate early exercise from walking to the recommended set of exercises ("McGill Big 3") without any worsening of pain or disability within the first 6 weeks of LBP. Both responding participants performed at least 3 of the 4 recommended exercises within the first week of pain and exercised at least 5 days during the

acute phase of their LBP including both walking and the recommended exercises. It was noted that the female participant only performed three of the four exercises. She did not perform the "curl-up" but she indicated she had not routinely performed either "curl-up" and "side plank" exercises at the baseline assessment. Neither of the participants reported seeking additional care with another provider or clinic after their additional visit.

Discussion

Despite only three participants being able to be recruited into this project, the findings (based on the two responding participants) demonstrated decreases in both level of pain with the NPRS as well as disability on the RMDQ. While a clear relationship between early exercise and improvements in acute LBP and disability cannot be demonstrated with the data collected from a very small number of subjects and the lack of a control group in this project, it does support additional investigation to explore the hypothesized relationship. Even though a majority of acute LBP episodes may resolve on their own or can be successfully managed with short-term pharmacologic treatments, the underlying causes of LBP such as movement and muscle dysfunction are not addressed. When not treated and managed appropriately, acute LBP can evolve into frequent recurrent episodes or may persist for longer periods of time. The goal of the DNP scholarly project was to develop a strategy that can be implemented at the first point of care that can address both acute LBP and disability while reducing risk for recurrent or persistent LBP.

This was a project with a very small available sample size despite the researcher attending clinic days outside of her work schedule to increase potential subject recruitment. Typically, the clinical recruitment site would have an average of 30 LBP patients in this time period. The small sample size is surmised to be due to the concurrent influenza season and the

novel coronavirus (COVID-19) pandemic. Over the 7-week recruitment period, it was noted by the researcher that a shift in presenting patient demographics occurred in which there was a dramatic increase in "cold-and-flu" patients and a decrease in patients with musculoskeletal symptoms, including acute LBP not related to an injury across all 13 clinic locations within the urgent care group. There was also an increase in patients seeking care for COVID-19 during this same period resulting in another shift of how patients with non-urgent or emergent symptoms sought care. Timing for the intervention period of the scholarly project was significantly impacted the ability recruit participants. Additionally, the abbreviated period for patient recruitment (7 weeks), the use of a single provider to enlist eligible acute LBP patients for participation, and the inclusion/exclusion criteria limited the ability to recruit the minimal sample of 15 participants for the project to meet a large effect size. Therefore, the project results were limited to piloting project data collection protocols, evaluation of the data collection instruments, and examining improvements for future study.

The data collection tools developed for the project were able to capture data to address potential confounders that may affect the outcomes such as medications and their subjective effect on pain as well other treatment modalities utilized by the participant. Additional data fields can be included in future studies and multivariate analyses to evaluate why participants may have tried some of the remedies or exercises recommended or may have avoided others, what activities may have potentially aggravated their pain or worsened disability level, and why they did not seek any additional treatment with a different clinic. It took subjects approximately 5-10 minutes to complete the EE Demographic Questionnaire, Baseline Demographic Questionnaire, and RMDQ at the initial visit. It took subjects approximately 5-10 minutes to complete the EE Follow-Up Questionnaire and RMDQ online using Google Forms (Google, 2020). Incorporating

additional measurement tools that measure quality of life, pain perception, and global rating of change during data collection at baseline and follow-up in future studies may provide greater insight into the perceived effect of the intervention.

Obtaining follow-up data from the participants proved problematic. All three participants requested that they be contacted for follow-up via text message. Despite sending text messages with a link to the online survey at the 4-week follow-up time frame, none of the participants responded within 5 days prompting a follow-up e-mail which only two participants completed the survey. A third follow-up e-mail was sent to the participant who had not responded to the previous two attempts for data collection without any reply. While loss of participants can be expected due to time and attrition, a short-term follow-up phone call, text message or e-mail two weeks after initial visit may be helpful in reminding subjects of their participation in the project as well as providing an opportunity for them to follow-up with the provider for any persistent or worsening symptoms.

The two participants that completed the online follow-up questionnaires had the ability to complete the surveys on their mobile devices or computers. Providing potential subjects with a similar digital format of the baseline data collection tools through the use of a tablet or a link that is texted or e-mailed to them may be useful for data collection and to avoid potential loss of paper documents. By providing potential subjects with the option to utilize a tablet or link through which they are able to complete the assessments on an online format, a link can also be provided with instructional videos on how to perform the recommended exercises that they are able to view while they are still in clinic and awaiting discharge.

While the findings from this exploratory study demonstrated decreases in both pain and disability, it could not be identified what the relieving factor was for either pain or disability. In a

majority of acute LBP episodes, pain will typically self-resolve without any treatment within the course of 4 weeks (Chou et al., 2018; Ferreira et al., 2010; Maher et al., 2017). Thus, future studies should be a two-group (i.e., with a control group) randomized clinical study design, in order to more clearly identify the impact of the intervention on pain and disability in this patient population. Performing a shorter-term follow up at 1 or 2 weeks after the intervention can evaluate if the velocity of pain resolution is related to an intervention and to identify what actually was the relieving factor (i.e., non-pharmacologic vs pharmacologic and if walking or exercise played a role). Given the number of confounding variables identified during this trial study associated with LBP, a multivariate statistical model, such as ANCOVA or logistic regression, would be preferable for statistical analyses in future studies. Furthermore, by performing a multi-variate analysis on the data collected in future studies, the outcome variables of pain and disability can be measured over time and with relation to different treatment modalities from acute LBP guidelines such as topical heat and medications (NSAID's, skeletal muscle relaxants) in addition to early initiation of exercise using the "McGill Big 3" to determine the effect each may have on pain and disability over time.

In order to increase the number of potential participants for future studies, additional urgent care providers should be trained to recruit subjects for the project. The current project utilized a single provider thereby limiting the opportunity to recruit participants to the hours worked by the provider and the urgent care locations that were assigned during that time frame. By extending the available hours and clinical sites for recruitment, potential participants can be screened at a higher volume and in a shorter time frame. Having a larger participant pool of acute LBP patients will allow for the ability to have a control group and to pursue a randomized controlled study design to improve statistical significance of the findings. Furthermore, by

adjusting the inclusion and exclusion criteria, outliers can be identified that have the potential to skew data. For example, the non-responder in this project was found to have a BMI of 37.5, had only participated in a sport for exercise (bowling), and had never done any of the recommended exercises in the past. This participant likely did not perform the recommended exercises based on previous history and was more likely to be non-compliant and not follow-up. For future studies, BMI greater than 30 may be added to the exclusion criteria which may result in improved compliance with the treatment intervention and follow-up.

Despite the small sample size, this project was able to demonstrate utility and feasibility of the intervention and use of the assessments. While statistical significance was seen with a one-tailed t-test, there was no control group in this project. To provide greater validity to the intervention and statistical significance of the findings, future projects should follow a randomized controlled study design.

Limitations

This project coincided with a pandemic affecting patient presentation to urgent care clinics and subsequently adversely impacted study sample size. In addition to the reasons mentioned above, during the final month of subject recruitment for this project, “shelter-at-home” orders were implemented throughout the project location of Orange County followed by the entire state of California for COVID-19 pandemic which resulted in dramatic decrease in patient volumes at the urgent care sites. The abbreviated implementation period of 7-weeks was also a limitation and contributed to the small sample size. Finally, the use of only one provider to recruit participants limited the ability to recruit an adequate sample. Thus, the findings of this project were limited to an exploratory scope.

Conclusions

Despite the small sample size, the DNP scholarly pilot project has been able to demonstrate feasibility of the study methodology for further investigation on the impact of early exercise on acute LBP and disability. If found to be effective with future study in reducing acute LBP and disability, the patient education tool developed for the intervention can be utilized not just in the urgent care but across all primary care settings for acute LBP patients thereby decreasing the overall burdens associated with LBP in healthcare utilization and costs as well as increasing patient quality of life. By continuing to explore the effect of exercise on pain and disability in the acute phase of LBP, more treatment opportunities may be added to clinical guidelines for acute LBP patients seeking care in urgent care settings. This may lead to not only reductions in pain and disability but also decreases in recurrent pain episodes and slowing or avoiding the progression to persistent or chronic LBP.

Appendix A

Early Exercise Demographic Questionnaire

Acute Low Back Pain Early Exercise Demographics

Date of visit: _____ Age: _____

Study ID: _____ Gender: _____

Ethnicity: _____ Height, Weight: _____

Medical History

1. Have you ever been diagnosed or treated for any of the following?
   - ☐ Hypertension *(i.e., high blood pressure)*
   - ☐ Diabetes *(i.e., high blood sugar)*
   - ☐ High cholesterol
   - ☐ Heart disease *(i.e., history of heart attack, stroke, aneurysm, irregular heart rhythm, blood clots, etc.)*
   - ☐ Osteoporosis or osteopenia
   - ☐ Mood disorders *(i.e., anxiety, depression, bipolar disorder, etc.)*
   - ☐ Previous history of cancer
   - ☐ Previous history of spinal trauma, injury, fracture or surgery
   - ☐ Previous orthopedic surgery

     If yes, please list what type of surgery: _____
   - ☐ Previous history of chronic low back pain *(persistent low back pain that has lasted more than 3 months)*
   - ☐ Previous history of acute low back pain

     How many episodes of low back pain have you previously had? _____

2. Please list any prescribed medications that you are currently taking:

   _____

   _____

   _____

Appendix A

Early Exercise Demographic Questionnaire

3. Are you experiencing any symptoms of acute illness or infection?
   - ☐ No
   - ☐ Yes
     - ☐ Fever, chills
     - ☐ Body aches
     - ☐ Urinary symptoms *(mid-back pain, blood in the urine, pain with urinating, difficulty urinating, urinary frequency, urinary urgency, etc.)*

4. Have you had pain that:
   - ☐ Radiates down your legs?
   - ☐ Causes numbness, tingling, or weakness?

Social History

5. Have you ever smoked cigarettes?
   - ☐ No
   - ☐ Yes
     - ☐ Former smoker
       How many years did you smoke? _____
       How many cigarettes or packs per day? _____
     - ☐ Currently smoking
       How many years have you been smoking? _____
       How many cigarettes or packs per day? _____

6. Do you drink alcohol?
   - ☐ No
   - ☐ Yes
     - ☐ Beer
     - ☐ Wine
     - ☐ Liquor
       How many drinks per day, week, month, or year? _____

Appendix B

Early Exercise Baseline Questionnaire

Acute Low Back Pain Early Exercise
Baseline Questionnaire

Study ID _____ Date of visit _____

Current episode of low back pain

Date of onset of pain _____

1. On a scale of 0 through 10, with a "0" having no pain at all and a "10" being the worst pain possible, please circle the number that matches the level of pain you are currently experiencing.

2. What remedies have you tried?

   Medications tried:
   ☐ Acetaminophen (Tylenol)
   ☐ Ibuprofen (Advil, Motrin)
   ☐ Naproxen (Aleve)
   ☐ Other (Previously prescribed muscle relaxants or pain relievers; homeopathic remedies; etc.)

   Did any of the medications "work" (i.e., relieved all back pain)? ☐ Yes ☐ No

   If yes, please list what remedies worked: _____

Appendix B

Early Exercise Baseline Questionnaire

2. What remedies have you tried? *(continued)*

Non-medication remedies tried:

☐ Rest
☐ Heat
☐ Ice
☐ Massage
☐ Acupuncture
☐ Chiropractic (spinal) manipulation
☐ Movement (stretching, exercise, yoga, etc.)
☐ Other

Did the non-medication remedies "work" (i.e. relieved all back pain)? ☐ Yes ☐ No

If yes, please list what remedies worked: _____

3. Do you exercise?

☐ No
☐ Yes

How many days per week? _____
How many minutes per day? _____

What type of exercise do you engage in?

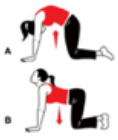
☐ Jogging, running
☐ Weightlifting
☐ Aerobics, conditioning classes
☐ High-intensity interval training
☐ Yoga
☐ Pilates
☐ Tai Chi
☐ Swimming
☐ Dance
☐ Gymnastics
☐ Sports, athletic training
☐ Other

Do you walk for exercise?

☐ No
☐ Yes

How many days per week? _____
How many minutes per day? _____

4. Do you routinely perform any of the following exercises with your regular exercise routine?

☐ Cat-Camel


☐ Curl-Up


☐ Side Plank


☐ Bird Dog


Images used in the Early Exercise Baseline Questionnaire were taken from Clipart Library (clipart-library.com) and MacDonald Fitness (macdonaldfitness.ca).

Appendix C

Early Exercise Intervention

Low Back Pain

Acute

Recommended Treatments for Acute Low Back Pain

- Stay active!
  - Start walking right away (even if you are having pain)
    - Begin with 5 to 10-minute walks three times per day
    - Gradually increase time, distance, and difficulty of your walks
  - Begin early exercises (see reverse side)
- Superficial heat
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
  - ibuprofen (Advil, Motrin)
  - naproxen (Aleve)
- Prescription medications (such as muscle relaxants)
- Physical therapy
- Spinal manipulation (with a physical therapist or chiropractor)
- Acupuncture
- Massage
- Yoga, Tai Chi, Pilates

Qaseem, A., Wilt, T. J., McLean, R. M., & Forciea, M. A. (2017). Noninvasive treatments for acute, subacute, and chronic low back pain: A clinical practice guideline from the American College of Physicians. Annals of Internal Medicine, 166(7), 514-530. doi:10.7326/M16-2367

hoag | Urgent Care

Low back pain is a common cause of pain which most people will experience at some point in their life. In many cases low back pain is not serious and usually gets better on its own, even without treatment.

Speak to your healthcare provider to determine the best recommended treatments for your pain.

Follow up with your healthcare provider or report immediately to the Urgent Care or ER:

- *if you have any falls or injuries to your back*
- *have numbness, tingling, or weakness to your legs*
- *lose bowel or bladder control*
- *have a fever*
- *or if your pain worsens or does not improve in 3 to 4 weeks.*

Appendix C

Early Exercise Intervention

Early Exercises for Acute Low Back Pain

hoag | Urgent Care

You can safely begin these exercises within the first two weeks of your acute low back pain once your initial pain subsides

Cat-Camel

- Assume a position on "all 4's."
- Slowly arch hips and spine in rounded position with head looking down and keep this position for a few seconds (camel)
- Slowly move into the opposite position with head looking up and keep this position for a few seconds (cat).
- Only go as far as a light stretch that does not cause pain. Repeat this cycle for cat-camel 5-6 times.

Curl-Up

- Lie on your back with one knee bent and the other straight.
  - Place hands under low back to keep slight arch.
- Pick your head up off the ground only a few positions and hold this position for 2-3 seconds (eventually increasing to 8-10 second holds) — and then relax your read back to resting position.
  - Do not move your low back
- Repeat this cycle 5 times, rest for 20-30 seconds, then repeat 3 times, rest for 20-30 seconds, and repeat one more time.

Side Plank

- Lie on your side with your knees bent and upper body supported through elbow.
  - Progress this movement by keeping the legs straight.
- Raise your hips so only forearm and knee support your bodyweight and hold this position for 8-10 seconds before returning back down.
- Repeat this cycle 5 times on each side, rest for 20-30 seconds, then repeat 3 times, rest for 20-30 seconds, and repeat one more time.

Bird Dog

- Assume a position on "all 4's."
- Begin with raising one arm and holding it out for 2-3 seconds and then switch arms. Repeat with legs by kicking one leg back and holding this position for 2-3 seconds and then switch legs.
  - Keep your back in a neutral position (do not arch!)
  - No movement should occur in the low back.
  - Progress this movement by kicking one leg backwards while raising the arm of the opposite side until both are completely straight. Hold for 2-3 seconds (eventually increasing to 8-10 second holds)
- Repeat this cycle 5 times on each side, rest for 20-30 seconds, then repeat 3 times, rest for 20-30 seconds, and repeat one more time.

A video tutorial on how to perform the above exercises (as well as simplified versions) is available at https://youtu.be/S8VFbkSjCsQ

Additional Resources:

Official Recommendations from the American Board of Internal Medicine
http://www.choosingwisely.org/wp-content/uploads/2018/02/Bed-Rest-For-Low-Back-Pain-NASS_2019-Updates091319.pdf
Official Recommendations from the American College of Physicians
https://www.acponline.org/practice-resources/patient-education/online-resources/low-back-pain
McGill, S. (2010). Core training: evidence translating to better performance and injury prevention. Strength & Conditioning Journal, 32(3), 33-46.
McGill, S. (2015). Back mechanic: The step-by-step McGill method to fix back pain. Ontario, Canada: Backfitpro, Inc.

Images used in the Early Exercise Intervention were taken from Shutterstock (shutterstock.com), Clipart Library (clipart-library.com), and MacDonald Fitness (macdonaldfitness.ca).

Appendix D

Roland Morris Disability Questionnaire

The Roland-Morris Disability Questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you ***today.***

As you read the list, think of yourself *today*. When you read a sentence that describes you today, check the box. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only check the box if you are sure it describes you *today*.

☐ 1. I stay at home most of the time because of my back.

☐ 2. I change position frequently to try and get my back comfortable.

☐ 3. I walk more slowly than usual because of my back.

☐ 4. Because of my back I am not doing any of the jobs that I usually do around the house.

☐ 5. Because of my back, I use a handrail to get upstairs.

☐ 6. Because of my back, I lie down to rest more often.

☐ 7. Because of my back, I have to hold on to something to get out of an easy chair.

☐ 8. Because of my back, I try to get other people to do things for me.

☐ 9. I get dressed more slowly than usual because of my back.

☐ 10. I only stand for short periods of time because of my back.

☐ 11. Because of my back, I try not to bend or kneel down.

☐ 12. I find it difficult to get out of a chair because of my back.

☐ 13. My back is painful almost all the time.

☐ 14. I find it difficult to turn over in bed because of my back.

☐ 15. My appetite is not very good because of my back pain.

☐ 16. I have trouble putting on my socks (or stockings) because of the pain in my back.

☐ 17. I only walk short distances because of my back.

☐ 18. I sleep less well because of my back.

☐ 19. Because of my back pain, I get dressed with help from someone else.

☐ 20. I sit down for most of the day because of my back.

☐ 21. I avoid heavy jobs around the house because of my back.

☐ 22. Because of my back pain, I am more irritable and ill-tempered with people than usual.

☐ 23. Because of my back, I go upstairs more slowly than usual.

☐ 24. I stay in bed most of the time because of my back.

Appendix E

Early Exercise Follow-Up Questionnaire

Early Exercise in Acute Low Back Pain Follow-Up

You have previously agreed to participate in a scholarly project evaluating the effect of introducing exercise in acute low back pain. This is your 4-week follow-up from your low back pain visit.

Please answer the following questions to the best of your ability. The following questionnaires should take approximately 5-15 minutes.

Thank you again for your participation!

* Required

Email address *

Your email

4-Week Follow-Up Questionnaire

1. How many days or weeks did it take for your lower back pain to improve?

Your answer

2. On a scale of 0 through 10, with a "0" having no pain at all and a "10" being the worst pain possible, please select the number that matches the level of pain you are currently experiencing.

	0	1	2	3	4	5	6	7	8	9	10	
No pain at all	○	○	○	○	○	○	○	○	○	○	○	Worst pain possible

Appendix E

Early Exercise Follow-Up Questionnaire

3. What medication remedies have you tried since your initial visit?

- [ ] Acetaminophen (Tylenol)
- [ ] Ibuprofen (Advil, Motrin)
- [ ] Naproxen (Aleve)
- [ ] Prescribed muscle relaxants (cyclobenzaprine, tizanidine, carisoprodol, methocarbamol, etc.)

3a. Did any of the medication remedies "work" (i.e., relieved all of your back pain)?

- ◯ Yes
- ◯ No

3b. If you answered "yes", which medications worked?

Your answer

4. What non-medication remedies have you tried since your initial visit?

- [ ] Rest
- [ ] Heat
- [ ] Ice
- [ ] Massage
- [ ] Acupuncture
- [ ] Chiropractic (spinal) manipulation
- [ ] Movement (stretching, yoga, etc.)
- [ ] Recommended exercises
- [ ] Physical therapy
- [ ] Other:

Appendix E

Early Exercise Follow-Up Questionnaire

4a. Did any of the non-medication remedies “work” (i.e., relieved all of your back pain)?

- ◯ Yes
- ◯ No

4b. If you answered "yes", which non-medications worked?

Your answer

5. If the medication and non-medication remedies worked, which one seemed to make the most difference in your pain relief?

- ◯ Medications
- ◯ Non-medications

6. Since your initial visit, have you started walking for exercise and to stay active?

- ◯ Yes
- ◯ No

6a. If you answered "yes", how many days per week do you exercise? How many minutes per day?

Your answer

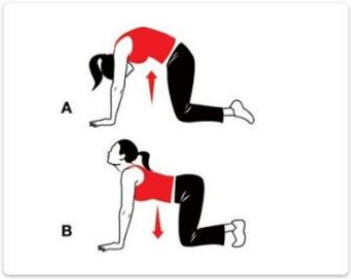
7. After how many days, weeks did you start performing the recommended exercises from the Low Back pain handout?

Your answer

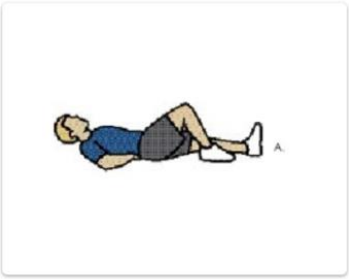
Appendix E

Early Exercise Follow-Up Questionnaire

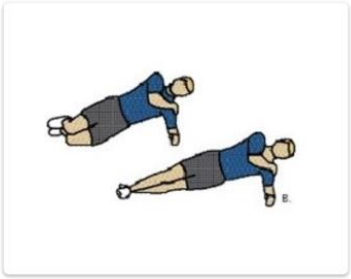
7a. What exercises from the handout did you perform?



☐ Cat-Camel



☐ Curl-Up



☐ Side Plank

☐ Bird Dog

8. Did you seek care from another provider or clinic after your initial acute low back pain visit at Hoag Medical Group?

◯ Yes

◯ No

8a. If you answered "yes", what additional treatment were you given?

☐ Imaging studies (x-ray, CT scan, MRI)

☐ Narcotic/opioid pain relievers such as tramadol (Ultram), hydrocodone (Norco, Vicodin) or oxycodone (Percocet)

☐ Benzodiazepines such as diazepam (Valium), alprazolam (Xanax), lorazepam (Ativan)

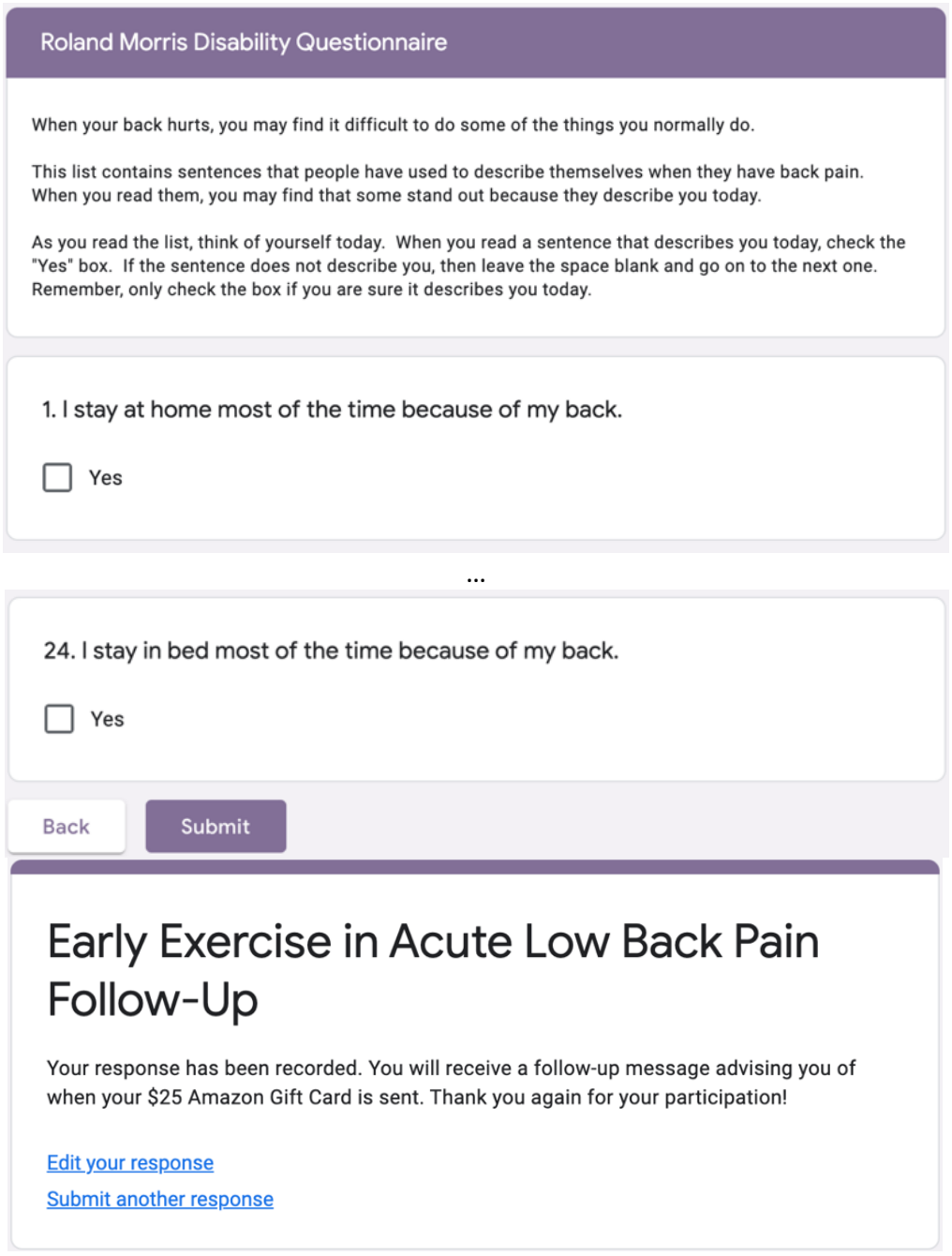
☐ Oral steroids such as prednisone or methylprednisolone (Solu-Medrol)

☐ Referral to orthopedic (spinal) surgeon

☐ Other: _____

Appendix E

Early Exercise Follow-Up Questionnaire



Images used in the Early Exercise Follow-Up Questionnaire were taken from Shutterstock (shutterstock.com), Clipart Library (clipart-library.com), and MacDonald Fitness (macdonaldfitness.ca).

Table of Evidence

Author, Year	Purpose	Sample & Setting	Methods Design Interventions Measures	Results	Discussion, Interpretation, Limitation of Findings

Fritz, J. M., Magel, J. S., McFadden, M., Asche, C., Thackeray, A., Meier, W., & Brennan, G. (2015). Early physical therapy vs usual care in patients with recent-onset low back pain: A randomized clinical trial. *JAMA: Journal of the American Medical Association, 314*(14), 1459-1467. doi:10.1001/jama.2015.11648	To determine if the initiation of early physical therapy (PT) – manual therapy and exercise – in patients with low back pain (LBP) is more effective in improving disability than usual care.	• Recruited from LBP patients seeking care from a primary care physician
		• Salt Lake City, Utah
		• Recruited between March 2011 through November 2013
		
		• 1220 potential patients identified
		• 220 participants enrolled
		  • Randomization assigned 112 patients to usual care and 108 patients to early PT
		  • 8 participants dropped out
		  • 207 participants completed 1 year follow up
		
		Usual Care group:
		  • 53% female
		  • Mean age 36.5
		  • Mean BMI 29.2
			Parallel-group randomized clinical trial (Level I)
			
			Blinded outcomes assessed at:
			  • 4 weeks
			  • 3 months
			  • 1 year after enrollment
			
			Primary Outcome
			• Oswestry Disability Index (ODI)
			
			Secondary Outcomes
			• Numeric pain rating
			• Pain catastrophizing scale (PCS)
			• Fear-avoidance beliefs questionnaire (FABQ) for physical activity
			• FABQ for work
			• 15-point global rating of change
			• 5-Dimensional EuroQol (EQ-5D)
				Primary Outcome
				• Early PT showed significant improvement in ODI score compared with usual care at 3-month follow up
				• ODI score also with significant improvement with early PT intervention at 4-week follow up but not at 1-year follow up
				
				Secondary Outcomes
				• Statistically significant differences showing greater improvement with patients receiving early PT
				  • PCS score
				  • FABQ for work
				  • Self-rating of success
				  • Self-rating of overall health
					• Magnitude of difference for statistical significance between usual care group and early PT intervention was modest
					  • Did not achieve minimum difference considered clinically important
					
					• Mixed results for secondary outcomes
					
					• There may be patient subgroups that are more likely to benefit from early PT
					  • Study's exclusion criteria limited population to acuity of symptoms (< 16 days)
					
					• Further research recommended to see if patients with somewhat longer duration of

		Early PT group: • 62% female • Mean age 38.3 • Mean BMI 28.9 Other characteristic data collected • Race • Marriage status • Education • Employment • Co-morbid conditions • Current medications for LBP • Smoking status • History of treated LBP	• Monthly diaries to collect data on healthcare utilization (advanced imaging), UC or ER visits, spine specialist visit, spinal injection, or surgery. Interventions • All patients educated on favorable prognosis of LBP • All patients advised to stay as active as possible • All patients received a copy of *The Back Book* • Usual care patients received no further interventions • Early PT patients began treatment with a trained PT within 72 hours of enrollment • Four treatment sessions were scheduled over a 3-week period • During PT patients received spinal manipulation treatment and instructions on home	• No statistically significant benefit for early PT at any follow up interval • Pain intensity • FABQ for physical activity • Health care utilization outcomes	symptoms may benefit from early PT • Further research also recommended for patients that may have psychosocial factors that influence interpretation of pain • May benefit from early intervention when psychosocial beliefs are still open to change • Patients with acute LBP will typically improve rapidly on their own • Limits treatment effects in early intervention studies • Passive physical therapy modalities such as ultrasound were not included since they were not evidence-based treatments • Physical therapy sessions were limited to 4 vs national average of 7 sessions for acute LBP • More research can determine effectiveness of

			exercises (range of motion and trunk strengthening)		number of PT sessions
					
					• Limitations
					  • More patients dropped out from usual care group vs PT group
					  • Secondary outcome results did not adjust for multiple comparisons
					  • No attention control group
					  • No assessment of adverse events in usual care group

Lehtola, V., Luomajoki, H., Leinonen, V., Gibbons, S., & Airaksinen, O. (2016). Sub-classification based specific movement control exercises are superior to general exercise in sub-acute low back pain when both are combined with manual therapy: A randomized controlled trial. *BMC Musculoskeletal*	To compare the effect of an individually tailored specific movement control exercise (SCME) combined with manual therapy to general exercise combined with manual therapy on the reduction of disability related to sub-acute low back pain (LBP)	• 223 subjects identified
		  • 70 patients met inclusion criteria
		  • 35 patients assigned to each SCME and general exercise groups after randomization
		  • 64 patients reached three-month follow up
		  • Drop-out rate 8.6%
		  • 61 patients reached twelve-month follow up
			Randomized controlled trial (Level I)
			
			Outcomes assessed at:
			  • Baseline
			  • 3 months
			  • 12 months after intervention
			
			Primary Outcome
			  • Roland Morris Disability Questionnaire (RMDQ)
			
			Secondary Outcomes
				Primary Outcome
				Three-month results:
				• Baseline to three-month measurement shows significantly superior improvement for SMCE group ($p < 0.01$) -2.4 (95 % CI -4.5 to -1.1)
				• Reduced disability >50%
				  • 87.1 % of SMCE group
				  • 54.5 % of general exercise group
				Twelve-month results:
				• Baseline to the twelve-month
					• SMCE group had significantly greater reduction in disability at 3- and 12-month follow-up measurements
					• Significant change in self-reported function for SMCE group at twelve-month follow up
					• Both groups with > 50% improvement on RMDQ
					  • 93% of SCME patients
					  • 77% of general exercise patients

Disorders, 17, 1-9. doi:10.1186/s12891-016-0986-y		• Final drop-out rate 12.9% General exercise group: • 62.9% female • Mean age 48 • Weight 80kg • Height 172cm SCME group: • 57.1% female • Mean age 51 • Weight 78kg • Height 172cm No other baseline characteristic data documented Setting: Private physical therapy clinic in Finland	• Patient-Specific Functional Scale (PSFS) • Oswestry Disability Index (ODI) • Movement control tests Interventions • General exercise (control) group • Participants taught exercises and supervised by PT • Short session of manual therapy • Given over five treatments • Goal: improve physical function, self-confidence in spinal use; targets abdominal and paraspinal muscles without involvement of deep muscle activation • SCME group • Participants taught movement pattern control in positions of sitting, four-point kneeling and standing by PT	measurement showed significantly superior improvement for SMCE group ($p < 0.01$) -1.7 (95 % CI -3.9 to -0.5) • Reduced disability >50% • 93.3% of SMCE group • 77.4% of general exercise group Secondary Outcomes of self-reported function (PSFS, ODI) • 3-month • Significant improvement in PSFS, ODI but no statistical significance • 12-month • SMCE showed significantly better result in self-reported function • Statistically significant lower need for medication in SCME group (not listed as an outcome measure and not identified in any of the mentioned data, tables)	• Result did not reach clinically significant three-point difference Limitations • Study registered retrospectively • Subjects and clinicians could not be blinded to intervention • Both groups received interventions aimed at cognitive control of spinal position • Patients with sub-acute state of LBP may have spontaneous resolution of symptoms • Longer follow up needed to evaluate sustainability of treatment effect • No information on pain intensity level was measured • Drop-out rate 12.9% • External validity can be influenced by skill of treating PT, number of sessions, time spend with each patient • Further research on effectiveness of specific exercise intervention

			• Supervised during exercises • Short session of manual therapy • Given over five treatments • Goal: improve individual direction-specific movement control of the lumbar spine, physical function and confidence in spinal use		(SMCE) on other sub-groups of LBP • Study can still suggest that combination of SMCE and manual therapy may be effective in reducing disability and improving function in non-specific recurrent sub-acute LBP, MCI more than the combination of general exercise and manual therapy

Lewis, C., Souvlis, T., & Sterling, M. (2011). Strain-Counterstrain therapy combined with exercise is not more effective than exercise alone on pain and disability in people with acute low back pain: A randomised trial. *Journal of Physiotherapy, 57*(2), 91-98.	To determine if Strain-Counterstrain treatment in addition to exercise therapy is more effective in reducing levels of pain and disability in patients with acute low back pain (LBP) vs exercise alone.	• 101 patients screened for eligibility
		  • 89 met inclusion/exclusion criteria, were deemed eligible and randomized
		  • 44 patients assigned to experimental group
		  • 45 patients assigned to control group
		  • 84 patients completed follow up
		
		Experimental group
		• Mean age: 40
			Single-center randomized controlled trial (Level I)
			
			Primary Outcome
			• Oswestry Disability Index (ODI)
			
			Secondary Outcomes:
			• SF-36 Questionnaire
			  • Quality of life
			• Visual Analog Scale
			  • Pain
			• Likert Scales
			  • Interference with work
			  • Satisfaction with symptoms
			  • Satisfaction with the intervention
				Primary Outcome
				• No significant difference in ODI scores between experimental and control groups at end of 2-week intervention period (95% CI -6 to 7)
				
				Secondary Outcomes
				• No significant difference in secondary outcomes at end of 2-week intervention period
				  • Percentage using medication
				  • Experimental group 88%
					• Adding Strain-Counterstrain (stretching) intervention did not substantially improve outcomes over exercise alone
					• Strain-Counterstrain treatment is a type of spinal manipulation, stretching therapy
					  • Research has shown that spinal manipulation was not more effective in the treatment of acute LBP than just PT exercises along
					  • Findings from study consistent with research

		• 57% female • Mean weight 78kg • Mean height 170cm • Duration of LBP 4.2 weeks • Using meds 22% Control group • Mean age: 40 • 67% female • Mean weight 80kg • Mean height 169cm • Duration of LBP 4.3 weeks • Using meds 16% Setting Outpatient physiotherapy department of a rural public hospital in Australia	• Global rating of change Interventions • All patients given same advice • Continue medications prescribed • Remain active • Avoid activities that aggravate LBP • Instruction on standardized exercise program and given printed handout • Side-lying abdominal bracing • Alternate knee-to-chest holds • Side-to-side lumbar rotation • Experimental group • Received Strain-Counterstrain treatment (passive positioning, stretching) • Attended twice per week for two weeks for treatment and review of standardized exercises	• Control group 73% • No significant difference (relative risk 1.22, 95% CI 0.98 to 1.50) • At the 6-week and 28-week follow-up periods there were no statistically significant differences for any outcomes • Percentage using medication at 6-week follow up • Experimental group 83% • Control group 73% • No significant difference (relative risk 1.13, 95% CI 0.90 to 1.43)	• About 40% of patients with acute LBP will recover on their own without any other treatment other than advice and medications • Could be cause for small effect of spinal manipulation therapy • Recommendation for sample homogeneity with regards to source of acute LBP • Develop algorithm to identify patients with acute LBP that would respond to intervention Limitations • Participants obtained from pools of patients already referred to physical therapy • No control group that did not go to physical therapy • Unable to blind physical therapist providing treatments • No control of medications prescribed to patients but medication use was similar at baseline so unlikely to be a confounding factor

			• Control group
			  • Attended twice per week for two weeks for revision and supervision of standardized exercises
			
			• After intervention period both groups received similar additional treatments
			  • Progression of home exercises
			  • Ergonomic instruction
			  • Soft-tissue mobilization
			  • Joint mobilization
					Strengths
					• Analyzed using intention-to-treat principle
					• Randomization of participants
					• Interventions provided by the same experienced physical therapist who was blind to outcome measures
					• Participants in both groups received the same number of interventions and had the same amount of contact with physical therapy
					• High follow up rate (>90%)
					
					• Optimal time frame to initiate exercise therapy after onset of LBP symptoms remains unclear

Machado, L. A., Maher, C. G., Herbert, R. D., Clare, H., & McAuley, J. H. (2010). The effectiveness of the McKenzie method in addition to first-line care for acute low back pain: A	To evaluate the short-term (3 week) effect of the McKenzie method (in addition to first-line treatment) on acute low back pain (LBP)	• 260 patients screened for eligibility
		• 148 met inclusion/exclusion criteria (two excluded after randomization)
		• 73 patients randomized to each group - first-line treatment alone and
			Multi-center randomized controlled trial (Level I)
			
			Primary Outcomes
			• Numeric Pain Scale
			  • At 1 week
			  • Mean pain over first 7 days
			  • At 3 weeks
				• Additional effects of McKenzie method on pain were statistically significant but smaller than pre-specified threshold of 1 unit
				  • Patients that received McKenzie method experienced
					• Addition of McKenzie method to recommended first-line treatment did not provide any additional clinically significant reductions on pain, disability, function, global perceived effect or risk of developing persistent symptoms

randomized controlled trial. *BMC Medicine, 8*, 10. doi:10.1186/1741-7015-8-10		first-line treatment & McKenzie method • 68 patients that received first-line care alone completed 3-month follow up • 70 patients that received first-line treatment & McKenzie method complete 3-month follow up Adherence rates • 66% over first week • 74% over treatment period • Maximum 5% lost to follow-up at any point in time McKenzie group • Mean age: 47.5 • 52% female • Taking meds 54% • Using NSAIDs 28% First-line care group • Mean age: 45.9 • 48% female • Taking meds 52% • Using NSAIDs 22% Height, weight, BMI were not included in characteristic data	• Global perceived effect • At week 3 • -5 to 5 scale • "vastly worse" to "completely recovered" Secondary Outcomes • Measured at weeks 1 and 3 • Roland Morris Disability Questionnaire (RMDQ) • Patient Specific Function Scale (PSFS) • Global perceived effect at week 1 • Persistent LBP at 3 months Interventions • First-line care group • Advice to remain active and avoid bed rest • Reassurance of favorable prognosis related to LBP • Instructions to take acetaminophen on a time-contingent basis	reduced pain by mean of 0.4 points on 0-10 pain scale at week 1 (95% CI, -0.8 to -0.1) and 0.7 points at week 3 (95% CI, -1.2 to -0.1). • Average pain over first 7 days was slightly lower with McKenzie group (mean effect, -0.3; 95% CI, -0.5 to -0.0) • For all other outcomes, additional effects of McKenzie method were near zero at all time points and not statistically significant • Development of persistent low back pain • 53% McKenzie group • 47% first-line care group • Difference not statistically significant (relative risk, 1.1; 95% CI, 0.8 to 1.6; *P* = 0.49)	compared to patients receiving only first-line treatment • First-line treatment group did seek more additional care for LBP than patients in McKenzie method group • Effect of McKenzie method on pain is small (0.7 points or less) and would not be considered worthwhile recommended treatment Limitations • Lack of blinding for participants and therapists • Specific education and training regarding McKenzie method provided to therapists may cause differences in the care provided • Adherence to protocol by therapists and physicians was not evaluated • Short-term follow-up limited scope of study • Lack of proper cost-effectiveness analysis Strengths

		Setting
		Primary care patients in Sydney, Australia seek care for LBP
			• McKenzie group
			  • First-line care interventions
			  • Immediate referral to physical therapy (PT)
			  • Initiate McKenzie method with PT within 48 hours of physician consultation
			  • Maximum of 6 sessions over 3 weeks
			  • Perform prescribed exercises at home
			  • Follow PT's postural advice at all times
			  • Provided with *Treat Your Own Back* book
			  • Some participants also receive lumbar roll at therapists' discretion
				• McKenzie group less likely to seek additional health care for back complaints after 3-week treatment period	• Provides additional treatment information that would be helpful in clinical decision making
					• Treatment provided by highly trained therapists
					• Satisfactory patient adherence during study
					• Low rate of loss to follow-up
					
					• Authors found that similar studies on McKenzie method found similar results
					
					• Useful study in determining correct exercise recommendations in addition to first line treatments
					
					• McKenzie method would not be a useful exercise addition to first-line treatment to obtain clinically significant outcomes

Wand, B. M., Bird, C., McAuley, J. H., Doré, C. J., MacDowell, M., & De Souza, L. H.	To determine the effect of timing of active interventions with patients that have acute low	• 804 patients considered for inclusion • 102 met eligibility criteria and were	Multi-center randomized, controlled, single-blind trial (Level I)	6-Week Follow-Up • Significant effect of treatment ($P < 0.05$) on: • STAIS	• Findings suggest that early treatment leads to improved outcomes in disability as well as general health, social

(2004). Early intervention for the management of acute low back pain: A single-blind randomized controlled trial of biopsychosocial education, manual therapy, and exercise. *Spine (03622436)*, *29*(21), 2350-2356.	back pain (LBP) and to compare outcomes with patients that were given advice to stay active and to wait on receiving treatment at the 6-week follow up and at long term follow up.	randomized to two groups: • Assess/advise/ treat – 50 patients • Assess/advise/ wait – 52 patients • One patient from each group excluded after randomization due to pending litigation • Six patients failed to complete baseline assessment • 65 patients (64%) completed 6-week follow up • 63 patients (62%) completed long-term follow up • No significant difference between groups in proportion of returned questionnaires Assess/advise/treat group (n=43) • Mean age: 34 • 44% female (n=19) • Mean BMI 26 • Not working due to LBP n=21	• Assessor is independent and blind to patient allocation to groups Primary Outcome • Roland and Morris Disability Questionnaire (RMDQ) Secondary outcomes • Visual Analogue Scale (VAS) • Usual Pain Intensity • 6 items from Spielberger State-trait Anxiety Inventory (STAIS) • Modified Zung Self Rate Depression Score (MZSRDS) • Modified Somatic Perception Questionnaire (MSPQ) • EuroQol health transition and health thermometer • Short Form 36 (SF-36) Interventions • Both groups received • Physical exam • Advice on staying active	• RMDQ • MZSRDS • EuroQol Total Score • EuroQol Health Thermometer • SF-36 Vitality • SF-36 Social Functioning • SF-36 Mental Health Long-term Follow-Up • Significant long-term effect of treatment ($P < 0.05$) on: • STAIS • MZSRDS • MSPQ • EuroQol Health Thermometer • SF-36 Role-Emotional • SF-36 Mental Health • SF-36 Health Transition	function, anxiety, depressive symptoms, mental health and vitality • Pain, disability not significant different at long-term follow-up • Assess/advise/wait model caused delay in improvement of disability without long-term ramifications • More research aimed at analyzing content of treatments and clinical reasoning by therapists providing treatments • Effective interventions need to be multi-modal and developed within a rehabilitative framework • Focus should be on philosophical construct vs individual interventions • Few studies on acute LBP focus on psychosocial variables as outcomes • Study shows that early active treatment can improve psychosocial outcomes

		First-line care group (n=51)
		• Mean age: 35
		• 55% female (n=28)
		• Mean BMI 25
		• Not working due to LBP n=17
		
		No other characteristic data noted
		
		Setting
		Physiotherapy Outpatients Department at Central Middlesex Hospital, London.
			• A copy of *The Back Book*
			
			• Assess/advise/wait Group
			  • Appointment to begin PT at 6 weeks from baseline
			
			• Assess/advise/treat Group
			  • Received immediate treatment with PT
			
			Major interventions used:
			• Manual therapy
			  • Spinal manipulation
			• Rehabilitative exercises
			  • To affect pain intensity and distribution
			  • To improve spinal stability, movement, posture, and alignment
			  • To improve overall fitness and strength of lower extremities and back
					Limitations
					• Large amount of missing follow up data (one-third of randomized cases)
					• Sensitivity analysis shows loss was unlikely to cause substantial bias in results
					• Bias is always a possibility with low follow-up rates

			• Advice on staying active • Education • Based on information from *The Back Book* • Biopsychosocial protocol used to assess patients • Goal-directed treatment plan created • Treatment protocol explained to patients • Short- and long-term functional goals reviewed and agreed Not included in treatment model: • Electrotherapy • Traction • General back exercises		

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