A COMPARISON BETWEEN STABILIZATION EXERCISES AND STABILIZATION EXERCISES SUPPLEMENTED WITH NEUROMUSCULAR ELECTRICAL STIMULATION IN PATIENTS WITH CHRONIC LOW BACK PAIN: A PHASE I RANDOMIZED CONTROLLED TRIAL

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Impaired motor control and atrophy of paraspinal muscles are commonly associated with chronic low back pain (LBP). Such impairments are treated with lumbar stabilization exercises aimed at creating muscular support for the lumbar spine, reducing pain and improving function. However, stabilization exercises are reported to have a limited long-term effect on pain and function. This limitation suggests that stabilization exercises alone may not activate the paraspinal muscles sufficiently. Thus, enhancement of the stabilization exercise effect on paraspinal muscle function may be warranted.

The two aims of this study are: 1) to investigate the potential effectiveness of neuromuscular electrical stimulation (NMES) as a supplement to stabilization exercise in people with chronic LBP; and 2) to report on the tolerability of NMES when applied to paraspinal muscles.

We conducted a phase I randomized controlled trial on 30 subjects with chronic LBP. Subjects were randomized into either a stabilization exercise group (n = 15) or a stabilization exercises plus NMES group (n = 15). Both groups received treatment twice a week for 6 weeks. Subjects were assessed pre- and post-treatment using the following outcome measures: the Modified Oswestry Disability Questionnaire (MODQ), the Numeric Pain Rating Scale (NPRS), the Fear-Avoidance Behavior Questionnaire,[iv] paraspinal muscle strength, and a NMES

tolerability scale. Subjects in both group were followed up 4 weeks after the end of the last treatment and assessed with the MODQ and NPRS.

The mixed analysis of variance shows that subjects in both groups significantly improved from baseline to post-intervention at 6 weeks on all outcome measures ($p < .05$). The improvements for the MODQ and NPRS were maintained at 4 weeks after the end of the intervention. There were no significant between-group differences ($p > .05$). All subjects in the stabilization plus NMES group found that the NMES was tolerable.

This phase I trial suggests that the application of NMES on the paraspinal muscles is tolerable. Future trials are necessary to determine the NMES usefulness as a supplement to stabilization exercise in treating chronic LBP.

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PREFACE

Praise to Allah Whose first revelation to prophet Muhammad (peace be upon him) was: “Read in the name of your Lord who created.[1] Created man from a clot.[2] Read! And your Lord is the most generous,[3] Who has taught by the pen.[4] Taught man that which he knew not”.[5]

[Al-Alaq: Ch:96]

I would like to thank many people for all what they have done in helping me prepare this work.

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1.0 INTRODUCTION

Lumbar spine stability is maintained by 3 interdependent systems: 1) the passive system that includes the bony structures, discs and ligaments; 2) the active system that includes tendons and muscles; and 3) the control system that includes the nervous system.[1] The passive and active systems continuously relay signals to the control system regarding the direction of lumbar spine movement and amount of load being applied to it, and the control system subsequently sends signals to the active system to create sufficient muscle tension necessary to ensure that the spine remains stable. Dysfunction in the passive system (e.g. spondylolisthesis, disc degeneration) can lead the control system to increase the activation of the lower back muscles in order to compensate for the lost stability from the passive system. This increased muscle activation may sometimes successfully compensate for the deficient passive system, and the spine remains stable. However, increased muscle activation at other times may not be sufficient to compensate for the deficient passive system. This may lead to an overload on the lumbar spine tissues, exposing them to repetitive injuries and long term muscle adaptations, including impaired motor control and atrophy.

1.1 MUSCULAR IMPAIRMENTS IN LOWER BACK PAIN

1.1.1 Motor control impairment

It is debatable whether impairment in motor control is a consequence of or a predisposing factor to lower back pain (LBP). Hodges et al.[2] showed that impairment in motor control can result after spinal injection at the L4 level with a hypertonic saline that experimentally produces pain. However, Cholewicki et al.[3] showed that impairments in motor control can be a predisposing factor for future LBP that can last even after complete resolution of LBP.[4] In people with LBP, impaired motor control was shown in the paraspinal muscles when they act as agonists during resisted isometric trunk extension or as antagonists during resisted isometric trunk flexion.[5, 6] During resisted extension, paraspinal muscle activity was shown to continue for several milliseconds (measured on electromyography) after the applied resistance was suddenly removed. During isometric flexion, paraspinal muscle activity was shown to be delayed for several milliseconds after the applied resistance was suddenly removed. This finding suggests that paraspinal muscle activation in people with LBP is not synchronized with the movement direction of the trunk, nor is proportional to the load applied to the lumbar spine.[7]

To protect the lumbar spine against impairments in motor control, muscle activity should be maintained to at least 5% of the maximum voluntary contraction (MVC).[8, 9] When this submaximal muscle activation is lost in at least one lower back muscle, the spine loses its stability and buckles (i.e. motor control error) resulting in injury and pain.[8]

1.1.2 Atrophy

Atrophy of the paraspinal muscles may occur as early as the first episode of LBP,[10] and has been identified on morphological and histochemical levels. On the morphological level, atrophy in the paraspinal muscles is seen on MRI[11] and CT scans[12] as reduced cross-sectional area (CSA) and increased fatty deposits.[11, 13] Greater atrophy of the CSA of paraspinal muscles is seen on the side of LBP or leg pain, which is consistent with the clinical finding of asymmetrical appearance of the paraspinal muscles.[10, 13, 14] Atrophy persists even after complete resolution of LBP symptoms;[15] and is identified to be specific to the injured segment of the lumbar spine.[16]

On the histochemical level, atrophy is identified by structural changes in type I and II muscle fibers.[17-19] While type I muscle fibers display a moth-eaten appearance, type II muscle fibers show selective atrophy; which has been attributed to muscle disuse,[19, 20] nerve root impingement,[17, 19] and spinal surgery.[19, 21] Selective atrophy of type II fibers is of particular interest, because these are the fast twitch fibers that are primarily recruited during functional tasks requiring higher muscular activation (e.g. lifting). This selective atrophy suggests that the paraspinal muscles may not be capable of producing the amount of force necessary to meet the demand of heavy functional tasks such as lifting, which in turn may overload the spine and makes it vulnerable to injury.

1.2 MUSCULAR IMPAIRMENT AND STABILIZATION EXERCISES

To reverse or prevent these muscular impairments, treatment approaches have relied mainly on lumbar stabilization exercises aimed at creating sufficient muscular activation for the lumbar spine. Different stabilization exercise approaches are described in the literature,[22-24] all of which have been shown to be effective in reducing pain and improving function in patients with chronic LBP.[22, 24-28] However, two issues concerning stabilization exercises effectiveness have been reported: the low magnitude of short-term treatment effect,[29, 30] and the limited long-term effect.[30] This limited success with stabilization exercise approaches can potentially be attributed to paraspinal muscle activation deficit. Muscle activation deficit results from reduction in the maximal discharge rate of motor units that are recruited during muscle contraction, indicating a central nervous system (CNS) processing impairment.[31-36] Also, muscle activation deficits can result from degeneration of type I muscle fibers and selective atrophy of type II muscle fibers, indicating reduction in the amount of force production by these muscles. In either of these cases, muscle activation deficit results in failure to *sufficiently* activate all required muscle fibers necessary to keep the spine stable.

A healthy lumbar spine in neutral positions (i.e. sitting, standing and walking) requires at least 5% MVC muscle activation to achieve spine stability.[8, 9] A healthy spine performing dynamic activities (i.e. bending and twisting) may require up to 25% MVC to maintain spine stability.[37] However, a compromised spine trying to maintain stability in neutral positions or dynamic activities would require muscle activation that is higher than what it is required for a healthy spine in order to compensate for the loss in stability resulting from the dysfunction in the passive system.[38-40] In a compromised spine, such higher levels of muscle activation may not be

achieved due to degeneration of type I muscle fibers and selective atrophy of type II muscle fibers. Inability to achieve sufficient muscle activation for stability might overload the spine, resulting in a vicious cycle of injury and pain during functional tasks.

1.3 MUSCULAR IMPAIRMENT AND ELECTRICAL STIMULATION

Studies have shown that muscle activation deficits can be rectified using neuromuscular electrical stimulation (NMES). When NMES is used as a supplement to muscle voluntary contraction, studies have shown that the force production increased compared with muscle voluntary contraction alone.[41-46] Fitzgerald et al.[41] examined the effect of NMES on quadriceps strength and knee function using 43 subjects who had undergone ACL reconstruction. The subjects were randomly assigned to a knee exercise program that either utilized NMES (NMES plus exercise group) or a control group (exercises only). At 12 weeks, the NMES plus exercise group showed greater gains in quadriceps femoris strength and knee function than the exercise only group. Also, the NMES plus exercise group was more ready to be advanced to agility training than the exercise only group. Snyder-Mackler et al.[45] also investigated NMES combined with voluntary exercises on a group of patients following ACL reconstruction, comparing it with exercises alone. They found that gains in quadriceps muscle strength were greater in the NMES group compared with the control group that received exercises alone. Furthermore, Piva and colleagues[42] showed that NMES is a viable treatment for improving quadriceps strength of subjects with rheumatoid arthritis. These studies indicate that using NMES as a supplement to standard exercise regimens can enhance knee muscle strength and improve functional

performance. NMES is now recommended by clinical practice guidelines as an adjunct modality to volitional exercise regimens following ACL reconstruction to increase quadriceps femoris muscle strength.[47] From studies cited earlier, NMES has been shown to increase muscle force production and improve functional performance when combined with exercise regimens.

The effect of NMES on muscle activation can be attributed to the way it induces muscle contraction. Unlike volitional muscle contraction that first recruits slow-twitch type I muscle fibers followed by fast-twitch type II fibers, the NMES induced muscle contraction has been shown to randomly recruit type I and type II muscle fibers.[48, 49] The NMES-induced contraction also recruits a greater proportion of type II fibers when compared to voluntary contraction at a similar intensity.[50-52] Our preliminary data show that in older individuals (ages 65 – 80 years), NMES contraction using 40% MVC of the quadriceps muscle increases CSA and the normal density muscle (NDM) by 2.61 cm and 2.41 cm respectively. Our data also show that NMES-induced contraction increased the CSA of type II muscle fibers of quadriceps femoris by 567.38 μm (21.46% change) from pre to post exercise.[53] Type II fiber activation is essential for activities that require higher force production, and their activation may also translate into improved functional performance.[53]

The therapeutic effect of NMES may also be attributed to alteration of the excitability of the nervous system. Trimble and Enoka showed that NMES provides cutaneous feedback to the CNS that increases the recruitment of additional motor units with a greater number of muscle fibers activated per unit.[54] As a result, NMES-induced contraction produces gains in muscle strength earlier than volitional contraction. These early gains cannot be caused by increased size of muscle fibers; but potentially by the increased excitability of the nervous system. Additionally, clinical observations show that strength gains do not only occur in the muscle to

which the NMES is applied, but also in the non-exercised comparable muscle of the contralateral limb; which supports the theory of neural alteration as a mechanism of action associated with the application of NMES.[54]

Conjointly, these studies suggest that NMES can augment the force production of muscle. There are two possible mechanisms by which NMES augments muscular force production: 1) by overriding paraspinal muscle voluntary activation deficit resulting from central nervous system processing impairment; and/or 2) by randomly activating type I and type II muscle fibers and recruiting a greater proportion of type II muscle fibers.

1.4 MUSCLE IMPAIRMENT, STABILIZATION EXERCISES, AND ELECTRICAL STIMULATION

After a LBP episode, paraspinal muscles exhibit impairments such as poor motor control, degeneration of type I muscle fibers, and selective atrophy of type II muscle fibers. These impairments can be improved with lumbar stabilization exercises, however, the magnitude of this treatment effect is small with limited long-term effects. Potentially due to muscle activation deficit, stabilization exercises alone might not be adequate to recruit the additional amount of muscle fibers required to produce sufficient muscle activation necessary to maintain spinal stability. We believe that the therapeutic effect of stabilization exercises on paraspinal muscles can be enhanced when combined with NMES. With respect to treatment of the impaired knee, the combination of NMES and exercises has been shown to result in greater force production and improved functional performance compared to exercises alone. However, despite the wide usage

of NMES to enhance muscle activation of the peripheral muscles around the knee, it has not been used widely to enhance the activation of the paraspinal muscles. Therefore, we will conduct a phase I trial to determine the potential effectiveness and tolerability of NMES as a supplement to stabilization exercise for patients with chronic LBP. We hope our study can lay the foundation for a future definitive trial.

2.0 METHODS

2.1 RESEARCH DESIGN AND AIMS

This was a 2-group phase I randomized controlled trial with the main objectives to assess feasibility and potential effectiveness of applying NMES regimens as an adjunct to traditional stabilization exercises (Appendix A). This pilot study randomized patients with chronic LBP into one of two treatment groups:

- Stabilization exercise program only (stabilization only).
- Stabilization exercise program supplemented with NMES (stabilization + NMES).

We compared the two groups on a number of outcome measures, and had three research aims:

Primary Aim: To compare the clinical outcome of function between the two groups using a validated disease-specific functional outcome measure, the Modified Oswestry Disability Questionnaire (MODQ).[55]

- Hypothesis: Chronic LBP subjects in the stabilization + NMES group will demonstrate greater improvement in their MODQ at the end of treatment as compared to the stabilization only group.

Secondary Aim: To report on tolerated intensities of NMES for individuals with chronic LBP in the Stabilization + NMES group.

- Hypothesis: NMES will be a tolerable intervention to a majority of patients.

Exploratory Aim: To compare lumbar extensor muscle strength, pain and fear avoidance beliefs between the two groups using:

- Computerized dynamometer (Biodex 3 Pro)
- Numeric Pain Rating Scale (NPRS)[56]
- Fear Avoidance Behavior Questionnaire (FABQ)[57]

Hypothesis: Chronic LBP subjects in the stabilization + NMES group will demonstrate greater muscle strength gains, as well as greater reductions in NPRS and FABQ scores than the stabilization only group.

2.2 INCLUSION/EXCLUSION CRITERIA

For a subject to be included in the study, the following criteria should be met:

- Age is between 18 and 60 years.
- Body Mass Index (BMI) less than 29.
- LBP duration of 3 months or greater.
- NPRS score of 3 or greater.
- MODQ score of 20 or greater.
- Can read, write and understand English.

Subjects were excluded if they have any one of the following criteria:

- Positive nerve root tension signs.
- Positive Babinski sign or progressive neurological deficit.

- Persistent sensory abnormalities.
- History of spinal surgery.
- History of inflammatory joint disease.
- Contraindications to physical exercise, including history of cardiac disease or being told by a physician not to engage in physical exercise.
- Contraindications to NMES, including cardiac pacemaker or skin allergy to adhesives.
- History of metastatic cancer in the previous 5 years or present treatment for cancer.
- Women who indicate that they are pregnant or plan to become pregnant.

2.3 RECRUITMENT

The population from which we drew our study sample was the general public of the Pittsburgh area. We approached the general public via the following strategies:

1. Postcard mailings targeted to people listed in the CTSI research registry, which is a listing of individuals who are interested in participating in research studies
2. Placing flyers in different areas of Pittsburgh
3. Utilizing the Craigslist.com website to post online advertisements

The above recruitment methods were not expensive, so they were exploited first to see if they were sufficient in helping us obtain our target number of participants (n = 30).

2.4 EVALUATION PROCEDURES

The evaluation procedures included the following items: The screening assessment for eligibility, feasibility assessment, outcome measures, and the physical examination procedure.

2.4.1 Screening

The screening procedure was conducted in two phases. First, the subject was screened via the phone in which he/she answered a number of questions that determined his/her potential eligibility to participate in the study. Second, if the phone screening indicated that the subject was potentially eligible to participate, he/she was scheduled a visit for a screening examination to determine if he/she met the inclusion/exclusion criteria. During the visit, the subject received detailed information about the study, signed a consent form and completed the MODQ, NPRS and FABQ questionnaires. After completing the questionnaires, the subject underwent a physical examination screening procedure. These findings were recorded as baseline data.

After successful screening, eligible subjects were randomized to one of the two intervention groups. All subjects in both intervention groups were scheduled for two sessions per week for a total of 6 weeks. After the intervention sessions were completed, subjects were reassessed during their final session (post-intervention assessment). Subjects were followed up again at 4 weeks after their final session. The total duration of the study was 10 weeks: 6 weeks of intervention and a 4 week post-intervention follow-up assessment (at 10 weeks).

2.4.2 Feasibility assessment

An important component of all pilot studies is assessing various aspects of study feasibility. The assessment of feasibility is aimed at a number of factors related to whether a full randomized trial could be conducted with NMES.[58] Feasibility assessment included determining ways to access participants and their willingness to be randomized. Also, it is important to determining barriers to participation, adverse events, and issues related to adherence to treatment protocol for both patients and clinicians. Additionally, feasibility assessment included factors related to the effectiveness of the randomization and blinding process, access to equipment and space, data completeness and analysis, and whether treatment effect and outcomes are consistent with expectations reported in the literature.

2.4.3 Outcome measures

There were 3 assessment time-points: 1) pre-intervention at baseline; 2) immediately post-intervention at week 6; and 3) 4 weeks after the end of the intervention at week 10. During each assessment point, various outcome measures were collected as shown below in Table 1.

Table 1: Outcome measures collected at each point of assessment

	Baseline	6 weeks	10 weeks
MODQ	✓	✓	✓
NPRS	✓	✓	✓
FABQ	✓	✓	
Strength	✓	✓	
NMES tolerability	✓	✓	
Satisfaction		✓	

2.4.3.1 Modified Oswestry Disability Questionnaire (MODQ) The MODQ is a self-reported measure of disability for patients with LBP. It consists of 10 items of functional activities relevant to patients with LBP: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, travelling and employment/homemaking (Appendix B). Each item has 6 possible choices (rated 0 – 5) with higher scores representing greater disability. The maximum possible total score of the MODQ is 50. The reported total score is multiplied by 2 to get a percentage score. The MODQ has excellent reliability and good construct validity in comparison to other pain and disability questionnaires.[55]

2.4.3.2 Numeric Pain Rating Scale (NPRS) The NPRS measures pain intensity on an 11 point-scale from 0 (no pain) to 10 (maximum pain). We used a version of the NPRS known as the "triple NPRS" in which the subject is asked to respond to three questions: 1) the intensity of current pain; 2) the best pain intensity in the past 24 hours; and 3) the worst pain intensity in the past 24 hours (Appendix C). These three subscores are totaled and divided by three, with the

final triple NPRS score reported as the mean of the three subscores. The triple NPRS has excellent reliability and good validity.[56]

2.4.3.3 Fear-Avoidance Behavior Questionnaire (FABQ) The FABQ is a measure of fear-avoidance beliefs in patients with LBP (Appendix D). It consists of a total of 16 items, divided into two subscales: physical activity (5 items) and work (11 items). Each subscale has 7 possible choices (rated 0 – 6) with higher scores representing greater fear-avoidance beliefs. The maximum possible total FABQ score is 88. Not all items in FABQ are included in the calculation of the final subscores. Item 1 is excluded from calculation of the physical activity subscore; items 8, 13, 14 and 16 are excluded from calculation of the work subscore. A total score (including both subscores) of 19 or lower indicates low fear-avoidance beliefs. The FABQ has acceptable levels of reliability and validity.[57]

2.4.3.4 Paraspinal muscle strength assessment The paraspinal muscle strength assessment was performed using the Biodex 3 Pro dynamometer (Figure 1). To assess paraspinal muscle strength, active extension of the trunk was performed with the subject in a semi-standing position; the subject's hips were flexed at 60 degrees with the feet resting on an adjustable footrest. On the chair the subject's thighs were secured to the seat with two Velcro straps. The subject's scapulae rested against a roll that is attached to the back of the arms. To ensure that the scapulae were in contact with the roll all the time, the subject's trunk was secured with two Velcro straps that crossed the front trunk forming the shape of an X. The subject was asked to extend the trunk by exerting maximal isometric contraction for 5 seconds against the scapular roll that was placed across the subject's scapulae. The average of three 5-second trials was

recorded. All subjects received the same verbal instruction that was neutral, short and precise: "Push your trunk against the bar as strong as you can".

Prior to the study initiation, 9 healthy subjects (mean age = 23; gender = 4 males and 5 females) performed the strength assessment protocol. It was determined that the protocol has excellent test-retest reliability ICC (3,1) = .98.

Figure 1: Paraspinal muscles assessment in a semi-standing position.

2.4.3.5 Neuromuscular electrical stimulation tolerability assessment Tolerability of NMES was investigated only for subjects in the stabilization + NMES group. This assessment was performed by asking each subject in the stabilization + NMES group to describe their subjective perception of the intensity of the NMES current using the verbal descriptors listed in Table 2. The 2 columns of descriptors separately assess the sensory aspect of the NMES current and the affective aspect of the current. The sensory and affective descriptors are each divided into 3 zones of 5 descriptors.

Table 2: Descriptors of intensity and discomfort aspects of electrical stimulation

Descriptors of Sensory aspect of the NMES current	**Sensory descriptors zones**		**Descriptors of Affective aspect of the NMES current**	**Affective descriptors zones**	
Extremely intense	15	High	Excruciating	15	High
Very intense	14	intensity	Intolerable	14	discomfort
Very strong	13	descriptors	Unbearable	13	descriptors
Intense	12		Agonizing	12	
Strong	11		Horrible	11	
Slightly intense	10	Moderate	Dreadful	10	Moderate
Barely strong	9	intensity	Frightful	9	discomfort
Moderate	8	descriptors	Awful	8	descriptors
Slightly moderate	7		Miserable	7	
Very moderate	6		Oppressive	6	
Mild	5	Low	Distressing	5	Low
Very mild	4	intensity	Uncomfortable	4	discomfort
Weak	3	descriptors	Unpleasant	3	descriptors
Very weak	2		Distracting	2	
Extremely weak	1		Bearable	1	

For the sensory aspect descriptors, there were low, moderate, and high intensity zones. Low intensity zone was formed by the descriptors 1 – 5; moderate intensity zone was formed by descriptors 6 – 10; and high intensity zone was formed by the descriptors 11 – 15. For the affective aspect descriptors, there was low, moderate, and high discomfort zones. Low discomfort was formed by descriptors 1 – 5; moderate discomfort was formed by 6 – 10; and high discomfort was formed by 11 – 15.

When the electrodes were placed on the paraspinal muscles, the subject was handed the NMES unit and asked to increase the NMES current to 20 mA. Once the 20 mA level was reached the subject was informed that this level of NMES corresponded to the "extremely weak" descriptor in terms of the sensory aspect of the current, and the "bearable" descriptor in terms of the affective aspect of the NMES current. The subject was asked to increase the intensity to his/her highest level of tolerance. Once the subject reported that the current was the highest he/she could tolerate, he/she was asked to provide a description of their perception of the current tolerability in relation to the 20 mA reference current on both sensory and affective components. The subjects were informed that the sensory and affective descriptions did not have to agree with each other. That is, the subjects were informed that the NMES current could be described as 'extremely weak' in terms of sensory aspect, yet 'excruciating' in terms of the affective aspect. The subject was also informed that the opposite could be true as well; or that the sensory and affective aspects could be equally intense. This approach to measuring patients' subjective NMES current tolerability has been described in the literature.[59]

2.4.3.6 Satisfaction with the treatment Subjects were provided with a 5-item scale to rate their satisfaction with the treatment at the 6 week assessment point. (Appendix E).

2.4.4 Demographics

The physical therapist collected information regarding the patient's age, gender, height, weight, BMI, and time of initial onset during the first visit (Appendix F).

2.4.5 History of LBP

The physical therapist collected information regarding current and previous episodes of pain, location of symptoms, behavior of symptoms, the aggravating and easing factors of pain and previous treatment (Appendix G).

2.4.6 Physical examination

After the subject completed the self-reported measures, the physical therapist started the physical examination (Appendix G). The physical examination was performed at baseline only. None of the physical examination components were expected to produce increased pain or discomfort to the patient. The physical examination is briefly described below:

2.4.6.1 Posture The posture of the patient can reflect underlying muscle deficits.[60] The physical therapist observed the patient's posture and recorded abnormalities such as: anterior pelvic tilt, posterior pelvic tilt, exaggerated lordosis or increased kyphosis.

2.4.6.2 Range of Motion The physical therapist observed trunk active range of motion using a single plane of movement (i.e. flexion, extension, side-bending and rotation). During trunk flexion, the therapist observed for the presence of aberrant movement patterns such as:

- Painful arc: symptoms are reproduced at a certain range of motion during flexion. Symptoms at initiation of flexion are absent, then appear at a certain range, then disappear toward the end range of flexion.[61]
- Reversed painful arc: symptoms are reproduced at certain range of motion when the subject returns from flexion.[61]
- Gower's sign: upon return from full flexion, the subject pushes on the thighs with both hands to stand upright again. This sign is also termed "thigh climbing".
- Instability catch: during flexion subject trunk deviates from the sagittal plane to one side and then return to it (i.e. side-bending to one side during flexion).[62]
- Reversed lumbopelvic rhythm: upon return from flexion, the subject first extends the lumbar spine and uses the hip muscles to return to the upright position.[63]

The Kappa value for inter-rater reliability of the flexion test is .60 (95% CI .47 - .73) which suggests moderate agreement.[64]

2.4.6.3 Nerve Tension Signs The physical therapist assessed for the presence of nerve tension signs via a number of tests: the slump test, straight leg raise, myotomal weakness and

hypo/hyper-reflexia. If any of these nerve tension signs were positive, the subject was excluded from the study.

2.4.6.4 Hypermobility While the subject was laying prone on the treatment table, the physical therapist assessed hypermobility by applying manual postero-anterior pressure on the spinous process of each lumbar segment starting from L5 and moving superiorly to L1. The therapist determined if each segment was hypomobile, normal or hypermobile. Also the therapist noticed any symptom reproduction during performance of the test.

2.4.6.5 Prone Instability Test While the subject was laying prone on the edge of the table with the feet resting on the floor, the therapist applied a posteroanterior mobilization on each lumbar segment starting from L5. Each time a segment was mobilized, the therapist assessed the subject's hypermobility and asked about symptom reproduction. The therapist then asked the subject to lift the feet off the floor and reapplied the posteroanterior mobilization starting from L5. This time, the therapist assessed hypermobility and asked the subject about symptom reproduction again. The test was considered "positive" if the subject's symptoms were produced during the resting position but subsided when the subject lifted the feet off the floor. For this test, Kappa value for inter-tester reliability is .87 (95% CI .80 - .94) which a substantial agreement.[64]

2.5 RANDOMIZATION

We used a randomization website (http://www.graphpad.com/quickcalcs/randomize1.cfm) to create a list from 1 – 30 subjects randomly assigned to the stabilization only group or stabilization + NMES group. The list was printed and kept in a locked cabinet. Every time a subject was determined eligible to participate, the cabinet was unlocked to obtain the randomization list and see which group the subjects was assigned to. The randomization was not concealed, however, the physical therapist (principal investigator) did not intentionally attempt to bias the subject assignment to either group. We hoped that the randomization created equal baseline characteristics particularly on age, BMI, gender, ethnicity and baseline outcome measures. However, any baseline characteristic (age, BMI, gender, and baseline outcome measures) that turned out unequal and could potentially affect the outcome was controlled for statistically.

2.6 BLINDING

The study was not blinded.

2.7 INTERVENTION

The study subjects underwent a treatment that consisted of either stabilization exercises only or stabilization exercises program supplemented with NMES. Each subject was scheduled for 2

treatment visits per week over a 6-week period (12 sessions in total). Each treatment visit lasted 30 - 40 minutes. Upon arrival to the clinic, subjects were asked to perform the exercises under the supervision of the physical therapist who addressed any of the subject's concerns. Also, the physical therapist guided the subject in the exercise progression. For the subjects randomized to the stabilization + NMES group, the physical therapist applied the NMES at the start of the session for 20 minutes. After the application of NMES, the subject performed the stabilization exercise program. The low back stabilization exercise program has been previously described in the literature[22, 65]

During the 6 weeks of intervention, the subjects in both groups were instructed to perform the exercises at home. They were provided with an exercise packet that described the exercises that they were asked to perform twice a day. However, we did not conduct any systematic monitoring of their compliance with home exercises during the 6 weeks of intervention. Additionally, at the end of 6 weeks of treatment, the subjects were also encouraged to continue doing the exercises on their own and make them a routine part of their lives. However, subjects were not monitored for compliance with these exercises between their last treatment session at week 6 and the follow-up assessment point at week 10.

These exercises are described in detail in Appendix A with the progression criteria. Briefly, during each treatment visit the subject was asked to perform the following exercises:

2.7.1 Abdominal bracing exercises

The patient assumed a supine position and was instructed to draw the navel in while "tightening the waist". This was a completely isometric activation of the abdominal muscles (i.e. no

movement occurs). The therapist observed the patient's pelvic movement and made sure it remained neutral. If pelvic movement was produced, it indicated that the exercise was not being performed isometrically. Once the patient learned the technique of abdominal bracing, the therapist could challenge the patient further by asking him/her to move the legs while maintaining the abdominal brace contraction.

2.7.2 Side support exercises

The subject assumed a side-lying position resting on one elbow with one leg above the other. The subject's other arm crossed the chest to support the opposite shoulder. The subject was asked to lift the hips off the table and maintain this position for 7 to 8 seconds and then relax. The subject did the exercise on both sides.

2.7.3 Quadruped exercises

The subject assumed a quadruped position and used his/her own legs and arms as levers to train the lower back muscles. Initially, the subject elevated one leg and extended the hip to 30 degrees while supporting the trunk on the remaining 3 limbs. Then the subject alternated with the other leg. Once the subject was capable of doing so, he/she was asked to use opposite arm and leg.

2.7.4 The neuromuscular electrical stimulation intervention

The NMES was administered by the physical therapist and applied to the lumbar paraspinal muscles using an Empi 300 portable unit. The physical therapist placed a pillow under the

abdomen of the prone-lying subject to create mild trunk flexion. The physical therapist then placed 2 large (12 cm x 6 cm) self-adhesive electrodes over the paraspinal muscles, one electrode on each side. The physical therapist set the NMES parameters to produce a pulse frequency of 75 pulses per second, a pulse duration of 250 microseconds, with a 4-second ramp up and ramp down time, a 6-second stimulation period at the maximum amplitude that was followed by a 50 second rest period to minimize fatigue. The intensity of the electrical stimulation should ideally be set at the subject's maximum tolerance level, and all subjects were instructed that the higher the current intensity, the better the muscle activation. The physical therapist also instructed the patient to perform trunk extension as soon as they felt the electrical current ramp up, and to return to the resting prone position when the current ramped down. The physical therapist was present with the patient during the 20 minutes of stimulation. At each visit, the physical therapist recorded the highest current intensity the subject could tolerate, and at each subsequent visit the therapist encouraged the subject to increase the current intensity. The NMES was only performed in the clinic, not at home.

2.8 SAMPLE SIZE ESTIMATION

The NMES parameters we used as an adjunct to stabilization exercise[65] have never been rigorously studied in the chronic LBP population. Therefore, we planned to conduct a phase I study with a sample of 30 subjects with chronic LBP. We did not conduct a power analysis, and we realize that our study could be underpowered. However, we utilized a smaller sample size in

order to investigate the NMES feasibility and report on its potential effectiveness before moving on to conducting a larger, more definitive RCT.

2.9 DATA ANALYSIS

We used descriptive statistics to report on the study's feasibility, satisfaction with the treatment and NMES tolerability. For the tolerability assessment, we used the zones in Table 2 to report on the proportion of the subjects in the sensory and affective component at baseline and post-intervention at 6 weeks.

Demographics and outcome measures were compared at baseline. If demographics and outcome measures were not similar at baseline, independent-sample *t* test or Mann-Whitney U test were used to assess if there was a significant difference between the groups. If there was, we adjusted for it statistically.

For our primary analysis, we used a 2 × 2 (group × time) mixed analysis of variance (ANOVA) to test for any statistical significance on the MODQ (primary), NPRS, FABQ, and muscle strength between and within groups. The assumptions were checked. The level of significance was set at $P \leq .05$ for all comparisons.

We also did a responder analysis[66] by dichotomizing subjects into those achieving more than 30% improvement on MODQ and NPRS, and those achieving 30% or less. Using the dichotomized variables, we calculated the proportion of subjects achieving more than 30% improvement on disability and pain in each group.

Missing data were managed by multiple imputation technique. This technique is a function in the SPSS version 21 known as chained equation imputation. This technique creates 5 sets of imputed data beside the original data set. Using the 5 sets of imputed data, we replaced each missing value by a value that is pooled from 5 sets of imputed data created by the SPSS program.

We conducted our analyses using the original data set and the new set of pooled imputed data. If both analyses agree, the result can be accepted with more confidence.[67]

3.0 RESULTS

3.1 RECRUITMENT AND PATIENTS FLOW

Recruitment was conducted between January 2014 and January 2015. The study was advertised using craiglist.com, flyers posted around campus, and mailing to patients whose addresses were obtained from a research registry related to University of Pittsburgh. Using these advertisement methods, 162 potentially eligible subjects contacted us for information about the study, 144 of whom we were able to conduct the preliminary screening via phone. Of those patients who we screened via phone, only 56 turned out to be potentially eligible for participation in the study and were scheduled for a physical examination screening visit. Of those who were scheduled, 16 did not show up, and 10 turned out to be ineligible after the physical examination screening process. The remaining participants (n = 30) consented to participate in the study and were randomized to one of the two treatment intervention groups (Figure 2).

The overall dropout rate in our study was 13%. Out of the 30 participants who were included and randomized in the study, 4 started treatment but dropped out before the post-intervention assessment (n = 2 per group); 1 in the stabilization only group dropped out because of time constraints, 1 in the stabilization + NMES group dropped out for increase in pain after lifting a heavy object, the remaining 2 dropped out for unknown reasons. At the follow-up

assessment at week 10, three subjects did not return their pain questionnaire; 1 from the stabilization only group and 2 from the stabilization + NMES group (Figure 3).

We screened between 13 – 14 participants a month (via phone and visits), of whom we were able to recruit an average of 3 participants a month.

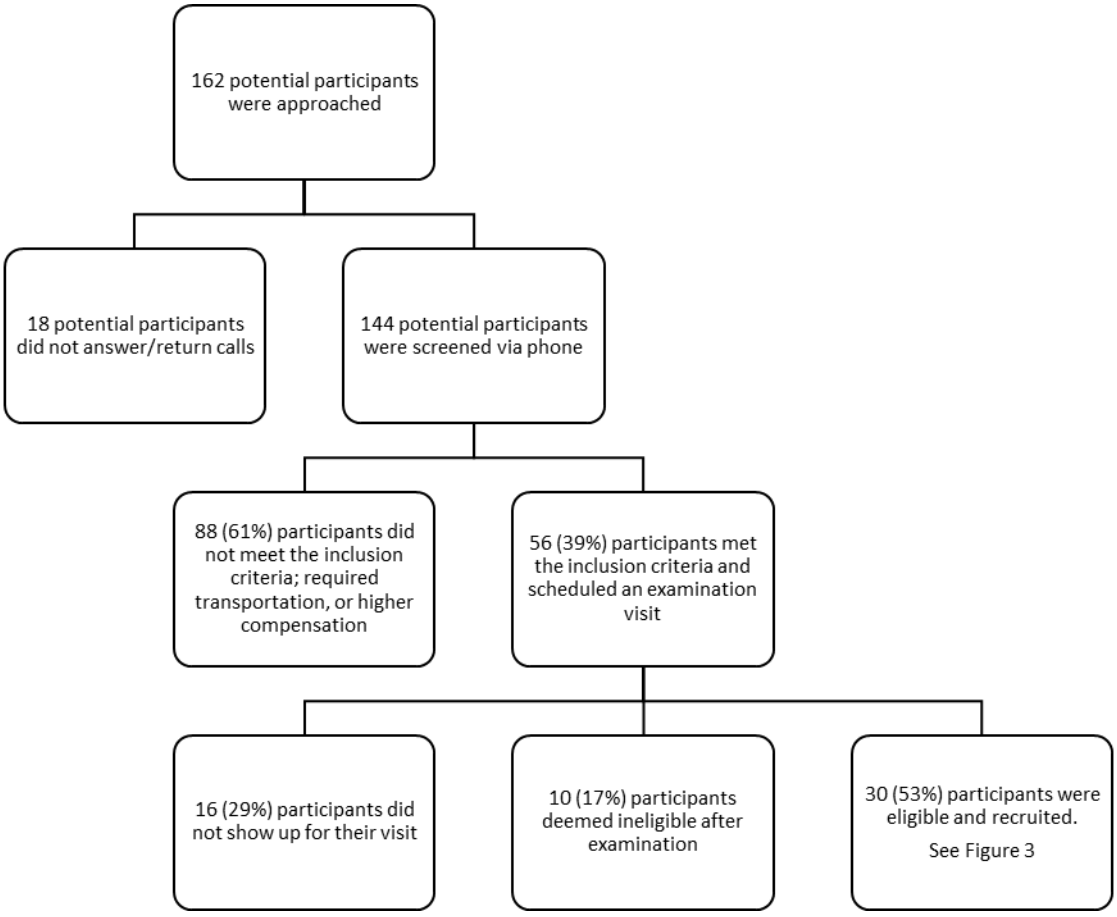


Figure 2: Flowchart outlining recruitment of potential participants.

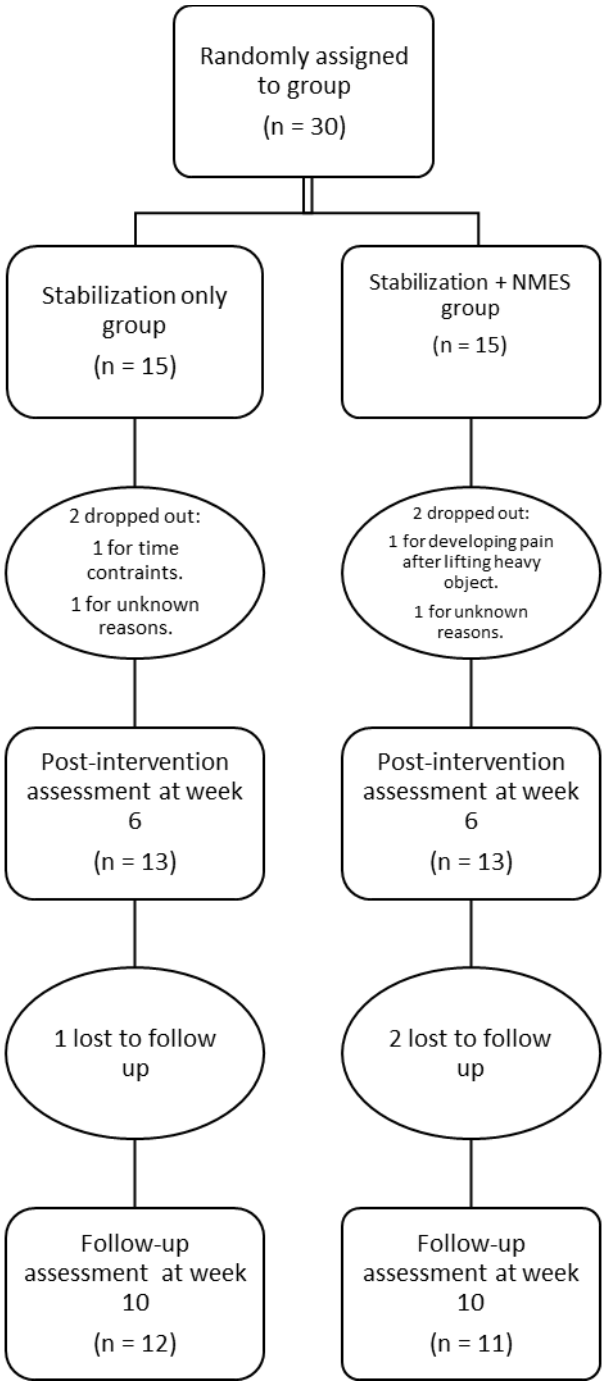


Figure 3: Flowchart outlining the subjects' progress through the trial

3.2 ADHERENCE AND TOLERABILITY OF TREATMENT

The participants were seen twice a week for a 6 week period, which totals 12 sessions for each subject in the study. We had 15 subjects in each group, which makes the total number of sessions for each group equal to 12 sessions × 15 subjects = 180 sessions/group. The stabilization only group attended 79% of the 180 sessions. The stabilization + NMES group attended 81% of the 180 sessions.

The delivery of the NMES was tolerated well without any report of adverse events. Subjects in the stabilization + NMES were able to increase the NMES current intensity from baseline to post-intervention at week 6 (Table 3). At baseline, 40% of the subjects described the sensory aspect of the NMES current using descriptors in the moderate intensity zone, while 60% of the subjects used descriptors in the high intensity zone (Table 2). However, 100% of the subjects at baseline described the affective aspect of the NMES current using descriptors in the low discomfort zone. At the end of the treatment, 76% of the subjects' who remained in the stabilization + NMES group (2 dropped out) described the sensory aspect of the NMES current using descriptors in the high intensity zone, while the 24% of the subjects used descriptors in the moderate intensity zone. However, 100% of the subjects described the affective aspect of the NMES current using descriptors in the low discomfort zone.

Table 3: Individual data for subjects (n=15) intensity and discomfort ratings

Sensory aspect of NMES at baseline (zone)	Affective aspect of NMES at baseline (zone)	NMES current intensity at baseline	Sensory aspect of NMES at week 6 (zone)	Affective aspect of NMES at week 6 (zone)	NMES current intensity at week 6
Very moderate	Distracting	52 mA	Moderate	Distressing	59 mA
Very moderate	Uncomfortable	28 mA	Intense	Uncomfortable	45 mA
Slightly moderate	Uncomfortable	30 mA	Intense	Uncomfortable	46 mA
Slightly intense	Unpleasant	68 mA	Slightly intense	Uncomfortable	73 mA
Slightly intense	Uncomfortable	27 mA	Intense	Uncomfortable	44 mA
Slightly intense	Distressing	60 mA	Moderate	Distressing	75 mA
Strong	Bearable	58 mA	Dropped out	Dropped out	Dropped out
Intense	Unpleasant	62 mA	Dropped out	Dropped out	Dropped out
Intense	Uncomfortable	50 mA	Intense	Uncomfortable	77 mA
Very strong	Unpleasant	42 mA	Very strong	Distracting	70 mA
Very strong	Distressing	39 mA	Intense	Unpleasant	75 mA
Very strong	Distressing	47 mA	Strong	Distracting	55 mA
Very strong	Distressing	65 mA	Very intense	Distressing	100 mA
Very intense	Distressing	33 mA	Intense	Bearable	50 mA
Extremely intense	Distressing	100 mA	Extremely intense	Uncomfortable	100 mA

NMES: neuromuscular electrical stimulation.
Sensory aspect of NMES is a description of the sensory quality of the NMES current.
Affective aspect of NMES is a description of the unpleasantness quality of the NMES current.

3.3 BASELINE CHARACTERISTICS

There were a number of differences between the groups. The stabilization + NMES group had younger participants, more males, and higher scores of paraspinal muscle strength compared to the stabilization only group. These differences between the groups were checked using *t* test and Mann-Whitney U test and found to be insignificant (Table 4).

Table 4: Between-group baseline characteristics

	Stabilization only	**Stabilization + NMES**	***P* Value**
Anthropometry[a]	Mean ± SD	Mean ± SD	
Age	38.33 ± 11.3	33.40 ± 9.0	.20
Height (cm)	164.98 ± 7.6	171.3 ± 10.0	.06
Weight (kg)	71.11 ± 14.2	77.71 ± 13.2	.20
Body mass index (kg/m^2)	25.89 ± 3.8	26.47 ± 2.9	.64
Gender[b]	Frequency	Frequency	.45
Male	4	7	
Female	11	8	
Ethnicity[b]	Frequency	Frequency	.16
White Caucasian	9	13	
African-Americans	4	1	
Asians	1	1	
Others	1	0	
Outcome measures[a]	Mean ± SD	Mean ± SD	
MODQ	30.80 ± 10.2	30.52 ± 7.8	.73
NPRS	4.44 ± 1.8	4.20 ± 1.9	.94
FABQ-PA	12.33 ± 5.5	14.27 ± 6.5	.39
FABQ-W	12.20 ± 10.9	11.67 ± 10.5	.89
Paraspinal muscles strength	117.29 ± 57.7	154.49 ± 59.1	.09

NMES = neuromuscular electrical stimulation; MODQ = modified oswestry disability questionnaire; NPRS = numeric pain rating scale; FABQ-PA = fear-avoidance behavior questionnaire – physical activity; FABQ-W = fear-avoidance behavior questionnaire – work. *P* value is for *t*- test. SD indicates standard deviation. [a] *P* value is based on t-test. [b] *P* value is based on Mann-Whitney U test.

3.4 STATISCAL ANALYSIS OF OUTCOME MEASURES

For our primary analysis, mixed ANOVA, the assumptions were checked for all the outcome measures separately. Normality was found to be violated for the MODQ (primary), the NPRS and the FABQ-W. However, we preceded with analysis regardless of normality violation as the mixed ANOVA is robust against violation of normality. The assumptions of homogeneity of variance, covariance, and sphericity were all met.

From baseline to post intervention, all self-report measures (primary: MODQ; exploratory: NPRS, FABQ-PA, and FABQ-W) showed no interaction of group with time ($P > .05$), and no difference between the groups ($P > .05$). However, both groups improved from baseline to post-intervention on the MODQ, the NPRS, and the FABQ-PA ($P < .001$), but not on FABQ-W ($P = .055$) (Table 6).

For paraspinal muscle strength testing, we ran a mixed ANOVA controlling for age, gender, ethnicity and baseline paraspinal muscle strength. From baseline to post-intervention, paraspinal muscle strength showed no interaction of group with time ($P = .12$), and no significant difference between the groups ($P = .12$). Both groups showed significant strength improvement from pre to post intervention ($P = .001$).

For our responder analysis, Table 7 shows the proportions of individuals achieving more than 30% improvement on the MODQ and the NPRS. For the MODQ, 93% of subjects in the stabilization only group achieved more than 30% in disability compared to 80% in the stabilization + NMES group. For the NPRS, 80% of the subjects in the stabilization only group achieved more than 30% reduction in pain compared to 60% in the stabilization + NMES group.

For all outcome measures, data analysis results were the same for both the original data set and imputed data set. Therefore, the results for the imputed data set are presented.

Table 5: Outcome measures scores for each group over time

	Baseline	6 weeks	10 weeks
Outcome, mean ± SD			
MODQ (0 – 100 scale)[1]			
Stabilization only	30.80 ± 10.2	12.81 ± 5.2*	10.00 ± 5.6
Stabilization + NMES	30.52 ± 7.8	14.49 (10.2)*	13.24 ± 8.0
NPRS (0 – 10 scale)[1]			
Stabilization only	4.44 ± 1.8	2.07 ± 1.1*	1.63 ± 1.0
Stabilization + NMES	4.20 ± 1.9	2.34 ± 1.5*	2.34 ± 1.5
FABQ-PA (0 – 24 scale)[1]			
Stabilization only	12.33 ± 5.5	8.41 ± 6.0*	
Stabilization + NMES	14.27 ± 6.5	10.75 ± 4.7*	
FABQ-W (0 – 42 scale)[1]			
Stabilization only	12.20 ± 10.9	8.87 ± 9.6	
Stabilization + NMES	11.67 ± 10.5	7.75 ± 7.6	
Paraspinal muscle strength (Biodex 3 Pro dynamometer)[1,2]			
Stabilization only	117.29 ± 57.7 Nm	162.30 ± 55.2* Nm	
Stabilization + NMES	154.49 ± 59.1 Nm	175.80 ± 58.4* Nm	

NMES = neuromuscular electrical stimulation; MODQ = modified oswestry disability questionnaire; NPRS = numeric pain rating scale; FABQ-PA = fear-avoidance behavior questionnaire – physical activity; FABQ-W = fear-avoidance behavior questionnaire – work.

[1] indicates no between group difference from baseline to week 6 ($P > .05$).

[2] controlling for age, gender, ethnicity, and baseline paraspinal muscle strength difference.

* indicates significant within group difference between baseline and week 6 ($P < .05$).

SD indicates standard deviation.

Table 6: Responder analysis data of subjects achieving more than 30% improvement

Group	Level of Improvement	Number of subjects	Percentage%
Disability (MODQ)			
Stabilization only	≤30% reduction in disability	1	6.7
	>30% reduction in disability	14	93.3
Stabilization + NMES	≤30% reduction in disability	3	20.0
	>30% reduction in disability	12	80.0
Pain (NPRS)			
Stabilization only	≤30% reduction in disability	3	20.0
	>30% reduction in pain	12	80.0
Stabilization + NMES	≤30% reduction in pain	6	40.0
	>30% reduction in pain	9	60.0

The responder analysis is from pre to post intervention. MODQ: modified oswestry disability questionnaire. NPRS: numeric pain rating scale.

3.5 TREATMENT SATISFACTION

For satisfaction with the treatment, 77% of subjects in the stabilization only group rated their satisfaction as 'very satisfied' compared to 62% in the stabilization + NMES group. Also, 23% of subjects in the exercise only group rated their satisfaction as 'satisfied' compared to 38% in

the stabilization + NMES group. No subject in either group rated their satisfaction level below "satisfied". Subjects in the stabilization only group were more satisfied with the treatment than subjects in the stabilization + NMES group.

4.0 DISCUSSION

4.1 RECRUITMENT AND SCREENING FEASIBILITY

We were able to recruit an adequate number of subjects from the city of Pittsburgh, PA without the need for expensive advertisement resources. We placed flyers in different locations around the city, used craiglist.com, and did targeted mailings to a list of patients obtained from a research registry related to the University of Pittsburgh.

Advertising through the research registry seemed to return the highest number of subjects who were interested in participating in the trial. This method of advertisement should be relied on in future trials to increase accessibility to potential participants. However, it should be noted that advertising through the registry returns a high percentage of participants who are "study shoppers". Study shoppers have a tendency to seek out studies that have high compensation rates, and also are prone to modify their answers during the screening process in order to fit the inclusion criteria. Alternatively, study shoppers may request higher compensation rates than what is allocated to them in the study in order to participate. This could explain why despite the high response rate from the research registry, the percentage of these subjects completing the study was only 14.5%. This is in contrast to 27% of subjects completing the study who were recruited from the flyers. We are not suggesting that the research registry should not be used, we are suggesting that participants contacting the study through the research registry should be

carefully screened for inclusion. The research registry still remains an excellent source to access potential participants.

The initial screening visit lasted about 2 hours which included: consenting the patient, filling out the questionnaires, conducting the physical examination, performing the paraspinal muscle strength assessment, randomizing and receiving allocated treatment. However, each successive visit lasted about 25 minutes for the stabilization only group and about 50 minutes for the stabilization + NMES group. The questionnaires were able to appropriately rule in or out participants using the inclusion criteria. The baseline physical examination procedures did not produce any unexpected pain.

The recruited participants were willing to be randomized to either treatment arm. A majority of the randomized participants [n = 29 (96%)] started their first treatment on the same day they were randomized. The barriers to participation were related to not fitting the inclusion criteria, lack of transportation means, and/or requesting more than $30 of compensation to participate in the study. These barriers to participation did not pose a severe threat to the recruitment process, in the future such barriers are to be expected and can be overcome.

Because of the nature of the interventions, blinding the subjects to their intervention group was not feasible. A number of subjects expressed their desire to be in the stabilization + NMES group as they were probably able to guess that it was the intervention arm.

Because the strength measurements and treatment interventions were all performed by just one physical therapist, blinding of this physical therapist was not possible in the study. However, the lack of therapist blinding would not have had an impact on the results of the MODQ, NPRS, FABQ-PA or FABQ-W because these were all patient self-reported outcome measures. Lack of blinding may have impacted the strength testing, as the assessor (the physical

therapist) could potentially bias the test by encouraging subjects in the stabilization + NMES group more than those in the stabilization only group. However, this does not seem to be the case in this study, as there was no significant difference in paraspinal muscle strength between the groups after the end of the treatment (Table 6).

4.2 TREATMENT FEASIBILITY

4.2.1 Adherence rates

The subjects in both groups had similar retention and treatment adherence rates (overall dropout rate = 13%). The rate of session attendance was similar between the groups (stabilization only = 79% vs. stabilization + NMES = 81%). This suggests that supplementing the stabilization exercises with the NMES had no negative effect on the retention rate or rate of adherence to treatment. However, we should be careful with such interpretation as there could have been a selection bias during our recruitment. That is, the text that we used in our advertisement stated explicitly that one treatment would include the use of NMES. This could have caused people who dislike NMES to refrain from approaching the study as they knew upfront that it was going to be one of the treatments they could potentially receive. Consequently, our study could have been only approached by participants who did not mind having the NMES as a potential treatment or those who did not know what the NMES was. This potential selection bias issue was inevitable, as the institutional review board mandated that we clearly describe the treatment in the text of our advertisement.

4.2.2 Adverse events

Adverse events were only related to the stabilization exercise program and included muscle soreness in the shoulder and neck regions that were particularly ascribed to the side support exercises in the stabilization exercise program (Appendix A). This muscle soreness was expected and explained to the subject during the process of consenting. For these subjects, the side support exercises were ceased and replaced with side-lying hip abduction and trunk curls. The side support exercises were resumed after the shoulder and neck muscle soreness was resolved, which took about a week. While the side-lying hip abduction and trunk curls enabled the subject to continue to exercise until the soreness resolved, we were not sure that they would create the same level of muscle activation as the side support exercises. In future trials, the shoulder and neck muscle soreness is likely going to emerge as an issue with performance of the side support exercises. Therefore, we suggest that this issue is accounted for by using a roman chair, which was not available in our laboratory during the study period.

Aside from muscle soreness, two subjects complained of wrist and hand pain and numbness while performing the quadruped exercise. The subjects ascribed the pain and numbness to a previous history of carpal tunnel syndrome. To resolve this issue, the hand position was slightly modified: rather than using the palm of the hand for support during the quadruped position, which kept the wrist in extension, the subject was asked to make a fist and support him/herself on the knuckles, which kept the wrist in neutral. This modification resolved the issue.

The NMES was tolerable on the lumbar paraspinal muscles without any adverse events. As expected, all of the subjects were able to increase the current intensity from baseline to post-

intervention at 6 weeks, suggesting that subjects are able to adapt to the current intensity over time. The NMES current intensities on lumbar paraspinal muscles were similar to the current intensities on the quadriceps femoris.[42, 45, 68, 69] For example, in the Snyder-mackler et al.[45, 68] and Laufer et al.[69] studies, a number of subjects were able to use the full available amperage of the NMES devices, which was 100 mA. In our study, we had similar findings; two subjects were able to reach the full available amperage (100 mA) (Table 3). This suggests that the NMES intensities that can be applied on lumbar paraspinal muscles is similar to the intensities that were applied on the quadriceps femoris muscle.

4.2.3 Discomfort with neuromuscular electrical stimulation

NMES discomfort level has been investigated previously in the literature. Some studies measured discomfort using subjects' self-report of preference for a particular level or intensity of current.[70, 71] In these studies we can only assume that the intensity of NMES current that was "preferred" by subjects was comfortable, but we do not actually know if that was the case.

Other studies[72-74] assessed the level of discomfort with application of NMES using the numeric pain rating scale. While the use of pain rating scores may provide an estimate of the discomfort level associated with NMES, pain ratings cannot differentiate between the sensory and affective aspects of the painful stimulus associated with the NMES current. In comparison to using categorical numeric pain ratings, Delitto and Rose[75] used a 20-cm-long visual analogue scale to assess the discomfort associated with the use of NMES applied to the quadriceps femoris. While this 20-cm-long analogue scale could inform us about how the subjects

perceived the discomfort of the NMES affectively, it does not tell us about how the subjects perceived the sensation of the NMES physically.

In our assessment of NMES discomfort, we attempted to record both the sensory and affective aspects of the NMES current. The subjects in our study appeared to be able to successfully distinguish between the sensory and affective aspects of the NMES current. At baseline, the subjects perceived the NMES current sensation to be moderately to highly intense but they were relatively comfortable with it. At week 6 post-intervention, the subjects were able to increase the intensity of the NMES amperage, and that increase was associated with increased in perception of the sensory aspect of the NMES as all the subjects described the NMES to be highly intense. However, despite that their sensory perception of high intensity, all of the subjects were comfortable with that high intensity level of current. This finding contrasts Delitto et al.[59] study where high NMES currents were applied to the quadriceps femoris in healthy subjects. Similar to our study, Delitto et al.[59] found that higher levels of current amperage resulted in the perception of moderate to high sensation of intensity, but unlike in our study, it resulted in the perception of high discomfort as well. The different results of discomfort levels between our study and the Delitto et al.[59] study could potentially be attributed to the different populations and muscle groups used in each trial. In the Delitto et al. study the population was healthy subjects, and the muscle group targeted with the NMES was the quadriceps femoris, as compared to our study which included people with chronic LBP with NMES applied to the lumbar paraspinal muscles

4.3 OUTCOME MEASURES

4.3.1 Primary analysis

The randomization process resulted in two groups with relatively similar demographic characteristics and baseline outcome measures (Table 4). There was some concern that the stabilization + NMES group had more men, younger and stronger subjects at baseline than subjects in the stabilization only group. However, we investigated the difference between these characteristics and the baseline outcome measures using *t* tests and Mann-Whitney U test and these differences were found to be insignificant. Baseline characteristics could still potentially influence the results of the pre/post-treatment assessments of paraspinal muscle strength, therefore, we controlled for age, gender, ethnicity and baseline paraspinal muscle strength assessment during the statistical analysis where muscle strength was the dependent variable.

Our findings showed that both groups achieved significant improvements on function, pain, fear of movement (physical activity), and muscle strength from baseline to 6 weeks. This improvement exceeded the minimum clinically important difference for the MODQ (6 points)[55] and the NPRS (2 points),[76] and was maintained at 10 weeks follow-up point (Table 5). Supplementing stabilization exercises with NMES created similar treatment outcomes as those with stabilization exercises alone.

Contrary to our hypothesis that the stabilization + NMES group would show improved results compared to the stabilization only group, we found no significant difference between the groups on any of the outcome measures. This lack of significant difference can be explained by 3 possibilities. The primary possibility is that this was a pilot study that was not adequately

powered to detect a significant difference due to the small sample size. The main purpose of this pilot study was to enable us to identify the feasibility and potential effectiveness of the NMES as a supplement to stabilization exercises in people with chronic LBP, before moving into a larger and more expensive definitive trial. Therefore, the results of this study should be interpreted within the context of its purpose. That is, the results should not be used to draw definitive conclusions about the efficacy or effectiveness of the NMES as a supplement to stabilization exercises, as the design does not allow such interpretation.[77]

The second possibility could be that the number of NMES sessions used in our study was not sufficient to make notable changes between the groups. In our study, the number of sessions per subject was 12, without home sessions. However, in the Snyder-Mackler study[68] NMES was delivered to the quadriceps muscle for 15 minutes, four times per day, for 5 days a week for 4 weeks. In the Piva et al. study[42] NMES was delivered for 60 sessions divided into 12 supervised sessions and 48 at-home-sessions. In these two studies, the number of the NMES applications and sessions significantly exceeded the number of NMES applications used in our study.

The third possibility could be that our study did not deliver a subgroup-matched intervention as suggested by treatment guidelines.[78] Subgroup-matched interventions have been a subject of research for over 20 years, and is considered a research priority.[79] Subgroup-matched interventions were suggested mainly because randomized trials comparing any two treatments on people with LBP have always resulted in no difference between the groups. This failure in finding significant differences between any two treatments led researchers to believe that not all patients with LBP are the same, but they could be composed of smaller subgroups each of which respond best to a particular treatment.

4.3.2 Effect size and power analysis

Even though it is not advisable to calculate sample size for future trials on the basis of the effect size obtained from a phase I trial,[58] we still would like to see the required sample size needed to detect a significant difference between the groups. This sample size calculation is simple using the GPower calculator.[80] Using the primary outcome measure (MODQ) to calculate the effect size from this study, we found a small effect size of .17. Using an effect size of .17, power of .8 and alpha level of .05, we calculated a total sample size that is needed to detect significant difference on the MODQ in future trials to be $n = 224$.

4.3.3 Responder analysis

To interpret the clinical importance of treatment outcomes in chronic pain clinical trials it is suggested that more than one type of analysis is conducted.[66] Therefore, we conducted a responder analysis to see if we could provide greater insight about our results. In our responder analysis, we used the recommendation that improvement of more than 30% in pain would reflect a moderate clinically important difference.[66] Even though this recommendation was only for pain, we tried to extend this recommendation to disability. Our findings showed that a higher proportion of subjects in the stabilization only group achieved more than 30% improvement on pain and disability outcomes compared to stabilization + NMES group (Table 7). These results are opposite to our expectation, however, the results should be interpreted cautiously as the chance of type II error is very likely, especially that this is a phase I trial.

4.3.4 Treatment Satisfaction

During the assessment of treatment satisfaction, the treating therapist instructed the subjects to rate their satisfaction with the treatment and not with the therapist. It is interesting to see that subjects in both groups were satisfied with their respective interventions, and none rated their satisfaction below "satisfied" (Table 6). However, from Table 6 we can see that subjects in the stabilization only group were more satisfied with the treatment than subjects in the stabilization + NMES group, but we do not know the reason(s) for this difference in satisfaction rates.

In the following sections, we will present a review of the literature regarding studies that investigated the effect of electrical stimulation on paraspinal muscles, and then we are going to compare and contrast the findings of each study to our study.

4.3.5 Electrical muscle stimulation for LBP

We believe that our study is the first randomized trial to investigate the effect of stabilization exercises[65] supplemented with NMES on patients with chronic LBP. However, we were able to identify 2 other studies investigating the effect of NMES on chronic LBP. One study by Durmus et al.[81] where 41 women with chronic LBP (> 3 months) were randomized into either an electrical stimulation plus exercises group or exercises only group. The electrical stimulation parameters and the exercise program used in Durmus et al. study were different from those used in our study. Durmus et al. used a symmetric biphasic wave with a frequency of 50 Hz and pulse duration of 50 msec. The stimulation time was 10 sec contraction and 10 sec relaxation. Four electrodes were placed over the paraspinal muscles for 15 minutes with the patient in prone

position, and over the abdominal muscles for another 15 minutes while the patient was in the supine position. The full amperage intensity was allowed to reach up to 120 mA. The exercise program was not a stabilization exercise program but was a group-based exercise session that lasted 30 minutes, performed 3 days a week for both groups. The exercise program included motion, flexibility, back strengthening exercises, stretching of the hamstrings, erector spinae and abdominals, the cat and camel exercise, and back extension exercises. Durmus et al. aimed to assess pain, disability, functional performance, endurance, quality of life, depression, and muscle strength. They used repeated measure *t* tests to investigate the within-group differences from pre to post intervention, and independent samle *t* tests again to investigate the differences between the two groups post intervention. Using the *t* test twice, the results of Durmus et al. study showed that there was a significant within and between group differences on all of the outcome measures. However, because of repeating the *t* test twice, the Durmus et al. study may suffer from the possibility of type I error.

The other study that investigated the effect of electrical stimulation on people with chronic LBP was published by Coghlan et al.[82] This study recruited 13 subjects with chronic LBP to receive electrical muscle stimulation on the paraspinal and abdominal muscles for 15 minutes one or two times a day for 6 weeks (no control group). All subjects were shown how to use the device in the first session, and then asked to continue the treatment on their own at home. In this study, the electrical stimulation parameters were also different from the parameters used in our study. Coghlan et al. used a biphasic symmetrical constant current with a frequency of 20 – 30 Hz and pulse duration of 480 msec. The stimulation time was 4 seconds on and 3 seconds off. The full amperage intensity was allowed to reach up to 150 mA. To measure improvement from pre to post intervention, Coghlan et al. used pain rating scores and muscle thickness change

of transverse abdominus, internal oblique and lumbar multifidus during resting position and leg movement using ultrasound imaging. They found that subjects' pain improved after the electrical stimulation. Also, muscle thickness increased during resting position for the transverse abdominus, internal oblique and lumbar multifidus. However, using leg movement, the transverse abdominus and internal oblique muscles increased their thickness, but not the lumbar multifidus. Because there was not a control group in the Coghlan et al. study, we cannot exclude the possibility that the observed improvement occurred naturally or due to other interventions received by the participants.

4.3.6 Electrical muscle stimulation for paraspinal muscles in healthy people

The earliest report investigating the effect of electrical stimulation on paraspinal muscle strength was by Kahanovitz et al.[83] In this study 117 healthy subjects were randomized into 4 groups: electrical stimulation A, electrical stimulation B, exercises, or a control group. Electrical stimulation A was a biphasic, symmetrical waveform current with a frequency of 35 Hz and pulse duration of 300 msec. The electrical stimulation B was a monophasic, modified waveform current with a frequency of 300 – 500 Hz and pulse duration of 400 – 600 msec. The stimulation duration was 30 minutes for both A and B electrical stimulation, at the subject's highest tolerance level. The exercise group received exercises for 30 minutes that included prone trunk extension, prone leg lifts, prone arm lifts and a combination of "all four" arm and leg lifts. The electrical stimulation (A and B) and the exercises groups received the treatment 5 days a week for 4 weeks. The control group received no treatment. Kahanovitz et al. used one way ANOVA to analyze the data. The findings show that subjects in the electrical stimulation groups and the

exercise group improved their isometric paraspinal muscle strength from pre to post intervention, while the control group did not. However, there were no significant differences between the electrical stimulation A, electrical stimulation B, exercise, and control groups.

Kahanovitz et al. also investigated the isokinetic strength in the four groups and found that the electrical stimulation A and exercise groups had a significant increase in isokinetic strength compared to the electrical stimulation B and the control group. These findings suggest that future investigation of NMES as a supplement to stabilization exercise should take into account the type of strength testing to be used.

A recent trial by Baek et al.[84] investigated the effect of 3 different frequencies of electrical stimulation on paraspinal muscles thickness on 20 healthy physically active male subjects. Baek et al. used a constant current of symmetrical biphasic waveform with pulse duration of 200 msec and frequencies of 20, 50, and 80 Hz. The stimulation time was 8 seconds and the relaxation time was 10 seconds. Four hydrogel electrodes were used, and all subjects were instructed to increase the intensity as high as they could tolerate. Baek et al. used ultrasound imaging to measure paraspinal muscle thickness change from resting to electrical muscle contraction at each frequency. The results show that thickness of paraspinal muscles increased from resting to electrical muscle contraction at each frequency, however, there was no difference between the frequencies.

4.3.7 Electrical muscle stimulation for LBP in case reports and conferences

The first case report that used NMES as supplement to stabilization exercises was published by Manal in a non-peer reviewed journal.[85] Manal described a 21-year-old figure skater who had an

L5-S1 fusion surgery 1 year earlier, and before the start of her physical therapy she had a second surgery for hardware removal. After the hardware removal, the skater complained of a constant LBP that increased with her activity, and limited her ability to return to skating. The skater described the pain as an electric shock from her back into her left buttock every time she landed during skating. Also, the pain would increase with standing for more than 30 minutes and laying prone. The pain averaged 4/10 on visual analogue scale, and her disability was rated 20% on the Oswestry Disability Questionnaire.

The skater was treated with a course of stabilization exercises similar to what is described in our study. After 6 treatments, the pain levels improved and became intermittent. Despite the noticeable gain in the skater's condition, she described an inability to correctly perform the exercises due to fatigue. At that point, the stabilization exercise was supplemented with NMES. After 15 treatment sessions of NMES, the Oswestry disability score was rated at 12%, and the patient had no pain with activities of daily living. The skater returned to skating gradually, and within 4 weeks she was able to return to compulsories without LBP except with extreme trunk twisting. The skater returned home for the summer and progressed to a Pilates based strengthening program. After 9 months she was able to skate 2 – 3 time/week without LBP.

Recently, 3 similar case reports were presented in the American Physical Therapy Association's Combined Section Meeting 2015 in Indianapolis, IN. The first case report was presented by Mahon et al.[86] in which he described a 22-year-old extreme skier who suffered back pain after he jumped from a helicopter and landed on his right side. After the skier was medically managed, he was referred for physical therapy. Upon examination, the skier had gross joint hypomobility of the lumbar spine and right hip that prevented him from participating in activities of daily living. Initially, the skier received mobilization and manual therapy to

improve the mobility of the hip and the lumbar spine, followed by stabilization exercises to the spine. After 8 visits, the skier improved function with activities of daily living, but was still unable to participate in sports due to lumbar pain. At that moment, the treating therapist decided to supplement the stabilization exercise program with NMES. At visit 19, the patient's function significantly improved, and his Oswestry score was rated at 0%.

The second case report presented by Roberto et al.[87] for a 20-year-old female Division I softball pitcher who injured her back during a game, which resulted in radicular symptoms. The pitcher underwent a L4-5 microdiscectomy, and then presented to the physical therapy clinic 2 months after the surgery with a pain level of 2- 3/10 on the NPRS and an Oswestry disability rating of 20%. Upon examination, the pitcher had poor paraspinal muscle activation during prone arm elevation and hip extension, diminished sensation at L5 dermatome, positive neural tension, and poor control of the trunk during movement of the lower extremities. The pitcher was prescribed stabilization exercises supplemented with NMES 3 times a week for 7 weeks. After the intervention, the pitcher had a NPRS of 2/10 and an Oswestry disability rating of 6%. The pitcher was able to participate in softball without LBP.

The last case report was a poster presentation for a 61-year-old female art professor with recurrent back pain.[88] The professor complained of pain during rising from a chair after prolonged seated position, standing for a prolonged time teaching a class or lifting heavy objects. The professor had a pain level of 5/10 on NPRS and rated her disability 28% on the Oswestry Disability Questionnaire. Using the treatment-based classification system, the professor was placed in the stabilization exercise category and received treatment for 8 weeks. Four weeks after the end of the treatment, the professor continued to have 6/10 pain on NPRS and disability rating of 36% on Oswestry Disability Questionnaire. At that moment, the treating therapist

decided to use the NMES to supplement the stabilization exercise program. After another 8 weeks of combining the NMES with stabilization exercises, the professor rated her pain 0/10 on the NPRS and her disability on the Oswestry Diability Questionnaire at 6%.

4.3.8 Challenges with paraspinal muscle strength assessment

In line with our study, Durmus et al.[81] and Coghlan et al.[82] showed that electrical stimulation can be applied to the paraspinal muscles and may result in improved pain and disability levels from pre to post intervention. However, the two studies showed that the electrical stimulation may also result in significant improvement in paraspinal muscle strength, which is not the case in our study primary analysis. In our study, the lack of significant difference between the groups in muscle strength could be due to our use of the semi-standing chair, which may not have been the most appropriate way to measure paraspinal muscle strength. During the paraspinal muscle strength testing, as the subjects pushed against the scapular roll to exert maximum voluntary contraction into trunk extension, we noticed that they partially activated the quadriceps femoris and gastrocnemius muscles. The activation of these muscles was probably due to being in a closed kinetic position as their feet were in contact with the footrest. We believe that the activation of those muscles was inevitable in order to stabilize the subject on the chair. Since the quadriceps femoris and the gastrocnemius were active during testing, we cannot exclude the possibility that their activation contributed to the score of the lumbar paraspinal muscle strength obtained from the dynamometer computer. Other studies that utilized computerized dynamometer testing chairs to measure paraspinal muscle strength found that there is a conjoint

activation of hip extensors equivalent to 50% MVC measured on electromyography,[89] which is in line with our visual observation.

Other tests that are commonly used to measure paraspinal muscle strength include the Sorensen test, handheld dynamometer, ultrasound imaging, and isokinetic measurement. Sorensen test has similar limitation to the computerized dynamometric tests in that the hip extensors and other trunk muscles are conjointly active with the paraspinal muscles. Also, the Sorensen test is argued to be an endurance test rather than a strength test.[90]

A handheld dynamometer was used in the Durmus et al.[81] study which also has limitations. Despite that it is easy to use, the handheld dynamometer is difficult to perform in a standardized manner and has low inter-examiner reproducibility.[91]

Ultrasound imaging was used in the Coghlan et al.[82] and Baek et al.[84] studies to view and measure paraspinal muscle thickness changes before and after the application of electrical stimulation. However, the use of ultrasound imaging is limited by the level of experience of the assessor.[92] Also, ultrasound cannot be used to determine the maximum force that the muscle can exert after a rehabilitation program, because changes in muscle thickness may not be directly correlated with gains in muscle strength.[93]

The isokinetic strength testing was used in the Kahanovitz et al. study,[83] and was shown to have different outcomes than static isometric paraspinal muscle assessment. This could be due to the fact that isokinetic testing has a number of advantages in testing the strength of the paraspinal muscles. Rather than just testing isometric muscle strength, it can test both concentric and eccentric muscle strength at different speeds, which is very important in assessing the dynamic strength of the lower back muscles. It could also be that only dynamic muscle strength improves with dynamic exercises, and therefore isometric testing may not be able to detect

improvements in dynamic muscle strength. The other advantage of isokinetic testing is that it has high test-retest reliability.[94] However, isokinetic strength testing has similar limitations to the computerized dynamometer, in that other muscles could be conjointly activated with the lumbar paraspinal muscles. Also, there is no standard method as to the optimal parameters of testing such as position, speed, angle, and strapping.[89]

That being said, the computerized dynamometer, despite its limitations, remains one of the best testing options for paraspinal muscle strength due to the high inter-session[89] and inter-rater reliability[95] that they possess. In future trials, better means to measure lumbar strength testing should be explored. This could be achieved by testing the paraspinal muscles in an open-kinetic position rather than a closed-kinetic position. That is, the subject's feet should not be touching the foot rest or the floor, which would mitigate the contribution of the lower extremity muscles.

4.3.9 Issues with neuromuscular electrical stimulation parameters

The optimal NMES parameters that should be used to elicit maximum muscle contraction with least discomfort have been widely debated in the literature. Delitto and Rose[75] showed that the waveform of the NMES current has no influence on discomfort level, and that different individuals had different preferences for the waveforms with which they could produce highest muscle contraction. In comparison, Laufer et al.[69] showed that the monophasic and biphasic waveforms resulted in greater contraction of the quadriceps femoris than the polyphasic waveform.

Other studies investigated whether the NMES pulse rate (high vs. low frequency) of the currents would have an influence on muscle contraction and discomfort level. Laufer and Elboim[74], and Lyons et al.[72] showed that the pulse rate resulted in no significant effect on the contraction or discomfort level. However, Ward et al.[71] and Baek et al.[84] showed that low frequency of the current is less comfortable than high frequency current.

Scott et al.[73] investigated whether pulse (phase) duration would have an influence on muscle contraction and discomfort level. They showed that short pulse duration (50 msec) and long pulse duration (200 msec) produced similar discomfort levels, however, the long pulse duration produced greater muscle contraction.[73, 96] In line with these findings, Ward and colleagues[71, 97, 98] showed that pulse duration is a more important factor in determine the comfort level with the NMES current than the number of cycles per burst.

These contradictory results may be reflective of the patient heterogeneity in studies that assess the NMES applications to augment muscle contraction. This heterogeneity can result from different subject populations (healthy vs. patients), various current parameters, muscle application site, and discomfort outcome measures that were used in each of these trials. These contradictory results may also be explained by the different NMES parameters utilized in the 4 trials cited above.[81-84]

4.3.10 Issues with neuromuscular electrical stimulation dosage

In our study we chose the parameters that are reported in the literature[41, 42, 45, 46, 68] and suggest by clinical practice guidelines[47] to produce improved muscle strength when combined with volitional exercises. We investigated whether those parameters were comfortable on the

paraspinal muscles. We found that the NMES parameters we chose were perceived as comfortable on the paraspinal muscles at levels as high as 100 mA, which was the full amperage level. This implies that using those parameters enabled participants to increase the current intensity to levels high enough to produce muscle contraction comfortably. Such findings are important because higher current intensity has been shown to have a positive dose-response relationship with muscle strength gains.[68, 99]

It should be noted that the NMES parameters we used were different from the parameters used in the Durmus et al, Coghlan et al, Kahanovitz et al, and Baek et al. studies. However, the NMES parameters we used were similar to the parameters used in the case reports discussed above,[85-88] except for the duration of muscle stimulation. The duration of stimulation in the case reports (12 seconds) was longer than the duration of stimulation we used in our study (6 seconds). The duration of muscle stimulation could play a role in improving the strength of the muscle because of the dose-response effect of the NMES. The duration of stimulation we used in our study was used by Piva et al.[42] on the quadriceps femoris, which showed improved muscle strength gains in patients with rheumatoid arthritis. However, it should be noted that in the Piva et al. study the number of sessions was higher (60 sessions) than in our study (12 sessions).

Another difference between the case reports above and our study was that in all of the case reports the NMES current was administered through 2 channels. Each channel had two small electrodes coming out of it and was placed on the paraspinal muscles (2 electrodes on each side). This could have made the NMES encompass a wider area of stimulation, as each side of the paraspinal muscle receives electrical simulation from two electrodes coming from two independent channels. In our study, we used two large electrodes coming out of one channel with each electrode applied to just one side of the paraspinal muscles. However, we do not

believe that size of the electrode mattered very much, as long as paraspinal muscle contraction was observed during stimulation. We leaned toward the use of larger electrodes because we felt they were more comfortable when we compared them to small electrodes prior to the initiation of our study.

In the case study by Mahon et al.[86], they used ultrasound imaging to determine at which NMES amperage multifidus activity started. This ultrasound imaging revealed that the minimum NMES dose required to activate the atrophied L4-5 multifidus was 50 mA at initial visits. However, as the atrophied multifidus gained strength and bulk, a 63 mA current was required to activate it. While we contend that such findings might be specific to the case Mahon et al. presented, we should recognize that these findings point to the importance of increasing NMES intensity from one visit to the next, in order to achieve desired muscle strength gains. In our study, 10 subjects reached intensity levels higher than 50 mA, and 8 subjects reached an intensity level of 63 mA (Table 3).

4.3.11 Subgroup-matching with neuromuscular electrical stimulation

From the above case reports,[85-88] we can extrapolate a number of subgroups who might preferentially respond to NMES when combined with stabilization exercises. The first subgroup could be patients being treated post lumbar surgical intervention. After lumbar surgery, multiple studies have shown that paraspinal muscle activity and cross-sectional area of the mulitifidi are reduced and infiltrated with fat.[21, 100, 101] Also, after lumbar surgery, selective atrophy of type II fibers was shown to persist for as long as 5 years.[19] These post-surgical muscular deficits can be readily rectified by supplementing the stabilization exercise program with NMES. NMES could

potentially enhance the paraspinal muscle voluntary contraction beyond that of the exercise program alone.[41, 45] Alternatively, these post-surgical deficits may respond preferentially to the way that NMES induces muscle contraction by randomly recruiting type I and type II muscle fibers.[48, 49] This random activation allows the NMES-supplemented contraction to recruit greater proportion of type II fibers when compared to voluntary contraction at similar intensity.[50-52]

Another subgroup that could respond preferentially to the NMES when combined with stabilization exercises are patients with a physically demanding activity who injured their back while doing their job or sport. This subgroup may not respond to a stabilization exercise regimen alone, as it might not be sufficient heighten their paraspinal muscle activity to levels that meet the demands of their activity. Thus, NMES-supplemented stabilization exercise program can help such individuals by boosting their ability to achieve higher muscle contraction.

The last subgroup that could respond to the NMES when supplemented with stabilization exercises are patients with some type of pathoanatomic instability such as spondylolisthesis. This subgroup is included based on our clinical observation. Our observation suggests that a number of patients with spondylolisthesis seem to have immediate relief of pain after a 20 – 30 minutes of a NMES dose alone. This post NMES pain relief appears to last for about 7 – 10 days before the patient needs to use NMES again. This temporary relief may become long-lasting relief if the application of NMES was supplemented with a stabilization exercise program. Future research should investigate how NMES can be best used as supplement to stabilization exercises, and whether there is any subgroup that preferentially responds to NMES-supplemented exercise programs.

4.4 STUDY IMPLICATIONS

Our study suggests that NMES is a feasible intervention to supplement stabilization exercises for people with LBP. To effectively apply NMES, however, a number of issues related to strength testing and NMES parameters/dosage need to be addressed. As far as strength testing, future trials should determine whether isometric versus isokinetic muscle testing is the best way to measure lumbar paraspinal muscle strength. Future studies should also determine the best way to isolate the lumbar paraspinal muscles, and distinguish their level of contractile force from the contribution of other muscles when conducting strength measurement using computerized dynamometers. At minimum, future trials should determine the best way to lessen the contribution of lower extremity muscles to the measurement of lumbar paraspinal muscle strength.

As far as the NMES parameters, future trials should rely on the parameters that were utilized in our study, as such parameters were shown to augment muscle strength when combined with volitional exercises.[41, 42, 45, 46, 68] Also, such parameters were shown in our study to be tolerable and comfortable on the paraspinal muscles on people with LBP.

As far as the NMES dosage, future trials should increase the stimulation time to 12 seconds, which is double the stimulation used in our study. Also future trials should investigate take into consideration the number of sessions using the NMES. These suggestion are because the NMES has a dose-response effect on muscle strength, increasing the number of sessions and the period of stimulation may be warranted.

As far as the LBP subgroups that we think might benefit from the NMES intervention when supplemented with stabilization exercises, we suggest 3 potential subgroups: 1) patients

entering post-operative rehabilitation after lumbar surgical procedures; 2) patients whose activity require higher muscle performance (e.g. job, sport); and 3) patients with specific pathoanatomic instabilities (e.g. spondylolisthesis).

4.5 LIMITATIONS

Our study was a phase I trial that had a number of limitations. Our study had a small sample size that limits our ability to make definitive conclusions about the treatment results on function, pain, fear-avoidance, and muscle strength improvement. Also, our study did not include a control group that received no treatment, which limits our ability to refute the argument that the observed improvement from pre to post intervention occurred naturally.

Even though we performed a computerized randomization, the randomization was not concealed and the treating therapist could have potentially biased the allocation of the patients to either group. Additionally, in our study there was no blinding, which could have biased the results. Further, the treatment time for the 2 groups was different, the stabilization + NMES group received double the time of the stabilization only group. Lastly, the muscle strength measurement in our study was measured using the Biodex 3 Pro semi-standing chair, which may have confounded our ability to isolate the measurement of lumbar paraspinal muscle strength. Using the semi-standing chair, it was observed that the quadriceps femoris and gastrocnemius were activated every time the subject was asked to isometrically extend their trunk to measure paraspinal muscle strength.

5.0 CONCLUSION

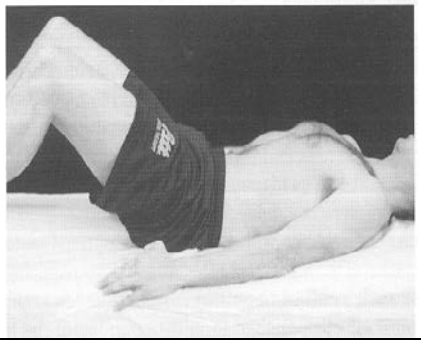
Our study is a phase I trial and should be interpreted within its context, that is, no efficacy or effectiveness conclusions can be drawn as the design does not allow such interpretation. In our study we showed that the NMES as a supplement to stabilization is a feasible intervention. Future trials of stabilization exercises supplemented with NMES are suggested based on the feasibility findings of our study.

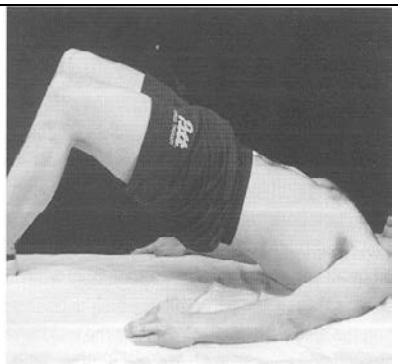
APPENDIX A

STABILIZATION EXERCISE PROGRAM

Both groups in this study will receive this stabilization exercise program. In each group, the subject will be instructed to only perform the exercises that the therapist has indicated. Also, the subject will be instructed to perform the exercises at least once daily. Before the subject begin their exercise, they will be instructed to perform 5-6 cycles of the cat/camel exercise (emphasis on motion in spine, not stretching). To do this, the subject starts on the hands and knees on the table, arch the back upwards (cat), then slowly lower the back towards the floor (camel).

A.1 ABDOMINAL BRACING

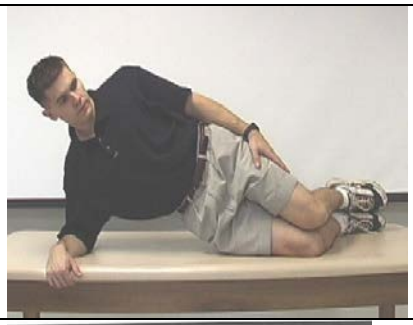
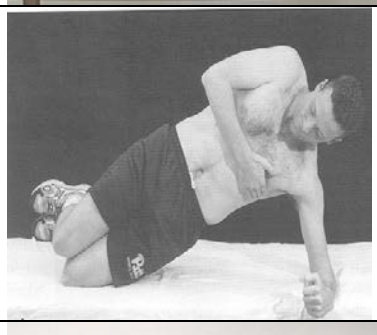
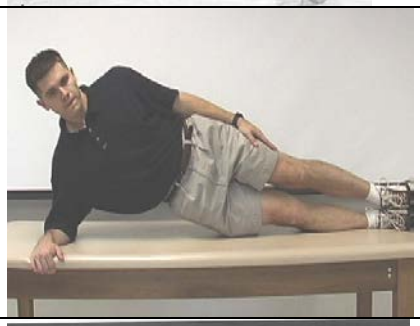
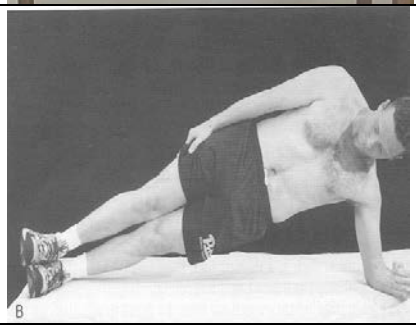
1. Abdominal bracing (supine) Lie on your back with your knees bent. Tighten your stomach muscles **without** pressing your back flat to the floor. Hold for 8 seconds, counting aloud to avoid holding your breath. Relax and repeat.	

2. Abdominal bracing (supine) with heel slide Lie on your back with knees bent as above. While tightening your stomach muscles (abdominal brace), slide the heel of one foot away from you until your knee is straight (3 second count). Then, slide your heel back towards you until your knee is in its original bent position (3 second count). Relax and repeat on opposite leg.	
3. Abdominal bracing (supine) with leg lifts Lie on your back with knees bent. While tightening your stomach muscles (abdominal brace), lift one foot about 6 inches off the floor for a 3 second count. Then, return it to the floor at a 3 second count. Relax and repeat with opposite leg.	
4. Abdominal bracing (supine) with bridging Lie on your back with knees bent. While tightening your stomach muscles (abdominal brace), tighten your buttocks and slowly lift them off the floor. Do not allow your back to arch. Hold for ____ seconds. Relax and repeat.	
5. *Bracing with single leg bridging Lie on your back with knees bent. While tightening your stomach muscles (abdominal brace), tighten your buttocks and slowly straighten one knee so that only one foot is on the floor. Then, slowly lift your buttocks off the floor. Hold for ____ seconds. Relax and repeat.	

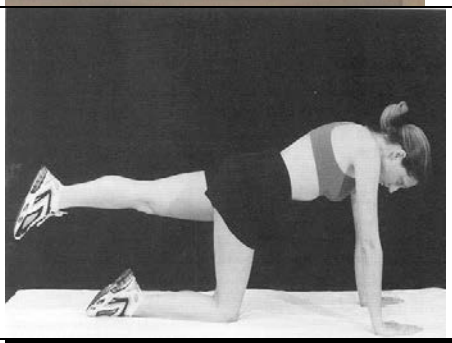
A.2 ABDOMINAL BRACING EXERCISES (WEIGHT BEARING)

1. Abdominal bracing in standing While standing, tighten your stomach muscles without changing the curve in the small of your back. Hold for 8 seconds. Relax and repeat.	
2. Isometric Torsion Stand in a slightly forward-bent position with one hand used as support on a table. Perform the **abdominal brace** and lift a light weight (2-3# dumbbell, can of soup, etc.) to the final position seen in the pictures to the right.	 
3. Abdominal Bracing with walking While walking, perform the abdominal brace. Hold 8 seconds. Relax for 10 seconds and repeat. Continue this cycle as you walk. Progress up to 10 minutes of walking.	

A.3 SIDE SUPPORT EXERCISES

1. Side support with knees flexed Lie on your side with knees bent and upper body supported on the lower elbow. Then, lift your body from the table with all weight borne on the lower knee and elbow. Hold for 8 seconds. Relax and repeat.	
2. Side support with knees flexed and bracing Perform the abdominal brace (tighten your stomach muscles) then do the side support as above. Hold for 8 seconds. Relax and repeat.	
3. Side support with knees extended Lie on your side with knees straight and upper body supported on the lower elbow. Then, lift your body from the table with all weight borne on the lower foot and elbow. Hold for 8 seconds. Relax and repeat.	
4. Side support with knees extended and bracing Perform the abdominal brace (tighten your stomach muscles) then do the side support as above with knees straight. Hold for 8 seconds. Relax and repeat.	
5. Advanced Side Bridge Perform the side support as described above. Roll from one elbow to the other while abdominally bracing to attain a side support position on the opposite elbow. Then, lower yourself from side support position on the opposite elbow to the floor.	

A.4 QUADRUPED EXERCISES

<table>
<tr><td colspan="2">No exercise begun in this group until able to complete Abdominal Bracing in supine (10 reps x 8sec hold)</td></tr>
<tr><td>1. Quadruped Arm Lifts with bracing
Start on your hands and knees. Tighten your stomach muscles. Then lift your right arm from the table. Hold for 8 seconds. Return to start position and repeat with left arm.</td><td>  </td></tr>
<tr><td>2. Quadruped Leg Lifts with bracing
Start on your hands and knees. Tighten your stomach muscles. Then extend your right leg so that your knee is lifted from the table. Keep your hips level with the table as you do this. Hold for 8 seconds. Return to start position and repeat with left leg.</td><td>  </td></tr>
<tr><td>3. Quadruped Opposite Arm and Leg Lift with bracing
Start on your hands and knees. Tighten your stomach muscles. Then extend your right leg so that your knee is lifted from the table and lift your left arm from the table at the same time. Keep your hips level with the table as you do this. Hold for 8 seconds. Return to start position and repeat with left leg.</td><td>  </td></tr>
</table>

A.5 CRITERIA FOR EXERCISE PROGRESSION

To progress the exercise, the subject must be able to achieve specific exercise goals before he or she can move on to the next exercise within one group of exercises. For example, before the subject progress from abdominal brace to abdominal brace with heel slide, he/she must complete 30 repetitions with 8 seconds hold time, and so on. If the subject reaches the final exercise in a

progression group, he/she should continue to perform the final exercise with increasing repetitions if possible.

A.5.1 Progression of abdominal bracing

Abdominal bracing (supine)	Able to complete 30 reps x 8 sec hold
Abdominal bracing (supine) with heel slides	Able to complete 20 reps per leg (4sec count)
Abdominal bracing (supine) with leg lifts	Able to complete 20 reps per leg (4sec count)
Abdominal bracing (supine) with bridging	For progression to single leg bridging, able to complete 30 reps x 8 sec hold. Continue with increased repetitions of bridging until able to perform single leg bridging
Bracing with single leg bridging	Goal is 30 reps x 8 sec hold

A.5.2 Progression of Abdominal Bracing Exercises (Weight Bearing)

For progression to abdominal bracing in weight-bearing positions, able to complete 20 reps x 8 sec hold of abdominal bracing with bridging.	
Abdominal bracing in standing	Able to complete 30 reps x 8 sec hold
Isometric Torsion (standing row in slight trunk flexion with one hand used as support on a table)	Able to complete 20 reps on each side (6 sec count)
Abdominal Bracing with walking	Goal is to walk for 10 min with abdominal bracing (8 sec hold and 10 sec rest)

A.5.3 Progression of Side Support Exercises

Side support with knees flexed	Able to complete 30 reps x 8 sec hold on each side. Able to complete Abdominal Bracing in supine (10 reps x 8sec hold)
Side support with knees flexed and bracing	Able to complete 30 reps x 8 sec hold on each side
Side support with knees extended	Able to complete 30 reps x 8 sec hold on each side
Side support with knees extended and bracing	Able to complete 30 reps x 8 sec hold on each side
Advanced Side Bridge (roll from one elbow to the other while abdominally bracing)	Continue to add reps until able to complete 30 reps x 8 sec

APPENDIX B

THE MODIFIED OSWESTRY DISABILITY QUESTIONNAIRE

Name: _____ Date _____

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 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 not effect on my pain.

Personal Care (Washing, Dressing etc.)

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, wash with difficulty and 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 (ex. 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 can not 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.

Pain prevents me from walking more than ½ mile

Pain prevents me from walking more than ¼ mile.

I can only walk 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 ½ 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 increases my pain.

Pain prevents me from standing more than 1 hour.

Pain prevents me from standing more than ½ hour.

Pain prevents me from standing 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 pain medication, I sleep less than 6 hours.

Even when I take pain medication, I sleep less than 4 hours.

Evens when I take pain 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 (ex. sports, dancing etc.)

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.

Traveling

I can travel anywhere without increased pain.

I can travel anywhere but it increases my pain.

My pain restricts travel over 2 hours.

My pain restricts my travel over 1 hour.

My pain restricts my travel to short necessary journeys under ½ hour.

My pain prevents all travel except for visits to the doctor/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 (ex. lifting, vacuuming)

Pain prevents me from doing anything but light duties.

Pan prevents me from doing even light duties

Pain prevents me from performing any job or homemaking chores.

Score_____/100%

!

APPENDIX C

THE NUMERIC PAIN RATING SCALE

On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain you have experienced, how would you rate your pain RIGHT NOW?

0 1 2 3 4 5 6 7 8 9 10

(No pain) (Worst pain)

On the same scale, how would you rate your BEST level of pain during the past 24 hours?

0 1 2 3 4 5 6 7 8 9 10

(No pain) (Worst pain)

On the same scale, how would you rate your WORST level of pain during the past 24 hours?

0 1 2 3 4 5 6 7 8 9 10

(No pain) (Worst pain)

APPENDIX D

THE FEAR-AOVIDANCE DISABILITY QUESTIONNAIRE

Name: _____ Date: _____

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 until 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

APPENDIX E

SATISFACTION SCALE

Please check the box that indicates how satisfied you are with the results of the physical therapy treatment.

□ Very satisfied

□ Satisfied

□ Neither satisfied or dissatisfied

□ Satisfied

□ Very dissatisfied

APPENDIX F

DEMOGRAPHICS FORM

Thank you for your participation in this study. We believe that the information you provide will help us to improve the LBP. All answers to the questions in this packet are confidential. There are no wrong answers to any questions. We ask that you take your time and carefully read and answer each question in this packet. Thanks again for your help.

Date:_____

Name:_____

Address:_____

City:_____ State:_____

Home Phone:_____ Work Phone:_____

Age:_____ Height:_____ Weight:_____

BMI: _____

Gender: Male_____ Female_____

Race: ____American Indian
____Asian
____Pacific Islander
____Black or African American
____White or Caucasian
____Hispanic
____Other_____

APPENDIX G

PHYSICAL EXAMINATION PROCEDURE

The physical examination will ensue after the subject (1) receive an explanation of the study and its aims, (2) read the consent form and sign it, and (3) fill out the self-report questionnaires. The physical examination will start by taking the subject's height and weight. All the components of the physical examination will be performed in a private examination room.

This physical examination of LBP will utilize the treatment-based classification system of low back disorders as a framework to determine the subject's appropriateness for a stabilization exercise intervention. This classification system suggests that LBP is likely to respond to stabilization exercise if the subject pain is chronic (> 3 months) and without signs and symptoms of serious pathology or dominant psychosocial issues, and fit the following criteria:

- Age < 40,
- Straight leg raise > 90,
- Aberrant motion during trunk flexion,
- Lumbar hypermobility,
- Fear-avoidance of < 19,
- Positive prone instability test.

These criteria do not necessitate exclusion from the study; subjects who do not fit these criteria may still benefit from a stabilization exercise program depending on physical examination findings. The physical examination will include: (a) historical information, (b) standing examination, (c) sitting examination, (d) supine examination, and (e) prone examination.

G.1 HISTORICAL INFORMATION

The following questions will be asked to the subject to gain an in-depth understanding of the subject's problem. The following questions will be used to formulate hypotheses about the source of chronic LBP, which will be confirmed or refuted during the physical examination.

How did your pain start?
Gradual: Subject is unable to identify a discrete moment when LBP began. Gradual onset points to the presence of degenerative process (e.g. arthritis).
Sudden: Subject is able to identify a discrete moment after which LBP began. Sudden onset suggests the presence of a disc lesion if LBP occurred after an activity that involves high stress on the lumbar spine (e.g. bending-twisting mechanism while lifting a heavy object); or it suggests a loss of lumbar spine stiffness (i.e. instability) if LBP occurred after a routine activity that involves very low stress on the lumbar spine (e.g. bending to pick up a light object).
Traumatic: Subject is able to identify a discrete moment after which LBP began, however, it was associated with an activity involving traumatic event (e.g. fall, car accident, sport activity).

Where do you feel your pain?
This information is gathered from the pain diagram and confirmed by asking the subject to point to the pain and its distribution on his/her own body.
There are four anatomical areas that can be involved. These anatomical areas are not mutually exclusive; that is, more than one of the following areas can be involved at the same time:

- Lumbar spine: The area between the lumbosacral junction and below the level of 12^{th} rib. In this area, the only description of symptoms accepted is pain. Pain can be central, unilateral or bilateral. Pain above the level of 12^{th} rib indicates that the lumbar spine is not the source of symptom, and the subject will be excluded. In addition, symptoms such as parasthesia (i.e. tingling, numbness) are not accepted in this area, and the subject will be excluded.
- Buttock: The area below the lumbosacral junction and above the gluteal folds. In this area, pain and/or paresthesia may be referred from the lumbar spine. Pain and/or paresthesia may be unilateral on the buttock cheek or central over the sacrum. Pain and/or paresthesia can be bilateral and slightly intense on one side more than the other. If pain and/or paresthesia are very severe unilaterally (nerve tension) or bilaterally (quada equina), the subject will be excluded. Also, if pain and/or paresthesia are felt inside the gluteal cleft or around the anus (S4 syndrome), the subject will be excluded.
- Thigh: The area below the gluteal fold and above the popliteal fold of the knee on the posterior and lateral aspect of the leg. In this area, pain and/or paresthesia may be referred from the lumbar spine or buttock. Pain and/or paresthesia are commonly in one thigh and present occasionally. They can be bilateral with pain slightly intense in one thigh more than the other. However, if pain and/or paresthesia are very severe unilaterally or bilaterally and present most of the time (acute LBP/nerve tension signs/quada equina), the subject will be excluded. Also, if pain and/or paresthesia are primarily distributed over the anterior thigh, subject will be excluded.

- Lower leg/foot: The area below the popliteal fold of the knee. In this area, pain and/or paresthesia may be referred from the lumbar spine or buttock. Pain and/or paresthesia are commonly in one lower leg/foot. However, if pain and/or paresthesia are severe unilaterally (nerve root sign involving one or more dermatomes) or bilaterally and present most of the time, the subject will be excluded.

Are these symptoms continuous or intermittent?

- Constant: Symptoms are always present with no variation in intensity.
- Variable: Symptoms are always present, but intensity varies.
- Intermittent: Symptoms are present at times, completely absent at other times.
- Subjects with symptoms that are constant or variable (*always present*) will be excluded (inflammatory process/visceral pain/non-mechanical). However, when the subject reports that symptoms are always present, he/she must be asked what he/she feels right now while lying on the treatment table? This question is necessary to truly confirm that symptoms are always present. If the subject reports that the symptoms are absent at the moment, then the nature of the symptoms will be labeled intermittent. But if the subject, while on the treatment table, reports that the symptoms are there, he/she will be excluded.
- Subject may also complain of progressive loss of ROM or muscle strength. Subjects with such complaint will be excluded.

What are the aggravating and easing factors of your symptoms?

- Subject will be asked to mention postures or activities that aggravate their symptoms (e.g. sitting, standing, walking, overhead activities, sport activities).
- Subjects with pathoanatomic instability will usually report pain with walking that is relieved immediately with sitting. Subjects with such report of pain are appropriate for stabilization exercises. However, the same report of pain is also true for subjects with neurogenic claudication and vascular claudication, both of which are not appropriate for stabilization exercises and should be excluded from the study. To distinguish between subjects with pathoanatomic instability, neurogenic claudication and vascular claudication, the following criteria should be followed:
    - Subjects with pathoanatomic instability are younger, less than 40 years of age, and highly active in sports. They may present with step deformity.
    - Subjects with neurogenic claudication or vascular claudication are mainly older and not highly active in sports. To distinguish between the two conditions, Table will be used.

Table: Criteria that aid in the distinction between neurological and vascular claudication

	Neurogenic	**Vascular**
Localization	Vague, including the back	Mostly in the calf
Paresthesia	Present	Absent
Walking	Worse	Worse
Standing	Worse	Better
Bending	Better	No change
Cycling	No change	Worse
Lying prone	Worse	No change

- Subjects may report that their pain starts with an ordinary activity such as picking a light object from the floor, reaching to wash the dishes, or put objects in an overhead cabinet. This indicates a compromised stiffness of the trunk muscles (non-specific instability). Subjects with such report will benefit from stabilization exercise intervention.

What time of the day are the symptoms worse?

- Morning: most likely arthritis.
- Midday: most likely disc abnormalities.
- Evening: most likely lumbar instability.

How long have you had your back pain?

- Subject with first episode of back pain and/or less than 3 months will be excluded.

When was the first time you had back pain?

- Subject provides a specific date or approximation.

Is this episode of back pain similar to the previous episodes you have had before?

- Subjects who report that the new episode is different will be questioned further about how this is different. If the examiner suspects that the current episode is not a mechanical LBP, the subject will be excluded. The questions that the examiner might ask to confirm that include location of symptoms, distribution of symptoms, mode of onset, etc.

What treatment have you had for your back pain?

- Subjects who indicate that they received stabilization exercise and/or NMES and did not benefit from the treatment will be excluded.
- Subject who indicates that they have had surgery for their back pain will be excluded.

Have you been diagnosed with joint inflammation such as ankylosing spondylitis?

- Subjects who answer "yes" will be excluded. Also subjects whom history description suggests the presence of ankylosing spondylitis will be excluded. History can be progressive loss of movement with alternating pain that is felt on each buttock during walking.

Do you have pain at night when you sleep? Or does the pain wake you up?

- Subjects who answer "yes" will be excluded.

Have you <u>recently</u> lost more than 10 pounds with no clear reason?

- Subjects who lost more than 10 pounds in a short period of time and have had no medical attention will be excluded.

Have you been diagnosed with cancer in the past 5 years? Or are you currently receiving treatment for cancer?

- Subjects who answer "yes" will be excluded.

Have you been told by you physician that you are not supposed to participate in physical exercises?

- Subjects who answer "yes" will be excluded.

Do you have a pacemaker?

- Subjects who answer "yes" will be excluded.

Are you pregnant or planning to become pregnant? (Female subjects only)

- Subjects who answer "yes" will be excluded.

G.2 STANDING EXAMINATION

The standing examination will start as soon as the subject's history taking is over with no findings indicating that the subject should be excluded. The standing examination will include posture observation, walking on heels and toes, step deformity test, palpation of lumbopelvic landmarks, active ROM test of lumbar spine and Trendelenburgh test.

Postural observation

- Anterior or posterior pelvic tilts and lateral trunk shift.
- Increase/decreased lumbar spine lordotic curvature.
- Paraspinal muscle hyper/hypotrophy.
- Scoliosis deformity (subjects with severe curvature of lumbar spine will be excluded).
- Step deformity

Walking on heels and toes

- Subject unable to walk on heels because of weak dorsiflexors will be excluded.
- Subject unable to walk on toes because of weak planterflexors will be excluded.

Step deformity test

- The examiner will slide his finger along the spinous processes starting from C7 and ending at the lumbosacral junction. If the examiner notices any spinous process that is off the alignment posteriorly, the test is positive for spondylolisthesis.

Palpation of lumbopelvic landmarks

- The examiner tests the alignment of the pelvis by placing his hands over the iliac crests. The examiner notices that the hands are of equal heights. If one hand appears higher, the test is positive for pelvic asymmetry.
- The examiner tests the alignment of the posterior superior iliac spine (PSIS) by placing his index fingers on the PSIS. If the fingers are not aligned, the test is positive for pelvic asymmetry.

Active ROM of lumbar spine

- Subject is to move into extension, side bending and flexion.
- With each of these movements, the subject is observed for the extent of active ROM: limited, normal and exaggerated. The extent of ROM is recorded using inclinometer.
- With each movement, subject is asked to report on symptoms reproduction and change in location. There are 3 possibilities: increase, decrease, or no change in symptoms.
- Subject with extensive limitation of all active ROM will be excluded.
- Older subjects with history of increased pain during walking or extension that is decreased with sitting or flexion may have lumbar spine stenosis. In these subjects, the examiner should notice the result of Pheasant's sign (described in prone examination). If Pheasant's sign is positive, subject will be excluded.
- The examiner should notice the result of active ROM of flexion. One of the following patterns may emerge:
    - Painful arc: symptoms are reproduced at a certain range of motion during flexion. Symptoms at initiation of flexion are absent, then appear at a certain range, then disappear toward the end range of flexion.

- Reversed painful arc: symptoms are reproduced at certain range of motion when the subject returns from flexion.
- Gower's sign: upon return from full flexion, the subject pushes on the thighs with both hands to stand upright again. This sign is also termed "thigh climbing".
- Instability catch: during flexion subject trunk deviates from the sagittal plane to one side and then return to it (i.e. side bend to one side during flexion).
- Reversed lumbopelvic rhythm: upon return from flexion, the subject first extends the lumbar spine and uses the hip muscles to return to the upright position.

- These 5 patterns suggest the presence of lumbar spine instability.

Trendelenburgh test

- The subject is asked to stand on one leg. If the subject's pelvis drops to the opposite side of the stance leg, the test is positive for gluteal medius weakness.

G.3 SEATED EXAMINATION

The sitting examination will start as soon as the standing examination is over with no findings indicating the subject should be excluded. The sitting examination will include thoracic rotation active ROM, reflex test, myotomal test, and slump test.

Thoracic trunk rotation

- Subject is asked to rotate the trunk to both sides and report on symptoms. At the end range of thoracic rotation, the examiner will apply passive pressure into rotation. During trunk rotation, symptoms are expected to occur in the thoracic spine, however, if symptoms are produced in the lumbosacral junction, it suggests instability.

Reflex test

- Knee jerk reflex (L2-4) and plantar reflex (L5-S1) will be tested. The reflex test will be scored normal, diminished, or increased. Subjects with clearly increased reflexes (i.e. light strike on the tendon produces exaggerated reflex) will be excluded.

Myotomal testing

- Myotomes will be tested with isometric resisted hip flexion (L2-3), knee extension (L2-4), dorsiflexion (L4-5), toe extension (L5), and planter flexion (L5-S1).
- Subjects with myotomal test of less than 3 out of 5 on manual muscle testing will be excluded.

Slump test

- Subject will sit slouch with neck flexion. The subject knee will be passively extended until it is completely straight and motion starts to occur into hip flexion. The subject will be asked about any reproduction of symptoms that he/she is familiar with. If the subject answers "yes", the test is positive for nerve tension sign and the subject will be excluded from the study. If, however, no symptoms are felt, the subject's foot may now be dorsiflexed. After dorsiflexion, subject will be asked again about any symptoms that he/she is familiar with. If the subject answers "yes", he/she will be excluded from the

study. If the subject answers “no” then the test is negative. The test is also negative if only muscle pain or tightness is reported.

G.4 SUPINE EXAMINATION

The supine examination will start as soon as the sitting examination is over with no finding indicating the subject should be excluded. The supine examination will include straight leg raise test, passive hip flexion ROM, FABER/Patrick test, and Babinski sign.

Straight leg raise test

- Subject each leg will be passively raised with the knee in complete extension and an inclinometer is at the tibial crest. The subject leg will be raised to the maximum tolerated straight leg raise not to the onset of pain. The ROM of the leg raise will be recorded. If ROM of straight leg raise is 45 degrees or less, the test is positive for nerve tension sign.
- The straight leg raise test should correspond with finding from slump test in sitting examination. If the slump test is negative, the straight leg raise test has to be negative. If these tests do not agree with each other, then the patient maybe malingering. However, if the slump test is positive, the straight leg raise can be negative.

Passive hip flexion ROM

- Subject’s hip is passively flexed to reach beyond 90 degrees. As the subject hip is progressed into flexion, the knee remains in flexion. If the subject thigh does not exceed 90 degrees, the test is positive for buttock sign and the subject will be excluded.

FABER/Patrick test

- Subject’s hip is passively flexed, abducted and externally rotated with lateral malleolus placed on the distal contralateral thigh. The hip ROM is observed as the leg slowly falls into external rotation toward the table (FABER). When the leg reaches the end range of external rotation, pressure is applied on the externally rotated leg (PATRICK). If the subject report any symptom in the groin, hip examination may be necessary.

Babinski sign

- Subject sole of the foot will be stroked with the heel of the reflex hammer. If the subject toes flared into extension, the test is positive for upper motor neuron lesion, and the subject will be excluded.

G.5 PRONE EXAMINATION

The prone examination will start as soon as the supine examination is over with no findings indicating the subject should be excluded. The prone examination will include femoral nerve tension test, Pheasant's sign, spring test and prone instability test.

Femoral nerve tension test

- Subject's knee is fully flexed and the subject is asked about any symptom produced in the anterior thigh. If the subject report that symptoms are produced in the anterior thigh and these symptoms are the main symptoms that he/she is familiar with, then the test is positive for femoral nerve tension and the subject will be excluded. The test in negative if only muscle stretch is reported.

Pheasant's sign

- Subject's knees are flexed bilaterally simultaneously to 90 degrees. While the subject in the prone position, the examiner checks the planter reflex every 30 seconds for 3 minutes. The planter reflex should remain unchanged throughout the period of 3 minutes. However, if the planter reflex became diminished to absent toward the end of 3 minutes, the test is positive for spinal stenosis and the subject will be excluded.

Spring test

- The subject interspinous spaces are assessed with a posteroanterior pressure applied by the examiner's hypothenar eminence. The posteroanterior pressure is applied starting from L5-S1 up to T12-L1 interspinous space. The examiner notices hypo/hypermobility, or reproduction of symptoms.

Prone instability test

- Subject lies on the edge of the table with the feet resting on the floor; the examiner applies posteroanterior mobilization on each interspinous space starting from L5-S1 up to T12-L1. Each time a segment is mobilized, the examiner assesses the subject hypermobility and asks about symptom reproduction. The examiner then asks the subject to lift the feet off the floor and reapplies posteroanterior mobilization starting from L5-S1 up to T12-L1. This time, the examiner assesses hypermobility and asks the subject about symptom reproduction again. The test is positive if the subject hypermobility or symptoms are produced during resting position but subside after the subject lift the feet of the floor.

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