RESEARCH PROPOSAL

Title: Immediate Effect Of Standing Trunk Extension Postures On Spinal Height And Clinical Outcome Measures In Low Back Pain: A Randomized Clinical Trial

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TABLE OF CONTENTS

ABSTRACT…………………………………………………………………………4
LIST OF FIGURES……………………………………………………………...5
LIST OF ABBREVIATIONS…………………………………………………….6
BACKGROUND…………………………………………………………………7
PURPOSE, AIMS, VALUES…………………………………………………12
RESEARCH QUESTIONS……………………………………………………13
HYPOTHESES…………………………………………………………………13
COMPARISON VARIABLES…………………………………………………14
Independent Variables……………………………………………………14
Dependent Variables……………………………………………………..15
Relationship Variables……………………………………………………15
METHODS……………………………………………………………………..16
Research Design…………………………………………………………16
Pre-Study Approvals………………………………………………………16
Subjects…………………………………………………………………….16
Testing Sequence…………………………………………………………17
DATA ANALYSIS………………………………………………………………22
RESEARCH PROJECT TIMELINE…………………………………………25
REFERENCES…………………………………………………………………26
APPENDICES…………………………………………………………………41

ABSTRACT

Background: Standing trunk extension postures have been used for many years as a mechanical approach to low back pain (LBP), sometimes directed by therapeutic intervention, sometimes subconsciously performed by patients to relieve LBP. However, no study to date has investigated the effect of standing trunk extension postures on spinal height and clinical outcome measures.

Objective: The purpose of this study will be to evaluate in subjects with LBP following a period of trunk loading, how spinal height and/or pain, symptoms' centralization, and function outcome measures respond to: (1) standing repetitive trunk extension posture; and (2) standing sustained trunk extension posture. Lumbar range of motion (ROM) achieved during these two trunk extension postures will be compared to spinal height and outcome measures.

Methods: A pre-test, post-test comparison group design (randomized clinical trial) will be used to determine how spinal height changes in response to sustained and repetitive standing trunk extension after a period of spinal loading. The study will use a 2 (between subjects – type of trunk extension: sustained vs. repetitive) x 3 (within subjects - time: before vs. after vs. 2 weeks after intervention) mixed design to evaluate the effects of sustained and repetitive trunk extension in standing on spinal height, pain, symptoms' centralization and function.

Statistical Analysis: A 2(Strategy) X 3(Time) mixed ANOVA will be used to statistically identify significant interactions and main effects for spinal height, pain and function outcome measures. Post-hoc pairwise comparisons will be used to locate significant differences between the different conditions (Time). Significance will be set at $\alpha = 0.05$. Pearson product-moment correlations will be used to measure correlations between lumbar ROM in relation to spinal height and outcome measures. The Kruskal-Wallis 1-factor ANOVA for difference scores will used to determine changes of intensity and location of symptoms following sustained versus repetitive standing trunk extension. Spearman Rank correlation will be used to evaluate the relationship between spinal height changes and changes of pain and location of symptoms for each group.

Word Count: 326

Key Words: Standing postures; trunk extension; spinal height change; stadiometer

Lay Summary

Standing back extension postures have been used for many years to treat people with low back pain.

No study to date has investigated the effect of standing back extension postures on trunk height, pain and function.

The **purpose** of this study will be to evaluate in subjects with low back pain how trunk height, pain and function respond to standing repetitive versus sustained trunk extension postures.

Methods: A randomized clinical trial will be used to determine how trunk height, low back pain and function change in response to sustained and repetitive standing trunk extension after a period of spinal loading.

Statistical Analysis will be used to measure the outcomes.

LIST OF FIGURES

Figure 1: Flowchart depicting testing sequence……………………………………31

Figure 2: Starting position for standing trunk extension (repetitive and sustained……………………………………………………………….34

Figure 3: Sustained trunk extension position and end position of repetitive trunk extension……………………………………………………………….35

Figure 4: Position of subject for spinal height measure in stadiometer unit……..36

Figure 5: Position of subject during spinal loading time in sitting………………...37

Figure 6: Home exercise program for repetitive trunk extension group……........38

Figure 7: Home exercise program for sustained trunk extension group…………39

Figure 8: Home instructions for each subject……………………………………….40

LIST OF ABBREVIATIONS

Analysis of Variance……………………………………………..…………ANOVA

Fear Avoidance Belief Questionnaire…..……………………………….....FABQ

Intervertebral Disc………………………………………..……………………. IVD

Institutional Review Board………………………………………………………. IRB

Low Back Pain………………………………………………………………….LBP

Numerical Pain Rating Scale………………………………………….……NPRS

Range of Motion……………………………………………………………….ROM

Standard Deviation………………………………………………………………SD

Research Question…………………………………………………………...RQ

Research Hypotheses…………………………………………………………..RH

Independent Variable……………………………………………………….....IV

Dependent Variable……………………………………………………………..DV

Relationship Variable……………………………………………………………RV

BACKGROUND

According to the United States Department of Labor, there were more than one million injuries and illnesses requiring days away from work amongst private industry, state and local government employees. Among these injuries and illnesses, 16.6 % were low back related equating to 191,479 low back injuries requiring days away from work (US Department of Labor, Bureau of Labor Statistics, 2016). An analysis funded by the National Institute of Health found that the cost of pain outweighed the cost of cancer and diabetes by thirty percent. The authors further reported that the annual cost of pharmaceuticals for pain management was $16.4 billion, and the cost of lumbar surgeries was $2.9 billion. Pain indirect costs estimates were $18.9 billion for disability compensation and $6.9 billion for productivity loss (Gaskin 2011, The Economic Costs of Pain in the United States).

A joint clinical practice guideline developed by the American College of Physicians and the American Pain Society classified low back pain (LBP) into three categories: (1) nonspecific LBP; (2) LBP potentially associated with radiculopathy or spinal stenosis; and (3) LBP potentially associated with another specific spinal cause. Of those three, lumbar intervertebral disc (IVD) herniation is one of the most common spinal degenerative disorders leading to LBP associated with radiculopathy (Chou 2007, Goupille 1998, McCall 2000). In order to better understand the IVD's role in the development or persistence of LBP and spinal stenosis, there have been many stadiometric studies primarily focused on lumbar spinal height changes associated with various positions and movements

(Kourtis 2004; Magnusson 1996; Lazzarini 2014; Simmerman 2011). These studies stem from IVD height preservation in the aging spine. Natural IVD height preservation is so important that the biomedical field has examined the use of growth factors for IVD biologic regeneration (Masuda 2004) in order to more naturally preserve IVD biomechanical and physiological function as opposed to surgical disruption. To further understand IVD functional properties, researchers have studied the IVD hydraulic permeability and the influence that age and/or degeneration have on fluid movement (Gu 1999). The authors reported that with IVD degeneration, the radial permeability of the anulus fibrosus decreased, mainly because of reduced water content. However, the axial and circumferential permeability coefficients increased, mainly due to structural change, leading to greater IVD isotropic permeability behavior (Gu 1999).

Sixty one percent of time in the work and home environment is spent in the standing posture (US Department of Labor, Bureau of Labor Statistics, 2016). Although prolonged weight bearing postures, such as standing and walking, have been associated with decreased spine height (Tyrrell 1985, Puntumetakul et al 2009), some studies reported that seated weight bearing postures could result in spine height gain (Magnusson 1996a). Sustained and repetitive lumbar extension postures frequently occur after periods of prolonged unloading such as sleep. These postures are periodically repeated throughout the day during activities such as standing and walking (US Department of Labor Bureau of Labor Statistics 2016).

People presenting with directional preferences that include lumbar extension tend to respond well to exercises geared toward trunk extension (Stankovic 1990, Swinkels 2009, Oliveira 2012). Significant and rapid changes in central and distal pain intensity and location have resulted from standing end-range trunk extension in patients with low back and referred pain (Donelson 1991). Additional studies reported that standing back extension exercises resulted in back pain episodes' prevention and decreased back pain in care workers (Matsudaira 2015; Dunsford 2011). Standing exercises have the advantage to be functional and easily performed in work and home settings (Tonosu 2016).

A positive relationship has been found between lumbar extension range of motion (ROM) and the centralization process in patients with LBP (Bybee et al 2009). The centralization phenomenon is part of the clinical examination findings used to identify specific treatment-based classification subgroups. Centralization is characterized by spinal pain and referred symptoms that are progressively abolished in a distal to proximal direction in response to therapeutic interventions including unloading or specific movement strategies (Brennan et al 2006, Laslett et al 2005). The operational definition and measurement techniques for centralization have been laid out in several studies (Aina et al 2004, Werneke et al 2008). A decreased spinal ROM is commonly associated with low back complications, and functional ROM needs to be restored to allow for the return to previous activity levels (Battie 1987, Vaisy 2015). Several methods have been used to increase spinal ROM including static, repeated, passive postures, and proprioceptive neuromuscular facilitation. Both standing and prone lumbar extension postures are effective for treating low back Dysfunction Syndrome (McKenzie 2003). However, which method is best suited for increasing spinal ROM remains debated (Sady 1982; Nordez 2017). One author found static prone postures to increase ROM more effectively with 30-60 second sustained postures as compared to 15-second postures, but no difference between the effectiveness of 30-second and 60-second postures (Bandy 1994; Page 2012).

Repetitive postures are another method used to increase ROM by elongating shortened connective tissue. The McKenzie classification of Dysfunction Syndrome is defined as the condition in which adaptive shortening of soft tissues and resultant loss of mobility cause pain by stretching shortened tissues that block full end-range movement (Hefford 2008). Poor postural habits, previous trauma and inflammatory or degenerative processes can lead to this dysfunction. These patients can develop contraction, scarring, adherence and adaptive shortening or imperfect repair and pain is felt when the abnormal tissue is stretched.

Treatment of the Dysfunction Syndrome consists of postural correction, along with repeated end-range movements to remodel contracted structures. This intermittent stress is reported to provide an adequate stretching effect and is most effective in the treatment of extension dysfunction (McKenzie 2003). One study found that patients with LBP chose to perform their extension posture for home exercise in standing 80.8 % of the time and only 19.2 % of the time in the prone position, resulting in similar clinical outcomes where both groups showed equal improvements in lumbar extension ROM (Bybee et al 2008).

Previous studies investigated the effects of postures and movements in lying (unloaded) or seated positions on spinal height (Owens 2009, Gerke et al 2010; Pape 2018). These studies primarily focused on spinal height following static patient positioning and showed that both the lying and supported seated positions resulted in mean spinal height gains of 2 to 5 mm. However, most rehabilitation programs focused on LBP prevention and management use both repetitive and/or sustained spinal extension exercises to improve patients' outcomes (Peterson 2015, Surkitt 2012). Such exercises can be performed in lying or standing position. Although patients with acute and recurrent low back and referred pain tend to respond well to directionally preferenced postures (Machado 2006), subjects with chronic symptoms tend to display greater signs of sensitization, biopsychosocial issues (Huysmans 2017), and tend to respond less favorably to directional preferences postures and exercises (Garcia 2017). In order to assess the biopsychosocial effect on clinical outcomes during this study, every subject will complete the Fear Avoidance Belief Questionnaire (FABQ) (Cleland et al 2008).

No study to date has investigated the effects of standing extension postures on spinal height, pain, centralization and function. Therefore, the purposes of this study will be to evaluate in a sample of LBP patients the effect of standing trunk extension, both sustained and repetitive, following a period of spinal loading, on (1) spinal height; (2) pain; (3) symptoms centralization and (4) functional measures.

PURPOSE, AIMS, VALUES

Purpose(s):

The purpose of this study is to assess the effect of commonly used standing trunk extension postures on spinal height as well as pain, symptoms' centralization, and function in patients with LBP.

Aim(s):

Our aim is to better understand the effect of standing sustained and repetitive trunk extensions on spinal height and LBP patients' symptoms intensity, centralization and function. With many patients commonly falling into a directional preference group and responding positively to mechanical spinal input, it is our aim to investigate if such trunk extension postures performed in standing affect spinal height in regard to growth or shrinkage and if these changes are associated with symptoms intensity, centralization and functional alterations.

Value(s):

No previous study has examined changes in spinal height following standing trunk extension postures and little is known on the effect of such standing postures on spinal height. The results of this study could impact rehabilitation programs that include standing trunk extension as a means of therapeutic intervention. This is valuable especially in aging population with degenerated IVD's, loss of IVD height and propensities toward spinal stenosis, as we do not know if those subjects with directional preferences toward spinal extension could use standing trunk extension postures at home or in the work environment to grow and/or prevent spinal shrinkage.

RESEARCH QUESTIONS, HYPOTHESES AND VARIABLES

Research Question(s) (RQs)-This project aims to answer the following research questions:

1. **RQ 1**: Does sustained and repetitive standing trunk extension following a period of spinal loading effect spinal height, pain, centralization and function testing outcomes immediately and two weeks following the interventions in patients with LBP?
2. **RQ 2**: Following a period a spinal loading, is there a difference in spinal height, pain, centralization and function testing outcome *changes* immediately and two weeks following sustained and repetitive standing trunk extension postures in patients with LBP?
3. **RQ 3**: Is there a correlation between the degree of trunk extension during standing lumbar extension posture and spinal height, pain, centralization and function testing outcomes *changes* immediately and two weeks following the interventions in patients with LBP?

Research Hypotheses- (RH) This student has devised the following research hypotheses:

1. **RH 1**: It is expected that following a period of trunk loading, both sustained and repetitive trunk extension postures in standing will result in increased spinal height, reduced pain, enhanced centralization and

function testing outcomes immediately and two weeks following the interventions in patients with LBP.

2. **RH 2**: It is expected that following a period of trunk loading, sustained standing trunk extension posture in standing will result in greater spinal height gain as compared to repetitive standing trunk extension postures, while repetitive standing trunk extension postures will result in greater improvements in pain, centralization and function testing outcomes as compared to sustained standing trunk extension postures immediately and two weeks following the interventions.

3. **RH 3**: It is expected that following a period of trunk loading, there will be a positive correlation between the degree of trunk extension during standing trunk extension posture and spinal height, centralization, pain and function testing outcomes changes immediately and two weeks following the interventions in patients with LBP.

Comparison Variables

Independent Variable(s)-The student plans to use the following Independent variable(s) (IV)

1. IV1: Trunk extension
    a. IV1: sustained
    b. IV2: repetitive
2. IV2: Time

a. IV1: before

b. IV2: after (immediately)

c. IV3: after 2 weeks

Dependent Variable(s)-The Student plans to measure the following dependent variable(s) (DV)

1. DV1: Spinal height using stadiometer (ratio scale).
2. DV2: Pain rating using numerical pain rating scale (NPRS) (ordinal scale).
3. DV3: Centralization (ordinal) using body diagram.
4. DV4: Modified Oswestry Pain Disability Questionnaire (ordinal scale)

Relationship Variable(s)- (RV) (if applicable)

1. RV1: Degree of spinal extension (ratio)
2. RV2: Spinal height using stadiometer (ratio scale).
3. RV3: Pain rating using numerical pain rating scale (NPRS) (ordinal scale).
4. RV4: centralization (ordinal).
5. RV5: Modified Oswestry Pain Disability Questionnaire (ordinal scale)

METHODS

Research Design(s)

A pre-test, post-test comparison group design (randomized clinical trial) will be used to determine how spinal height changes in response to sustained and repetitive standing trunk extension after a period of spinal loading. The study will use a 2 (between subjects – type of trunk extension: sustained vs. repetitive) x 3 (within subjects - time: before vs. after vs. 2 weeks after) mixed design to evaluate the effects of sustained and repetitive trunk extension in standing on spinal height, pain, centralization and function outcome measures.

Pre-study Approvals

The study will be submitted to the Texas Tech University Health Sciences Center Institutional Review Board (IRB) for approval. The trial will then be registered at https://clinicaltrials.gov .

Subjects / Specimens

Systematic consecutive sampling of up to 100 subjects with LBP (40 subjects completing both days of data collection) attending “Sports medicine and Physical therapy clinic” in Fredericksburg (Texas) as patients or for the purpose of health and wellness will be recruited. Flyers will also be posted at physician offices and the general Fredericksburg community and surrounding areas to inform subjects about the study (Appendix A).

Inclusion Criteria: (1) Ability and willingness to come twice to the clinic for approximately 60 minutes each; (2) Subjects with LBP and directional preference in back extension; (3) Age 18-80 (Yarznbowicz et al 2018); (4) Ability to stand for 5 minutes; (5) Ability to sit for 10 minutes; and (6) Low back pain on Numerical Pain Rating scale (NPRS) of at least 2/10 and less or equal to 9/10 (Ferreira-Valente 2011).

Exclusion Criteria: (1) Pregnancy by subject report; (2) history of back surgery or spinal fractures within the last six months; (3) history of spinal fusion or physician's diagnosis of spinal instability; (4) current history of acute systemic infection, active inflammatory disease, or malignancy; (5) subjects engaged in legal/compensation claims for their back symptoms; and (6) subjects unable to understand or speak English.

Testing Sequence

Subjects will be asked to attend two physical therapy sessions over approximately a 60-minute period each to complete the study.

Session 1

Participants will complete a pre-screening questionnaire regarding inclusion (Appendix B). Each subject will watch an audio-visual power point presentation explaining the study, test procedures and describing the interventions (standing repetitive trunk extension and standing sustained trunk extension). Written informed consent will be obtained. To determine directional preference, the investigator (JH) will use the guidelines set forth in the directional preference definition (Werneke 2011) and based off of standards set forth in randomized clinical trials (May et al 2008). Directional preference has been defined as either (1) a specific direction of trunk movement or posture noted during the physical examination or (2) a specific easing factor reported by the patient during the subjective history that alleviates or decreases the patient's pain, with or without the pain having changed location and/or increased the patient's lumbar range of motion (Werneke 2011). A questionnaire including pertinent medical history will be completed (Appendix C). Subjects will complete (1) a Numerical Pain Rating Scale (NPRS) to rate their current, minimum, maximum and average LBP over the last two days (Ferreira-Valente MA 2011) as well as paresthesia signs/symptoms intensity (Appendix D); (2) Body Diagram for indicating location of symptoms (Appendix E); (3) Modified Oswestry low back pain questionnaire (Fritz 2001) (Appendix F); (4) Fear Avoidance Belief Questionnaire (Cleland et al 2008) (Appendix G). A researcher will record subject's height and weight. A Flow chart illustrates study sequence in details (Figure 1).

If the subject meets criteria for inclusion in the study, the subject will complete a familiarization procedure to determine the consistency to reposition themselves in the stadiometer. Subjects able to reposition themselves in the stadiometer with a SD of 1.3mm or less for five consecutive measurements (Stothart et al 2000; Gerke et al 2011; Owens et al 2009) will be included in the study. The digital display will be covered to blind the researcher performing the measurements. The data will be automatically recorded by the stadiometer and manually downloaded to a laptop computer.

At the beginning of data collection, a randomization plan generator (http://www.randomization.com) will assign each subject to one of two interventions: (1) standing *repetitive* trunk extension at a rate of 10 per 45 seconds (Figure 2), repeated five times with 15-second rest breaks; or (2) standing *sustained* trunk extension for 5 x 45 seconds with 15-second rest breaks (Figure 3). Each subject will complete one intervention. The intervention number assigned will be recorded by the subject next to their name to allow blinding of the investigator as to which intervention the subject is assigned to. The subject will undergo the test sequence after a 10-minute period of trunk unloading in a supine posture to ensure spinal height is normalized, head in neutral posture, knees supported over a small bolster pillow, hands placed on the abdomen (Kourtis et al 2004; Magnusson et al 1996a; Gerke et al 2011; Owens et al 2009). The subject will reposition on the stadiometer and spinal height will be measured after a relaxed exhalation (Measurement 1) (Figure 4). The subject then will undergo a five-minute period of loaded upright sitting with a 4.5kg bag secured on each shoulder and spinal height will be measured (Measurement 2) (Figure 5) (Kourtis et al 2004; Owens et al 2009; Gerke et al 2011). As continued spinal height reduction has been demonstrated following loaded sitting, the subject will undergo an additional five minutes sitting without load and spinal height will be measured (Measurement 3) (Kourtis et al 2004; Owens et al 2009; Gerke et al 2011). Inclinometers will be used to take an initial measure of each subject trunk extension prior to intervention. The subject will then undergo one intervention for 5 minutes as previously described, according to the randomization assignment. In order to determine how sustained and repetitive interventions related in terms of change in spinal height, the time to perform the sustained lumbar posture matches the time necessary to perform the repetitive lumbar extension postures.

The subject will reposition on the stadiometer and spinal height will be measured (Measurement 4). Trunk extension will be measured to determine the strength of correlations between the degree of trunk extension during standing trunk extension posture and spinal height, pain and centralization testing outcomes changes (MacDermid et al 2015). The subject will score their low back and lower extremity symptoms using NPRS (Ferreira-Valente MA 2011), and *map their pain* on a body pain diagram (Appendix E) prior to intervention, immediately after and 2-week following the intervention to determine pain rating and centralization of symptoms (Simmerman et al 2011). The principal investigator will apply a numeric overlay template to the patient's body diagrams to document the most distal pain location scores between 1 and 6 (Appendix I). Higher score will indicate a more distal symptoms' location.

<u>Home instructions</u>

Subjects will be instructed to continue to use their medications, including medications aimed at decreasing their pain, as prescribed by their primary healthcare provider and not to change them during the follow-up two-week period. A sheet including home exercise instructions will be provided to each patient. Instructions will include repetitive or sustained trunk extension based on random group assignment, performed approximately 5 times per day. Each subject will complete a sheet recording home exercise compliance upon arrival in session 2 (Appendix I).

Session 2

Subjects will complete: (1) a NPRS to rate their current, minimum, maximum and average LBP over the last two days as well as paresthesia signs/symptoms intensity (Appendix D); (2) Body Diagram for indicating location of symptoms (Appendix E) (3) Modified Oswestry low back pain questionnaire (Fritz 2001) (Appendix F); (4) Fear Avoidance Belief Questionnaire (Cleland et al 2008) (Appendix G). Each subject will then complete a familiarization procedure to determine the consistency to reposition themselves in the stadiometer as described in session 1. The subject will undergo a 10-minute period of trunk unloading in a supine posture to ensure spinal height is normalized as described in session 1. The subject will reposition on the stadiometer and spinal height will be measured after a relaxed exhalation (Measurement 1) (Figure 4). The subject then will undergo a five-minute period of loaded upright sitting with a 4.5kg bag secured on each shoulder and spinal height will be measured (Measurement 2) (Figure 5). The subject will then undergo an additional five minutes sitting without load and spinal height will be measured (Measurement 3). Inclinometers will be used to take an initial measure of each subject trunk extension prior to intervention. The subject will then undergo the same intervention as in session 1 for 5 minutes as previously described (standing repetitive trunk extension or standing sustained trunk extension). The subject will reposition on the stadiometer and spinal height will be measured (Measurement 4). Trunk extension will be measured to determine the strength of correlations between the degree of trunk extension during standing trunk extension posture and spinal height, pain and centralization testing outcomes changes (MacDermid et al 2015). The subjects will then score their low back and lower extremity symptoms using NPRS (Ferreira-Valente MA 2011), and *map their pain* on a body pain diagram (Appendix H).

<u>Investigator Blinding</u>

One investigator will be involved with data collection. The investigator, Jeremy Harrison, PT, DPT will carry out inclinometer measurements of lumbar and sacral posture, supervised positioning in the stadiometer and stadiometric measurements. The investigator will be blinded to the intervention (each subject will receive a hidden random number and will perform independently the intervention in a treatment room) and the stadiometric measurements during the experiment. He will also be responsible for assigning subjects to their initial groups, supervising the subjects' positioning in the different standing postures and confirming that a stadiometer reading is recorded on an Excel spreadsheet.

<u>Subjects Compensation</u>

Subjects will receive a one-month free membership to Hill Country Memorial Wellness Center in Fredericksburg, Texas if they consent to participate in the study.

<u>Subjects Charges</u>

There will be no charge for the two physical therapy sessions, including examination and intervention. Following the two intervention sessions, subjects referred by primary care providers (physicians, chiropractors, nurse practitioners, physician assistants) to physical therapy for LBP will have the choice to receive standard care and be charged for physical therapy intervention.

Confidentiality and data protection

Electronic Transmission of Personally Identifiable Information (PII) and Protected Health Information (PHI) will be followed and computer device has been encrypted (password protected). Excel spreadsheet will be used to store the data. No Personally Identifiable Information will be retained in the Excel spreadsheet where the data will be stored.

Data Analysis

Descriptive and inferential statistics will be used utilizing SPSS 23.0 for Windows (SPSS, Chicago, IL).

1. **Descriptive analyses**: Descriptive statistics including mean, median, mode, standard deviation, minimum and maximum values, frequency counts will be collected for age, height, weight, body mass index, pain, centralization, function (Oswestry Low Back Pain Disability Questionnaire), Fear Avoidance Beliefs Questionnaire, spinal height, and spinal height changes after repetitive and sustained standing trunk extension after a period of spinal loading.
2. **Inferential analyses:** Levene's test and Shapiro-Wilk test of normality will used to test for variance and distribution of measurements of spinal height,

changes in spinal height, degrees of spinal extension, pain, and function outcomes.

For *experimental hypothesis 1,* a paired-t-test (or Wilcoxon sign-rank test if the data do not meet assumptions for parametric inferential statistics) will be used to assess differences in spinal height, centralization and pain outcomes improvements following sustained and repetitive trunk extension postures.

For *experimental hypothesis 2*, 2 (between subjects - type of trunk extension: sustained vs. repetitive) x 3 (within subjects - time: before, immediately after and 2-week after) mixed ANOVA's will examine differences in (1) spinal height; (2) pain; and (3) function outcomes, as a result of sustained and repetitive standing trunk extension after a period of spinal loading. Post hoc paired t-tests will explore further for significant differences in spinal height, pain and function outcomes between the six conditions.

Experimental hypothesis 3 will be tested with Pearson product-moment correlations to determine the strength of correlations between the degree of trunk extension during standing trunk extension posture and spinal height, pain and function, outcomes changes in patients with LBP. Spearman's Rank Order correlation will be used to determine the strength of the correlation between centralization and the degree of trunk extension posture in standing.

Alpha level will be set at 0.05 for significance for all tests and Bonferroni corrections performed as needed.

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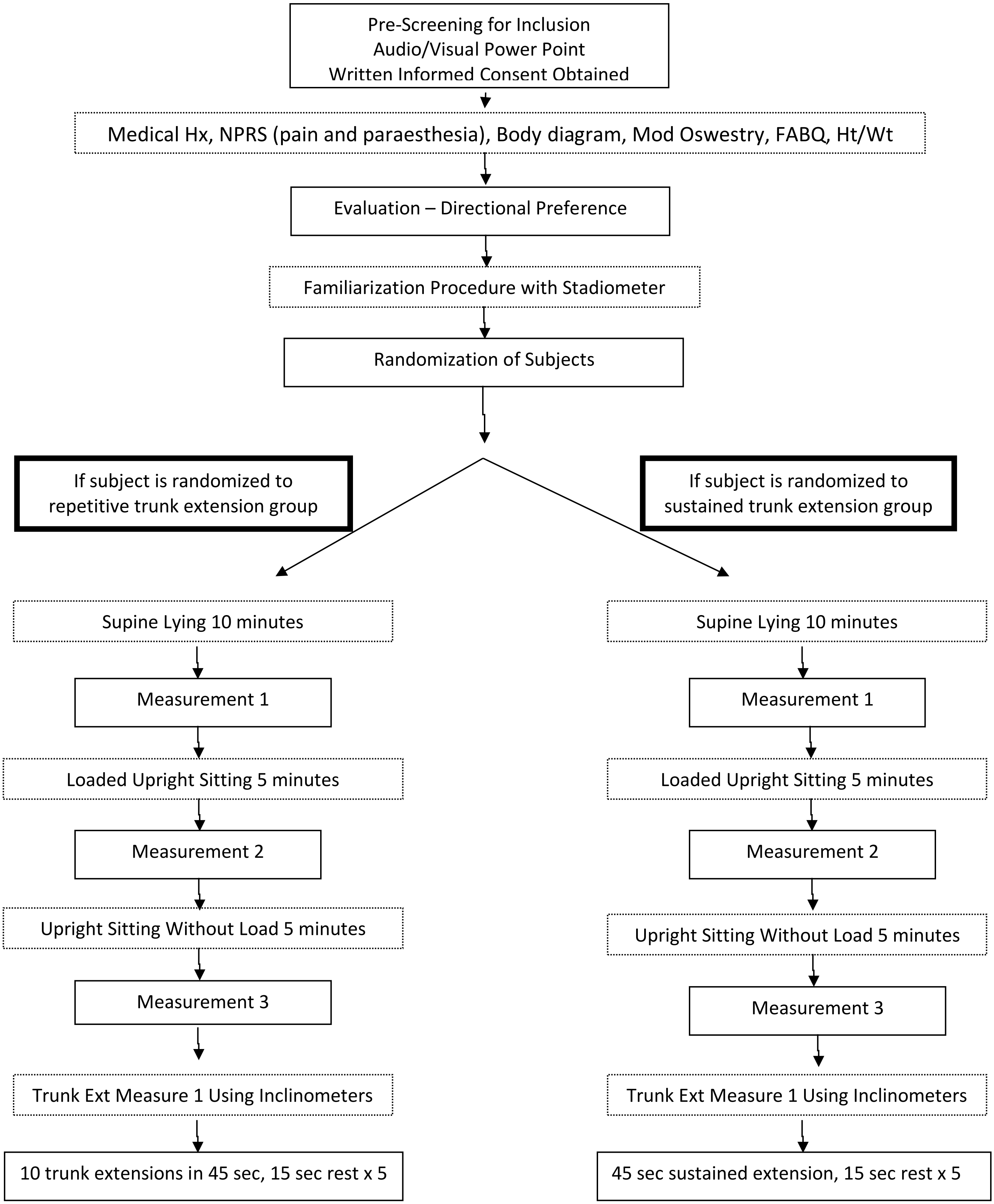
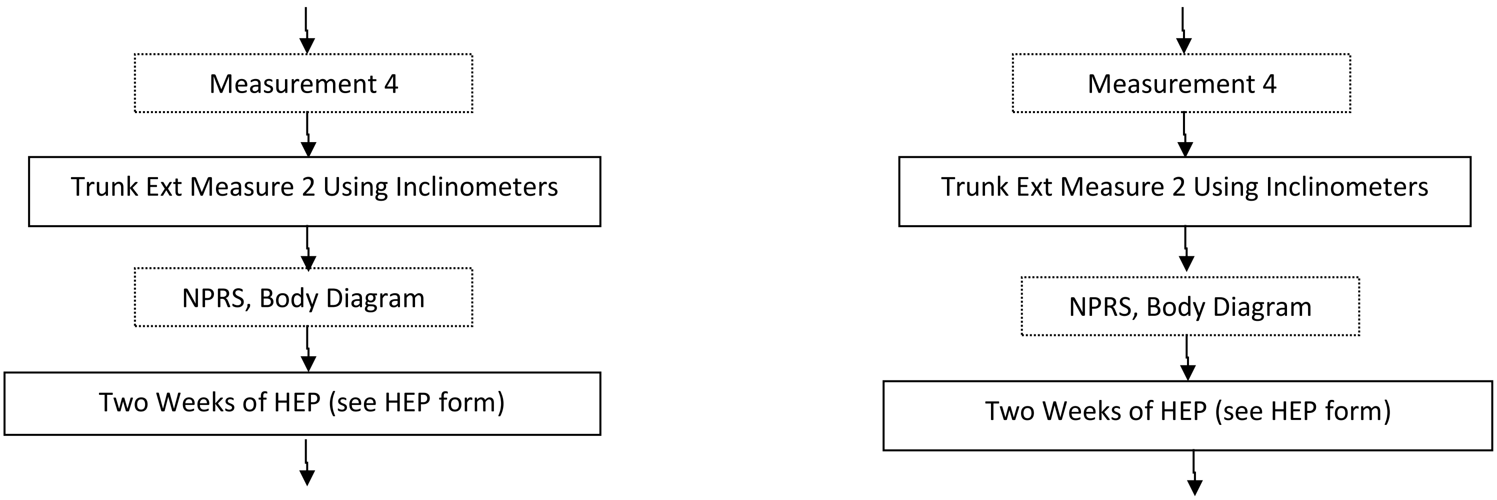
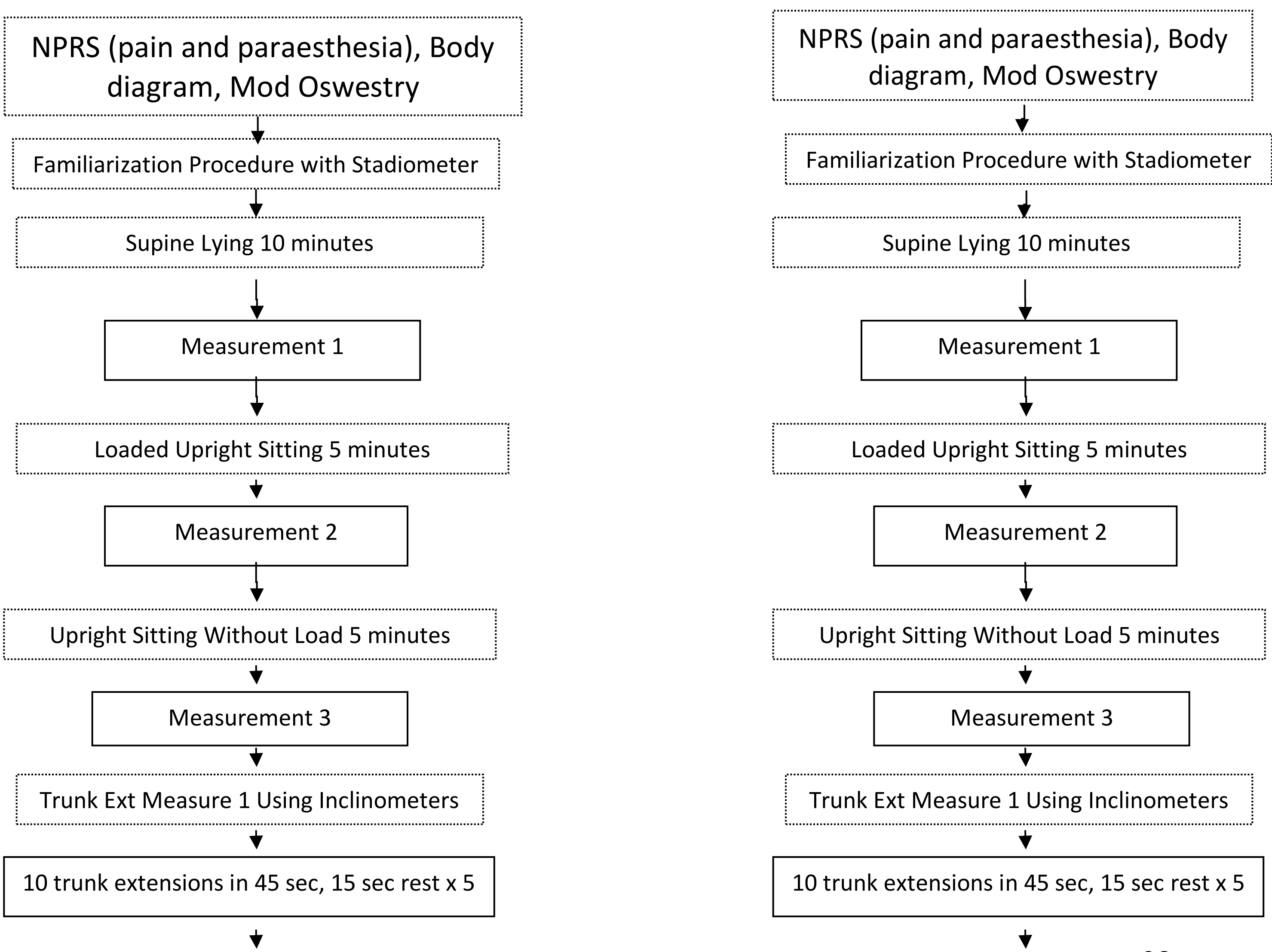
Figure 1: Flow chart of test positions and testing sequence





Second Visit



Measurement 4

↓

Trunk Ext Measure 2 Using Inclinometers

Measurement 4

↓

Trunk Ext Measure 2 Using Inclinometers

Figure 2: Starting position for trunk extensions.

Figure 3: Sustained trunk extension position and end position of repetitive trunk extensions.

Figure 4: Position of subject for spinal height measure in stadiometer unit.

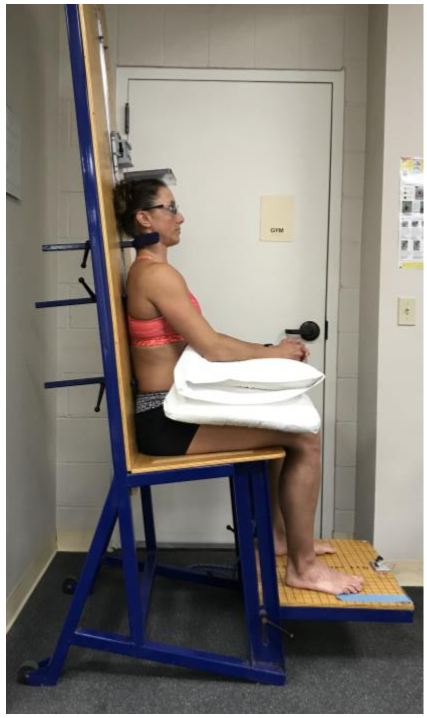
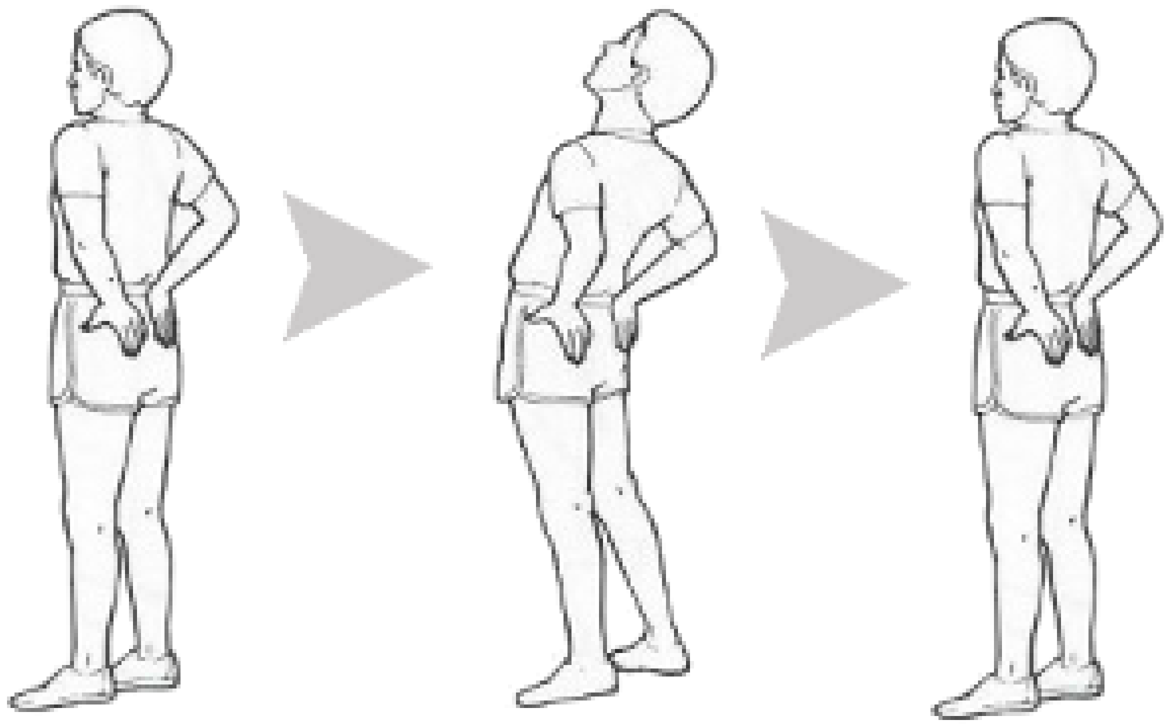


Figure 5: Position of subject during spinal loading time in sitting.

Figure 6: Home instructions for Repetitive Trunk Extension

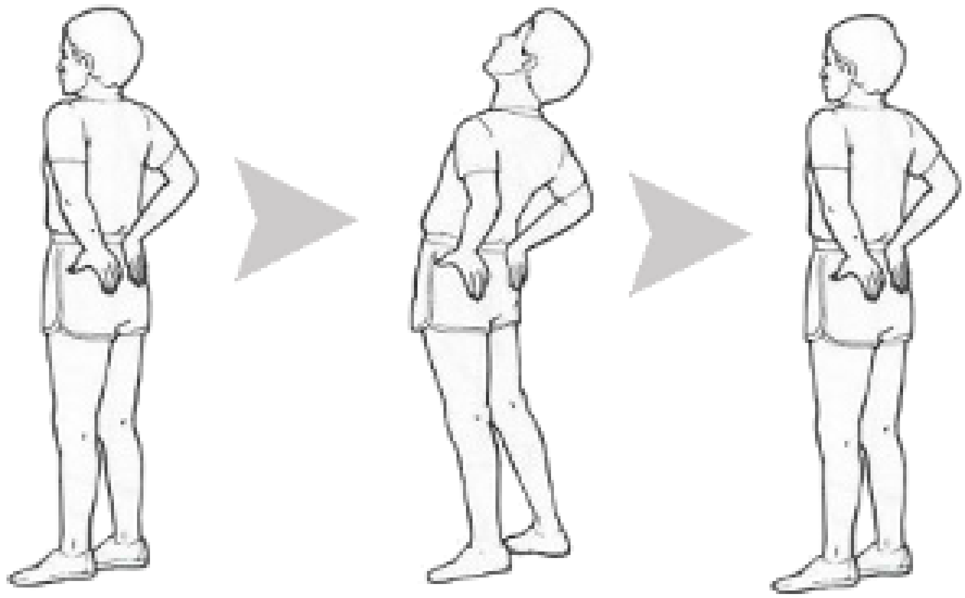


STANDING REPETITIVE EXTENSIONS

-Start by standing with your feet shoulder width apart and place your hands on your hips. Lean back to arch your back then return to starting position. (Lean back as far as you can tolerate with each repetition)

Sets: 1
Repetitions: 10 (Performed in 45 seconds, rest 15 seconds)
-Perform sets in succession
Frequency: 5 times per day

Figure 7: Home instructions for Sustained Trunk Extension



STANDING SUSTAINED EXTENSIONS

-Start by standing with your feet shoulder width apart and place your hands on your hips. Lean back to arch your back, HOLD for time listed below, then return to starting position. (Lean back as far as you can tolerate with each repetition)

Sets: 1
Repetitions: 1 (hold extension 45 seconds, rest 15 seconds)
-Perform sets in succession
Frequency: Five times per day

Figure 8: Home instructions

Continue to use your medications, including medications aimed at decreasing your pain, as prescribed by your primary healthcare provider/physician. Please avoid changing them during the follow-up two-week period.

We will ask you to complete a sheet recording home exercise compliance when you come to the second treatment session in about two weeks.

Thank you.

APPENDIX A

Volunteers Needed for a Research Study!

Title of the study:

"IMMEDIATE EFFECT OF STANDING TRUNK EXTENSION POSTURES ON SPINAL HEIGHT AND CLINICAL OUTCOME MEASURES IN LOW BACK PAIN: A RANDOMIZED CLINICAL TRIAL"

The purpose of this research is **to help Physical Therapists better treat patients with low back pain** by understanding the effects of motion on spine height.

Volunteers between the ages of 18-80 who currently have low back and/or leg pain are needed to participate in a Physical Therapy study conducted by the

Texas Tech University Health Sciences Center

Other ***requirements for participation*** *in the study:*

- *Ability to stand for 5 minutes*
- *Ability to sit for a minimum of 10 minutes,*
- *Currently have low back pain that rate in the range of 2-9 on 10-point pain rating scale*
- *Subjects MUST NOT: be pregnant, have history of back surgery, spinal fractures, spinal fusion or spinal instability, current infection, inflammatory disease, cancer or be engaged in legal compensation claims for their back symptoms.*

Participation is FREE. You will be asked to attend two, 1- hour sessions in 2-week period.

To compensate you for your time, you will receive free 1-month membership to Hill Country Memorial Wellness Center in Fredericksburg, Texas.

Contact Jeremy Harrison, PT, DPT, COMT

(830)997-2001 jeremy.harrison@ttuhsc.edu

APPENDIX B

PRE-SCREENING QUESTIONNAIRE LUMBAR PAIN STUDY

Please answer the following questions:

1. Are you interested to participate in a research project related to low back pain and spinal growth in which you will be asked to come twice to our clinic and be evaluated and treated twice for a 2-week period? You will be evaluated and treated free of charge for two sessions only. Yes / No

2. Are you between the ages of 18 and 80 years old?
    a. Yes
    b. No
3. Are you able to stand for 5 minutes?
    a. Yes
    b. No
4. Are you able to sit for 10 minutes?
    a. Yes
    b. No
5. Do you experience low back and/or leg pain of at least 2/10 and less or equal to 9/10?
    a. Yes
    b. No

---

6. Do you have any history of spinal surgery and/or fractures within the last 6 months?
    a. Yes
    b. No

7. Do you have a current history of acute systemic infection, active inflammatory disease, or malignancy?
    a. Yes
    b. No

8. Do you have any history of spinal fusion or diagnosed by a physician with spinal instability?
    a. Yes
    b. No

9. Are you currently engaged in legal/compensation claims for your back symptoms?
    a. Yes
    b. No

10. Is there a possibility that you could be pregnant?
    a. Yes
    b. No

Which, if any of the following positions, helps to relieve your back pain?

a. Sitting
b. Sitting with support in your back
c. Standing
d. Standing backward bending of your back
e. Other: ___________________________
f. No position seems to feel better than the other

<u>FRONT OFFICE USE ONLY</u>		
Diagnosis of Lumbar Pain and/or Radiculopathy:	Yes	No
Patient referral for Physical Therapy:	Yes	No

If you are interested to participate, contact

Jeremy Harrison, PT, DPT - Investigator

(830) 997-2001

jeremy.harrison@ttuhsc.edu

Questionnaire Key

The purpose of this questionnaire is to take the burden off of participating physicians who are assisting with patient recruitment for this study. Simply add this questionnaire with your normal intake forms for all patients who are seeing the physician for low back pain and leg pain.

Patient can be included in the study if:

Questions 1-5

- All answered “YES”

Questions 6-10

- All answered “NO”

Office Use Only section

- Qualified for study inclusion YES / NO
- Study Number:____________

Referral contact information:

Jeremy Harrison, PT, DPT, COMT

Texas Tech University HSC

830-997-2001

APPENDIX C

Intake Questionnaire:

To be filled out by the participant:

Date: ________________________________ ***Time:*** _______________***am pm***

Last Name: ___________________________ **First Name:**________________________

Phone # :(day)______________***(evening)***____________***(cell)***______________

E-mail address: ____

Age:_____ ***Gender***: **M / F.**

Do you currently have (within the past 24 hours) pain, numbness, tingling or burning in any of the of following areas (please circle yes for all that apply)

Low back symptoms	Y / N
Buttock symptoms	Y / N
Thigh symptoms	Y / N
Lower leg symptoms (below the knee)	Y / N
Foot symptoms	Y / N
Toe symptoms	Y / N

How long ago did your current episode of pain start? ____days ____months ____years

Do you take pain medications? Yes / No

If yes,

i. **Name the pain medications**______________________________
____

ii. **How many hours ago did you take your last pain medication?**

_________**hours**

<u>Do you currently have any of the following: (please circle yes for all that apply)</u>

Yes/No Inability to sit for a minimum of 5 consecutive minutes

Yes/No Inability to stand upright for a minimum of 5 minutes

Yes/No Neurological disorders such as multiple sclerosis, spinal cord injury, spinal tumors

Yes/No History of spinal fusion/surgery

Yes/No Pain in shoulders or neck

Yes/No Vertebral fractures

Yes/No Current vertebral infection

Yes/No Any unhealed bone fracture

Yes/No Diagnosis of cauda equina syndrome

Yes/No Pain level reported above 9/10 on Numerical Pain Scale.

Yes/No Pain level reported at 0/10 at time of testing (no pain)

Yes/No Non-English speaking

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Height: __________inches **Weight: ____________lbs**

APPENDIX D

Date:____/.____/20 **Time: ____am ___ pm** **Study #: __________**

Please fill in the following Pain scales regarding the pain in your *BACK* circling the number that correctly describes your pain

What is the **least** amount of pain you have experienced in the last 2 days in your **back** (*circle the number on the line below*)?

0 1 2 3 4 5 6 7 8 9 10

What is the **most** amount of pain you have experienced in the last 2 days in your **back** (*circle the number on the line below*)?

No Pain ***Moderate Pain*** ***Unbearable Pain***

0 1 2 3 4 5 6 7 8 9 10

What is the **average** amount of pain you have experienced in the last 2 days in your **back** (*circle the number on the line below*)?

No Pain ***Moderate Pain*** ***Unbearable Pain***

0 1 2 3 4 5 6 7 8 9 10

What is the amount of pain you are experiencing in your **back right now**?

No Pain ***Moderate Pain*** ***Unbearable Pain***

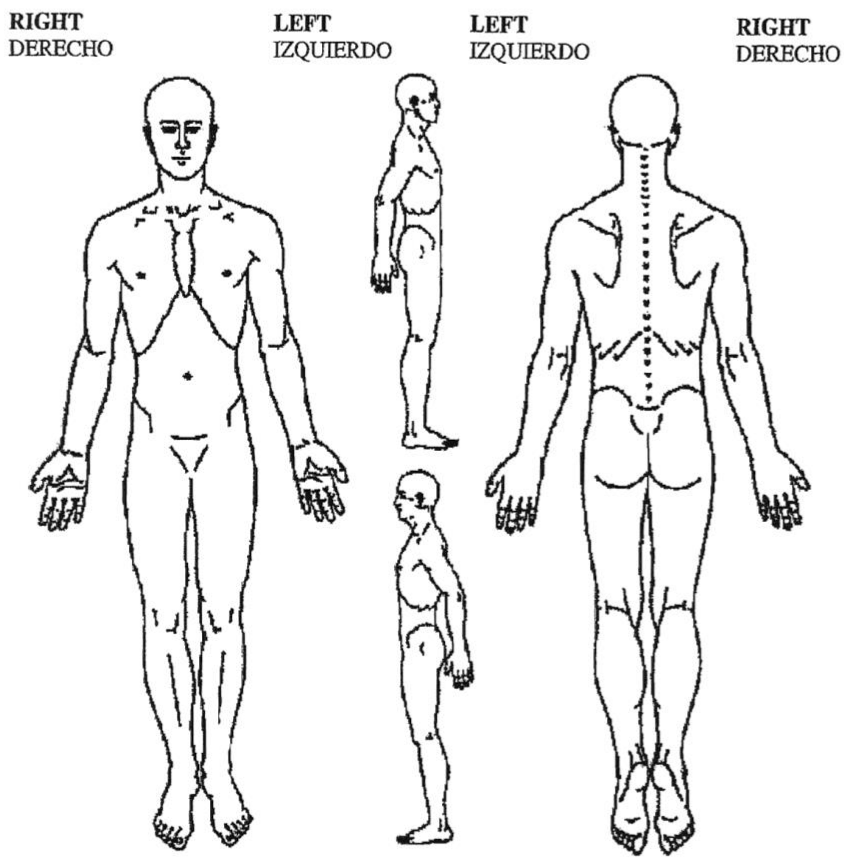
0 1 2 3 4 5 6 7 8 9 10

APPENDIX E

Date:____/.____/20 **Time: ____am ___ pm** **Study #: __________**

Please shade in the area of lower-back and /or legs where you have symptoms today.
(Symptoms include: Pain, tingling, numbness)

Por favor marke el area de su espalda baja o piernas donde tiene sintomas, el dia de hoy.
(Sintomas incluir: Dolar, hormigueo, o entumecimiento.)



Please circle the appropriate number below showing how bad your pain is now:
Por favor marque abajo el numero que mostra que malo su dolor es ahora mismo.

No pain 0 **1** **2** **3** **4** **5** **6** **7** **8** **9** **10** **Worst possible pain**
Sin dolor **Dolorsisimo**

APPENDIX F

Date:_____/._____/20   Time: ____am ___ pm   Study #: __________

Modified Oswestry Low Back Pain Disability Questionnaire[a]

This questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in everyday life. Please answer every question by placing a mark in the **one** box that best describes your condition today. We realize you may feel that two of the statements may describe your condition, but **please mark only the box that most closely describes your current condition.**

Pain Intensity
- ☐ I can tolerate the pain I have without having to use pain medication.
- ☐ The pain is bad, but I can manage without having to take pain medication.
- ☐ Pain medication provides me with complete relief from pain.
- ☐ Pain medication provides me with moderate relief from pain.
- ☐ Pain medication provides me with little relief from pain.
- ☐ Pain medication has no effect on my pain.

Personal Care (e.g., Washing, Dressing)
- ☐ I can take care of myself normally without causing increased pain.
- ☐ I can take care of myself normally, but it increases my pain.
- ☐ It is painful to take care of myself, and I am slow and careful.
- ☐ I need help, but I am able to manage most of my personal care.
- ☐ I need help every day in most aspects of my care.
- ☐ I do not get dressed, I wash with difficulty, and I stay in bed.

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

Walking
- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me from walking more than 1 mile. (1 mile = 1.6 km).
- ☐ Pain prevents me from walking more than 1/2 mile.
- ☐ Pain prevents me from walking more than 1/4 mile.
- ☐ I can walk only with crutches or a cane.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Sitting
- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than 1/2 hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Standing
- ☐ I can stand as long as I want without increased pain.
- ☐ I can stand as long as I want, but it increases my pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than 1/2 hour.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

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

Social Life
- ☐ My social life is normal and does not increase my pain.
- ☐ My social life is normal, but it increases my level of pain.
- ☐ Pain prevents me from participating in more energetic activities (e.g., sports, dancing).
- ☐ Pain prevents me from going out very often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have hardly any social life because of my pain.

Please complete questionnaire on other side.

Traveling

- ❑ I can travel anywhere without increased pain.
- ❑ I can travel anywhere, but it increases my pain.
- ❑ My pain restricts my travel over 2 hours.
- ❑ My pain restricts my travel over 1 hour.
- ❑ My pain restricts my travel to short necessary journeys under 1/2 hour.
- ❑ My pain prevents all travel except for visits to the physician / therapist or hospital.

Employment / Homemaking

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

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Score: /50 x 100 = ____% points

Scoring: For each section the total possible score is 5: if the first statement is marked the section score = 0, if the last statement is marked it = 5. If all ten sections are completed the score is calculated as follows:

Example: 16 (total scored)
50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:

16 (total scored)
45 (total possible score) x 100 = 35.5%

Minimum Detectable Change (90% confidence): 10%points (Change of less than this amount may be attributed to error in the measurement.)

Name: ______________________________ **Date:** ______________

Source: Fritz JM, Irrgang JJ. A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. *Physical Therapy*. 2001;81:776-788.

[a]Modified by Fritz & Irrgang with permission of The Chartered Society of Physiotherapy, from Fairbanks JCT, Couper J, Davies JB, et al. The Oswestry Low Back Pain Disability Questionnaire. *Physiotherapy*. 1980;66:271-273.

APPENDIX G

Date:_____/.____/20   Time: ____am ___ pm   Study #: __________

Fear-Avoidance Beliefs Questionnaire (FABQ)
Waddell et al (1993) Pain , 52 (1993) 157 - 168

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect *your* back pain.

	Completely disagree			Unsure			Completely agree
1. My pain was caused by physical activity……………………………..	0	1	2	3	4	5	6
2. Physical activity makes my pain worse……………………………….	0	1	2	3	4	5	6
3. Physical activity might harm my back………………………………..	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse…...	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain

	Completely disagree			Unsure			Completely agree
6. My pain was caused by my work or by an accident at work…………	0	1	2	3	4	5	6
7. My work aggravated my pain…………………………………………	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain………………………..	0	1	2	3	4	5	6
9. My work is too heavy for me…………………………………………..	0	1	2	3	4	5	6
10. My work makes or would make my pain worse……………………..	0	1	2	3	4	5	6
11. My work might harm my back………………………………………..	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain……………….	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain…………………...	0	1	2	3	4	5	6
14. I cannot do my normal work till my pain is treated…………………..	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work………..	0	1	2	3	4	5	6

Scoring
Scale 1: fear-avoidance beliefs about work – items 6, 7, 9, 10, 11, 12, 15.
Scale 2: fear-avoidance beliefs about physical activity – items 2, 3, 4, 5.

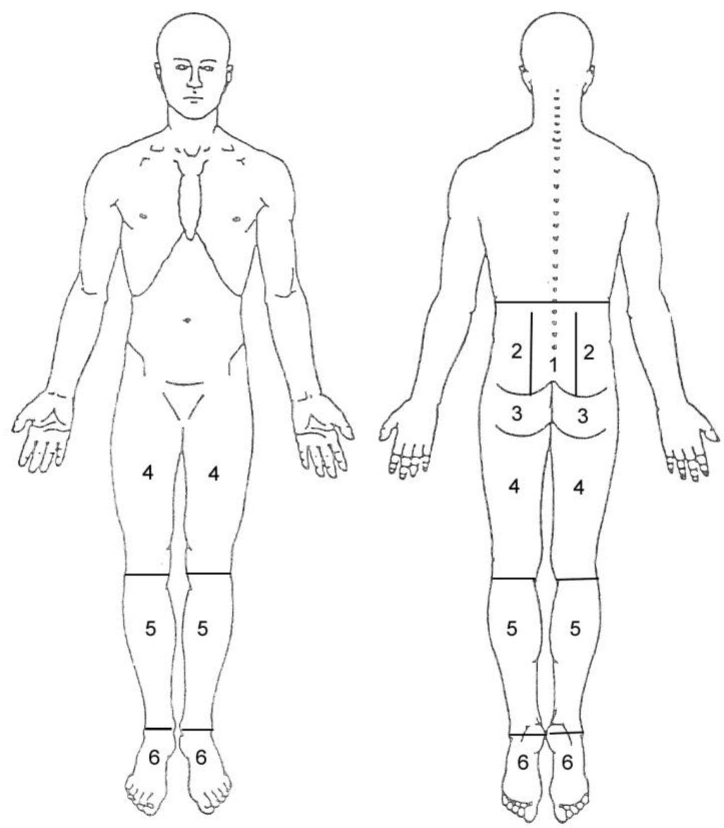
Source: Gordon Waddell, Mary Newton, Iain Henderson, Douglas Somerville and Chris J. Main, A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability, *Pain*, 52 (1993) 157 – 168, 166.

APPENDIX H

Body diagram with template for centralization

Date:____/.____/20 Time: ____am ___ pm Study #: __________

Numeric Overlay Template to the Patient's Body Diagrams



APPENDIX I

Date:____/.____/20 **Time: ____am ___ pm** **Study #: __________**

Please complete the following form regarding compliance with your exercises:

Standing trunk extension exercises

I did not do the exercise	I did the exercise 25% of the time	I did the exercise 50% of the time	I did the exercise 75% of the time	I did the exercise 100% of the time

Were the exercises of backward bending

Very helpful	Helpful	Neutral	Not helpful	Not helpful at all