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Physical Therapy Approach for Adults with Diabetic Peripheral Neuropathy

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**Physical Therapy Approach
for Adults with Diabetic Peripheral Neuropathy**

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ABSTRACT

Background/Purpose: Diabetes Mellitus (DM) is a common disease in the United States with more and more people diagnosed each year. A form of DM known as type II has many serious complications, including peripheral neuropathy. Diabetic peripheral neuropathy can result in both sensory and neural damage which can lead to a host of impairments. The purpose of this evidence-based analysis was to analyze the effects of physical therapy intervention in people with diabetic peripheral neuropathy.

Case Description: The patient is a 50-year-old Native American male referred to physical therapy for peripheral neuropathy complications associated with a diagnosis of DM II to determine the best treatment outcome for improving balance and gait deficiencies.

Outcomes: A review of current available evidence revealed that an individualized exercise program administered by a skilled professional physical therapist can significantly improve balance, strength, gait and overall functional abilities in a person with diabetic peripheral neuropathy.

Discussion: This evidence based analysis describes a well-rounded evidence based approach for providing treatment for a patient with diabetic peripheral neuropathy. The available research provides treatment strategies that can be implemented in a wide range of clinical settings. Although there is a need for a high-quality evidence that can be generalizable to a greater population. Overall, current evidence suggest that the progression of peripheral neuropathy can be halted or damped by performing an individualized exercise program. In addition to the many benefits of exercise.

INTRODUCTION

1.BACKGROUND AND PURPOSE

Diabetes mellitus has become a concerning health epidemic with an increase in prevalence and incidence of type 2 diabetes. According to the Centers for Disease Control and Prevention a recent report showed that approximately 30.3 million people of all ages had been diagnosed with diabetes in 2015, which did not include those who were undiagnosed with diabetes.¹ In addition, of all ethnicities compared in the same report American Indian/Alaska Natives had the highest prevalence of those men and women diagnosed with diabetes.¹ Diabetes Mellitus Type II is the most common type of diabetes and is associated with many complications.¹

Diabetic peripheral neuropathy is the most common diabetic complication.²⁻⁴ Diabetic peripheral neuropathy affects both sensory and motor nerve fibers.² A deficit in both sensory and motor fibers could lead to a host of issues including gait abnormalities, muscle weakness, decreased sensation, and reduced balance leading to a high fall risk.²⁻⁶ Research has found consistent gait abnormalities in patients with diabetes who have peripheral neuropathy including a longer stance time, higher plantar pressures during the stance phase of gait and a decreased stride length when compared to healthy control subjects.^{3,4} According to a review article by Parasoglou et. al (2017) found people with diabetes and peripheral neuropathy have declining skeletal muscle function.⁷ This review also found accumulation of intramuscular adipose tissue, loss of muscle volume and loss of subcutaneous adipose tissue in people with diabetes with neuropathy compared to healthy controls and subjects with diabetes without peripheral neuropathy.

Current treatments available for diabetic neuropathy consist of medications, exercise, and education on lifestyle modifications. In severe cases of diabetic neuropathy surgical interventions may be warranted.⁸ Therefore, the Pico question was formed and the evidence based analysis has shed light on how intervention from a skilled physical therapist could impact a person with balance and gait deficiencies as a result of diabetic peripheral neuropathy.

2. CASE DESCRIPTION

Patient is a 50-year-old male who was referred to outpatient physical therapy with a diagnosis of low back pain. Patient comorbidities include hypertension and diabetes mellitus type II. During treatments sessions, physical therapist noted patient having difficulty with balance and observed gait deviations. Patient's low back pain was treated successfully although patient was advised to seek medical advice for symptoms associated with diabetes mellitus type II. Patient was later seen at outpatient physical therapy for evaluation and treatment for peripheral neuropathy complications associated with the diagnosis of diabetes mellitus type II. Per medical record revealed lab values of FPG of 200mg/dl and HBA1c 13%. Physical therapy evaluation significant findings include decreased SLS of 10 seconds eyes open on level surface, decreased dynamic standing balance, and a shortened stride length during ambulation. Patient observation of body type endomorph, height is 5'8'' with a BMI of 40. Other relevant information include patient is American Indian.

Would physical therapy interventions including exercise improve balance and gait deficiencies in males with a diagnosis of type II diabetes who have diabetic peripheral neuropathy compared to no intervention?

3. EVIDENCE BASED ANALYSIS

Methodology of Search:

An evidence-based search was done to learn more about the following PICO question:

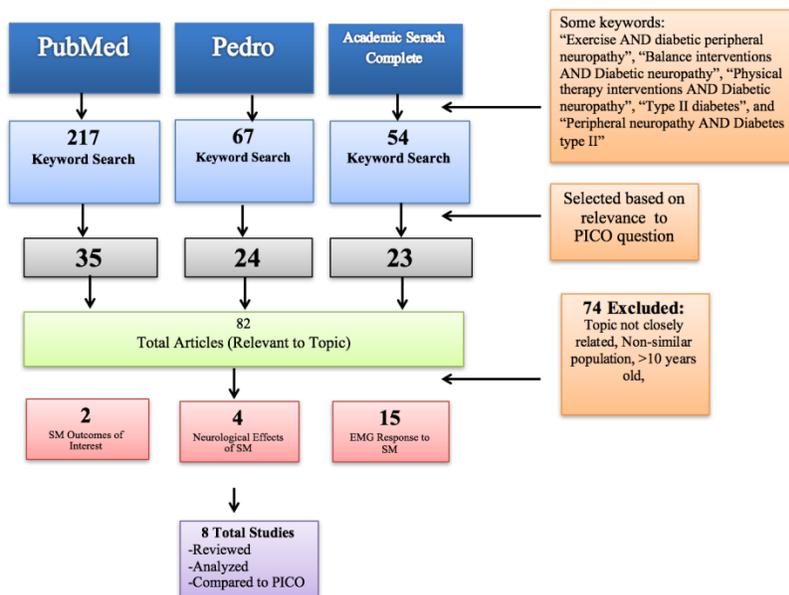
Would physical therapy interventions including exercise improve balance and gait deficiencies in males with a diagnosis of type II diabetes who have peripheral neuropathy compared to no intervention? PEDro, PubMed, and Academic Search Complete database engines were used to search using these phrases: “Exercise AND diabetic neuropathy”, “Balance interventions AND Diabetic neuropathy”, “Physical therapy interventions AND Diabetic neuropathy”, “Type II diabetes”, and “Peripheral neuropathy AND Diabetes type II” (Figure 1).

Selection Criteria:

Articles were included in the final evidence base selection if (1) subjects age were 45 years or older (2) article was published from 2008 to 2018. Exclusion criteria for articles selected included: (1) Articles that only looked at type I diabetes. (2) Did not include type two diabetes

Figure 1: Article Search methodology

Figure 1. Part I Methods: Articles Included and Excluded for Analysis



Article #1 Reference # 10 Abou-Shady, N. Effect of task oriented training on postural stability in patients with type II diabetic neuropathy.

Level of Evidence: 1b Oxford Level of Evidence

Purpose: The purpose of this study was to compare two groups using various outcome measures to assess whether task oriented training could impact postural stability in patients with type II diabetes with neuropathy.

Methods: A total of thirty subjects were randomly and equally assigned to two groups. The first group received task oriented training in combination with physical therapy treatment. The second group received physical therapy treatment only. The physical therapy treatment consisted of wobble board training, range of motion activities, stretching exercises, and gait training. Both groups received their designated intervention for 12 sessions held every other day, each for an hour. Both groups underwent pre- and post-tests of various outcomes including a postural stability test using a Biodex stability system. In addition, clinical outcome measures used were the Berg Balance Scale, Timed Up and Go and the Functional Reach Test.

Results: For all post-test outcome measurements, the study found significant improvements for both groups. The task oriented training group had even better results than the physical therapy treatment group alone.

Critique/Bottom Line: Overall, the task oriented group combined with physical therapy treatment is considered to be more effective than physical therapy treatment alone. It is a safe and feasible treatment option that can be easily done in any type of physical therapy clinical setting.

Article #2 Reference # 15 Dixit, S. Effect of aerobic exercise on peripheral nerve functions of population with diabetic peripheral neuropathy in type 2 diabetes: a single blind, parallel group randomized control trial.

Level of Evidence: 2b Oxford Level of Evidence

Purpose: The purpose of the study was to examine moderate intensity aerobic exercising using heart rate reserve from 40-60% in subjects with diabetic peripheral neuropathy in a single blind parallel group randomized controlled trial. Research was conducted in India.

Methods: A total 87 subjects were randomized in to two groups after being stratified according to their degree of peripheral neuropathy. Both groups were given education on diet and foot care. The experimental group exercised at a range of 40-60% of heart rate reserve, 3-6 days/wk for 8 weeks. The experimental group was instructed to exercise for 150 min/week to a limit of 360 mins/week. The control group received telephone calls on the second week of each month regarding dietary habits and foot care for 8 weeks. Controls subjects were also evaluated by their primary care physician at the 4th and 8th week of the study. When the study was over, the control group was instructed to exercise under supervised.

Electrophysiological evaluations were done for both groups at baseline and at the end of week 8.

Results: The subjects who performed the moderate intensity aerobic exercise saw improvements in conduction velocity compared to the control group. Overall, according to this study the authors stated the effects of moderate aerobic exercise can modulate neuropathy, when combined with standard medical care it can yield greater benefits.

Critique/Bottom Line: Overall, the study had 21 dropouts lost at the follow up. In addition, the study was conducted in India, its generalization to a US population can be a limiting factor. However, this study was the first of its kind to perform an electrophysiological evaluation for

each subject. More research is needed to examine the effects of aerobic exercise in the diabetic neuropathy population.

Article #3 Reference # 14 Handsaker, JC. Resistance exercise training increases lower limb speed of strength generation during stair ascent and descent in people with diabetic peripheral neuropathy.

Level of Evidence: 1b Oxford Level of Evidence

Purpose: The purpose of the study was to examine a resistance training program on speed of knee and ankle strength generation during stair descent and ascent in people with diabetic neuropathy.

Methods: A total of 43 subjects were included in this study. Three groups were studied over the course of 16 weeks. The first group consisted of nine subjects with diabetic peripheral neuropathy, the second group consisted of thirteen subjects who were diabetic living without neuropathy. The third group was made up of twenty-one healthy subjects. Of these groups, they were randomly assigned to an intervention group or a non-exercising control group. Researchers analyzed each subject using a Bespoke eight step staircase with four embedded force plates and ten motion system cameras. In addition, while performing pre-and post-test measurements each subject was analyzed with electromyographic electrodes place on over their ankle and knee extensor muscles.

Results: The researchers found that ankle and knee strength generation during stair ascend and descent were significantly higher after the 16-week intervention (those who completed the resistance training program) in people with diabetes and peripheral neuropathy compared the healthy subjects.

Critique/Bottom Line: Overall, this study highlights the possibility of improving speed of strength generation in people with diabetes and peripheral neuropathy. This study also proved that neuro damage can be reversible with specialized treatment.

Article #4 Reference #12 Kruse, R. Fall and balance outcomes after an intervention to promote leg strength, balance, and walking in people with diabetic peripheral neuropathy: Feet first randomized controlled trial.

Level of Evidence: 2a Oxford Level of Evidence

Purpose: The purpose of this study was to examine the effects of a lower extremity and walking intervention on balance and weight bearing exercise on foot ulceration in subjects with diabetes and peripheral neuropathy. In addition, fall incidence and lower-extremity strength were examined.

Methods: A total of 79 subjects were randomly divided into an exercise group and a control group. Both groups received foot care education, regular foot care and eight sessions with a physical therapist. The experimental group completed balance and leg strengthening exercises. They also completed a graduated walking program. The experimental group also received motivational phone calls to assist them with their exercises for a total of 12 months.

Results: After examining the two groups the researchers found no statistically significant differences between the two groups for falls at the follow up session. In addition, there were no differences between strength or balance measurements. Although at the twelve months follow up the experimental group improved in their ability to stand on one foot with their eyes closed compared to the control group.

Critique/Bottom Line: Overall, the intervention approach had little to no effect on the experimental group compared to the control group. This study did point out an important treatment concept regarding weight bearing activities in this population. It can be noted that increasing weight bearing activity did not alter the rate of falling for subjects in intervention group compared to the control group. Also, people who are less active and who live with diabetes and peripheral neuropathy appear to have the ability to increase activity without increasing the amount of times they fall.

Article #5 Reference #9 Mueller J., M. Weight-bearing versus non-weight bearing exercise for persons with diabetes and peripheral neuropathy: a randomized control trial. Archive of Physical Medicine and Rehabilitation. May 2013; 94(5) 829-838.

Level of Evidence: 1b Oxford Level of Evidence

Purpose: The purpose of this study is to compare weight bearing exercises to non-weight bearing exercises in people with diabetes and peripheral neuropathy. The subjects in the study were compared using various outcome measures including the 6- minute walk distance, average daily step count and several domains from the International Classification of Functioning, Disability and Health.

Methods: A total of 29 subjects who fit the inclusion and exclusion criteria were randomly allocated into each group. Subjects were evaluated at baseline, and after the intervention. Both intervention groups performed one hour group sessions made up of 1-4 subjects. The groups were supervised by a physical therapist and an assistant. The Weight bearing group performed exercises involving standing body weight exercises and an aerobic exercise component either walking on a treadmill or walking around a large hallway. The weight bearing group was also

instructed to increase their step count by 24% every two weeks on the three days they performed their exercise program. The non-weight bearing group performed all exercises while lying down or sitting using elastic band for resistance. In addition, the aerobic component for the non-weight bearing group was done on a stationary upright or recumbent cycle ergometer. The non-weight bearing group was also told to increase their average step count in the same way as the weight bearing group. Both intervention groups were taken through outcome measures at baseline, and after 12 weeks. In addition, there was a follow survey given to subjects to return via mail.

Results: Greater improvements in the 6-minute walk distance and average daily step count was seen in the weight bearing group compared to the non-weight bearing group (p value <.05). The non-weight bearing group had greater improvements in hemoglobin HA1c compared to the weight bearing group (p value <.05)

Critique/Bottom Line: The study protocol is more intense and structured compared to previous research looking at the same outcome measures. Overall, weight bearing exercises using body weight was effective in improving 6-minute walk distance and average daily step count. Both outcome measures are widely used in the Physical therapy practice. This study suggests weight bearing exercises can be use in the clinic to help improve outcome measures in patients with diabetes and peripheral neuropathy. Most physical therapy clinics have equipment and resources available to take a patient through the same weight bearing intervention.

Article #6 Reference #11 Rojhani-Shirazi, Z. Comparison the effects of two types of therapeutic exercises Frenkel vs. Swiss ball on the clinical balance measures in patients with type II diabetic neuropathy.

Level of Evidence: 1b Oxford Level of Evidence

Purpose: The purpose of this study was to compare three groups for improving balance, two groups consisted of different exercise interventions and the third was a control group. All groups were assessed by three difference clinical outcome measures.

Methods: A total of 60 subjects aged 45-65 year old were included in this study based on their body mass index, Michigan Neuropathy Screening Instrument score, referred by a physician and had a diagnosis of type II diabetes with peripheral neuropathy. Subjects were equally and randomly divided into three groups. One group completed a Swiss ball training program, the second completed a Frenkel training program and the control group received information on diabetes. All groups completed pre-and post-test measurements. The clinical outcome measured included Single Leg Stance Test, Berg Balance Scale, and a Star Excursion Balance Test.

Results: Overall both intervention exercises including ball training and Frenkel training showed significant differences from pre-to post test measurements for both intervention groups. This study was done with a three week follow up which provides sufficient time that one would be seen in an outpatient clinic.

Critique/Bottom Line: Overall, these exercises have strong evidence that they can help improve balance in a person with type two diabetes with peripheral neuropathy.

Article #7 Reference #16 Sartor, C. Effects of Strengthening, stretching, and functional training of foot function in patients with diabetic neuropathy: results of a randomized controlled trial.

Level of Evidence: 1b Oxford Level of Evidence

Purpose: The purpose of this study was to examine the effects of an exercise regime on foot rollover process during gait in patients with diabetic polyneuropathy. Researcher's looked at various loading variables including peak pressure, time-to peak pressure, and pressure-time integral in six foot areas. In addition, to ankle kinematics/kinematics and mean center of pressure. They also assessed each subject with multiple clinical outcomes including functional tests of the ankle and foot, and intrinsic/extrinsic muscle function.

Methods: A total of 55 subjects were randomized into an intervention group and a control group. The intervention group received exercises for foot/ankle and gait training twice a week for 12 weeks. The control group received standard medical care with no exercises. Both groups were seen at a follow up session at 12 weeks and the intervention group was seen for an additional follow up at 24 weeks. Various outcomes were assessed in both groups.

Results: Overall, the intervention group did not show statistically significant difference from the control group in the six-foot areas. Although after intention-to-treat analysis revealed softening of heel strike $p=.03$, better eccentric control of the forefoot $p<.01$, increase function of ankle dorsiflexion $p<.05$, earlier lateral forefoot contact compared to medial forefoot $p<.01$, and increased role of hallux $p=.03$ and toes (medium effect size). For most subjects in the intervention group the values returned to baseline at the end of 24 week follow up.

Critique/Bottom Line: Overall, the exercises in this study can have an effect on foot function and have the potential to change foot rollover towards a more physiological process. Supervised

treatment from a physical therapist along with patient education can preserve foot-ankle integrity.

Article #8 Reference #8 Streckmann, F. Exercise intervention studies in patient with peripheral neuropathy: a systematic review

Level of Evidence: 2a Oxford Level of Evidence

Purpose: The purpose of this systematic review was to examine the effectiveness of multiple exercise interventions in patients with peripheral neuropathy. Several origins of peripheral neuropathy were examined in this study, the majority being diabetic peripheral neuropathy. The overall goal of the review was to generate recommendations for exercises in this population, justify therapeutic treatment, improve quality of life and improve future research.

Methods: A total of three reviewers searched online databases, articles had to include exercise interventions in patient with peripheral neuropathy. Articles were chosen on level of evidence grade, study design, quality, results, and the ten gradations of quality according to Oxford levels of evidence. Articles were excluded for not having a control group, additional interventions, expert opinion, other reviews, and no exercise intervention described. A total of 10 randomized controlled trials were selected and 8 controlled clinical trials.

Results: The systematic review found that balance training is the most effective form of exercise intervention. Aerobic training plays an important role in metabolically derived neuropathies. Exercise interventions consisting of strengthening, or a combination of strengthening and endurance tend to have a low impact in providing benefits to people with peripheral neuropathy. The evidence of this systematic review suggest that supervised therapeutic exercise intervention should be done twice a week for 12 weeks focusing on balance and aerobic training.

Critique/Bottom Line: Overall, exercise plays an important role in physical therapy and can be easily introduced in a variety of physical therapy settings. These kinds of exercises can be easily integrated into clinical practice and have been shown to have successful outcomes, although much more research is needed for further recommendations regarding this population.

5. Overview of Articles

The articles below were selected to be analyzed. Refer to Appendix A for detailed article analysis worksheets.

#	Author(s)	Oxford Level	Pedro Score	Purpose	Outcome Measures	Results	Relevant to PICO?
1	Abou-Shady, N. et al. (2017)	1b	8/10	Investigated the effect of task-oriented training on postural stability in patients with type II diabetes and neuropathy	Postural Stability Test Berg Balance Scale Functional Reach Test Timed Up and Go Test	Overall, this study revealed significant evidence that task-oriented training on postural stability along with physical therapy treatment can significantly improve balance specifically postural stability in patients with diabetes with neuropathy.	Yes
2	Dixit, S., et al. (2013) India	2b	6/10	Studied the effects of moderate intensity aerobic exercise of Heart Rate Reserve in subjects with diabetic peripheral neuropathy.	Electrophysiological evaluation ...Latency ...Duration ...Conduction velocity	Results revealed a significant difference between groups regarding distal peroneal nerve conduction velocity at eight weeks	Yes

						<p>with a p-value <0.05.</p> <p>In addition to a significant difference seen in sural sensory nerve's conduction velocity at eight weeks with a p-value <0.001.</p> <p>Also observed was a significant difference between groups regarding means scores of MDNS after eight weeks with a p-value <0.05.</p>	
3	Handsaker, JC. et al. (2015)	1b	8/10	The purpose of the study was to examine a resistance training program on speed of knee and ankle strength generation during stair descent and ascent in people with	<p>Modified Neuropathy Score</p> <p>Motion capture camera system</p> <p>Bespoke eight-step staircase</p>	<p>Increased speed of strength generation of primary absorptive joint by 27% in the knee joint during ascent and 35% in the ankle joint during ascent.</p>	Yes

				diabetic neuropathy.		Increased speed of generation of the secondary absorptive joint was increased by 60% in the ankle during descent and 78% at the knee joint during descent.	
4	Kruse, R. et. al. (2010)	2a	8/10	The purpose of this study was to examine the effects of various exercises in people with diabetes and peripheral neuropathy. In addition to assessing the effects of a walking intervention on balance and fall risk.	Berg Balance Scale Timed Up & Go Test One Leg Static Stance Test Falls Efficacy Scale The Foot Functional Index Disability Scale	The results of this study revealed that the training program that was implemented in the study had little effect on the subject's balance and lower extremity strength. In addition, increasing weight bearing exercises did not affect the rate of falling. Also, people with diabetes and peripheral	Yes

						neuropathy who are sedentary can increase their physical activity without increasing their rate of falling. Overall this study emphasized the need for a balance and strength exercise program to be individualized and challenging for each subject.	
5	Mueller, J. M., et al. (2013) US	1b	8/10	To compare weight bearing exercise and non-weight bearing exercise in patients with diabetes and peripheral neuropathy.	6-Minute Walk Distance Daily Step Count 2 nd outcome measures represented domains across the <i>International Classification of Functioning, Disability and Health</i> .	Results showed weight bearing group had greater improvements in the 6 MWD and average daily step counts with a p-value of <0.5. In addition, to greater improvements in average daily steps with a between	Yes

						group difference of 1178 compared to the non-weight bearing group. In the non-weight bearing group the results revealed this group had greater improvements in hemoglobin A1c values compared to the weight bearing group.	
6	Rojhani-Shirazi, Z. et al. (2017)	1b	8/10	Examined and compared the effects of two exercise training on clinical balance measures in subjects with type two diabetes and peripheral neuropathy.	One Leg Stance Test Berg Balance Scale Star Excursion Balance Test	Overall, this study showed that both intervention groups (Swiss ball exercises and Frenkel exercises) can significantly improve balance when compared to a control group. Significant improvements were seen in all three	Yes.

						outcome measures assessed. When both intervention groups were compared to one another the Swiss ball training group had more significant results than Frenkel exercises.	
7	Sartor,C., et al. (2014) Brazil	1b	8/10	Examines effects from a stretching, strengthening and functional training program in patients with diabetes and polyneuropathy.	Peak Pressure over plantar surface and additional loading variables Kinematic/Kinetic variable of the ankle joint Foot and ankle muscle function Functional test for foot and ankle Michigan Neuropathy Screening Instrument Activities-specific Balance Confidence Scale	This randomized control trial found significant results in ankle/foot function (p<.05) and slower center of pressure mean velocity (p=.05). Intention to treat comparisons revealed softening of heel strike p=.03, better eccentric control of the forefoot p<.01, increase function of ankle dorsiflexion	Yes

						<p>p<.05, earlier lateral forefoot contact compared to medial forefoot p<.01, and increased role of hallux p=.03 and toes (medium effect size). Overall according to the authors, the intervention protocol discreetly changed foot rollover towards a more physiological process in regard to improved plantar pressure distribution and improved functional condition of the foot ankle complex.</p>	
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8	Streckmann, F., et al. (2014) Germany	2a	N/A	Systematic Review assessed exercise interventions for people with neuropathy to determine if there were any benefits of exercise.	Studies in this systematic review had to include the following: Examine effects of exercise, Oxford level of evidence 1-4 and examine patients with neuropathy.	Overall, the systematic review found that balance training is the most effective form of exercise intervention. Aerobic training plays an important role in metabolically derived neuropathies. Exercise interventions consisting of strengthening, or a combination or strengthening and endurance tend to have a low impact in providing benefits to people with peripheral neuropathy.	Yes
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Discussion:

The studies analyzed primarily looked at improving function in patients with diabetic neuropathy. As many people become diagnosed with type two diabetes the need for a multidisciplinary team approach including physical therapy is needed. All studies analyzed showed that skilled therapeutic interventions can improve diabetic peripheral neuropathy complications.

The studies analyzed regarding this topic found therapeutic interventions that incorporated all components of a good individualized exercise program. It was concluded that an exercise program to treat neuropathy should be done twice a week for 12 weeks to see improvements.⁸ In three high quality articles balance improved in this population with weight bearing activities compared to non-weight bearing activities, also task specific activities yielded better improvements in stability, and Swiss ball and Frenkel ball exercises significantly improved balance.⁹⁻¹² Also wobble board training and double leg support on a rubber disc filled with air improved balance.^{10,13}

In three articles the reduction of fall risk was found when subjects improved their speed of strength generation by performing lower extremity strengthening exercises, and foot and ankle strengthening activities.^{9,13,14} Performing aerobic exercise at 40-60% of heart rate reserve three to six times per week for 150 minutes per week was found to improve distal peroneal and sural sensory nerve conduction.¹⁵ Stretching of the ankle and foot musculature was found to improve the functional condition of the foot and ankle complex and improve postural stability.^{10,13} Gait training activities were studied in several articles in this analysis these articles revealed evidence based exercises one could perform to improve their overall functional abilities.^{8,9,13,14,16}

Furthermore, the information found during this article analysis has provided a framework for treating patients like my client. My client like many other Native Americans in the Southwest live in remote areas of the reservation and often have to travel several miles to the nearest city to receive skilled physical therapy services. In addition, many Native Americans often live in low socioeconomic living situations that limit the amount of resources and services for their health. The information gathered has allowed me to provide an exercise regime one could use for treating patients similar to my client's characteristics. The exercise regime, as shown in Table 1, takes in to consideration the comorbidities faced by my client, the limited number of visits my client will be able to attend, the increasing complexity of the tasks to challenge my client, and a safe approach with therapeutic benefits. Overall this exercise blueprint is modifiable to accommodate varying patient presentations.

In addition, the exercise regime incorporates exercises found in many of the articles that have been proven statistically significant when compared to other exercise interventions. A significant assessment tool many of the articles used was the Michigan Neuropathy Screening Instrument. This assessment tool will be used when tracking the progress of my client along with on of the balance outcome measure (Berg Balance Scale, TUG and Functional Reach Test).

Overall, additional research on this specific population is needed to develop a gold standard of treatment to reverse the effect of peripheral neuropathy before it becomes severe. In addition, more research is needed to generalize these finding to all ethnicities. As many of these studies did not include those who were Native American/Alaskan Native like my client. This evidence-based analysis was done to find the best well rounded approach to treating a patient with diabetes and peripheral neuropathy. The exercises and activities found from this analysis will be used in the future to help similar patients improve their overall function.

Table 1: Exercise regime

Week/1hour sessions ^{8,13}	Activity/Exercise
1	<p>Exercise education/recommendation working toward Mod intensity 3-6x/wk; minimum of 150mins/wk to maximum 350 mins/wk with RPE 12-13 = 40-60% HRR¹⁵ or increase step count every 2 weeks by 5-10%⁹</p> <p>Stretching some muscles involved in balance: gluteal, erector spinae, hamstrings, rectus femoris⁹⁻¹¹</p> <p>1st component of task oriented training sit to stand exercise¹⁰</p> <p>Walking over heel of forefoot, lateral border, medial border of feet¹³</p>
2	<p>Stretching muscles iliopsoas, gastrocnemius, soleus, and pectoral muscles ^{10,11}</p> <p>Ball Training sitting on ball while performing active movements- flexion, extension, abduction, adduction of one Upper extremity¹¹</p> <p>2nd component of task oriented training sit to stand then walk 5 steps forward¹⁰</p> <p>Sitting with foot flat on the floor grab an object with toes ¹³</p> <p>Walking in tandem^{12,13}</p>
3	<p>Stretching flexors and extensors of toes¹³</p> <p>Ball training sitting on ball active movements of two upper extremities, trunk movements (bending forward, and rotation)¹¹</p> <p>3rd component of task oriented training sit to stand, then walk 5 steps then upstairs 3 steps ¹⁰</p>

	<p>Sitting with foot flat on the floor extension of toes and hallux no dorsiflexion allowed ¹³</p> <p>walking with softening the heel and forefoot contact during normal walking¹³</p>
4	<p>Ball training sitting on ball raising heels, raising toes, raising heels and toes simultaneously.¹¹</p> <p>4th component of task oriented training complete entire cycle 3 times ¹⁰</p> <p>Supine with knees extended, flexion, inversion and eversion of ankle against the resistance of Thera band ¹³</p> <p>Walking grabbing the floor with toes ¹³</p>
5	<p>Ball training sitting on ball resistance against perturbation and weight shifting on ball. ¹¹</p> <p>Standing planter flexion and dorsiflexion with hand supported^{12,13}</p> <p>Walking with good foot rollover including heel strike, mid foot, lateral forefoot, medial forefoot, and hallux contact¹³</p>
6	<p>Ball training standing moving the ball up and down in an oblique line with two upper extremities. ¹¹</p> <p>Single leg stance two hand support ¹²</p> <p>Foam cushion training with hand support¹⁰</p> <p>Task oriented training complete cycle 6 times¹⁰</p> <p>Progress rigidity of objects having to pick up with toes¹³</p> <p>Progress gait training exercise 1-2 to 200 feet¹³</p>

7	<p>Ball training standing: throwing the ball against the wall with hand¹¹ Single leg stance one hand support eyes open¹²</p> <p>Task oriented training complete cycle 8 times¹⁰</p> <p>Progress resistive Thera band for ankle movements¹³</p> <p>Progress gait training exercise 3-5 to 200 feet¹³</p>
8	<p>Ball training standing: throwing the ball against the wall with feet.¹¹</p> <p>Single leg stance no hand support eyes open¹²</p> <p>Task oriented training complete cycle 10 times¹⁰</p> <p>Progress standing plantar flexion/dorsiflexion to single leg support¹³</p> <p>Gait training all exercises 1-5 to 200 feet¹³ Gait training walking over obstacle between parallel bars without hand support¹⁰</p>

*sets, reps and hold time parameters for stretches and exercises dependent on patient baseline capability

Conclusion:

In conclusion the PICO question: Would physical therapy interventions including exercise improve balance and gait deficiencies in males with a diagnosis of type II diabetes who have peripheral neuropathy compared to no intervention? This question can be answered based on the articles analyzed as some showed significant evidence for improvement in balance, postural stability, speed of strength generation, gait improvements and overall functional ability. Overall, many of these studies found intervention exercises to significantly reduce the risk of falling. Although more high-quality research is needed to generalize this to greater population.

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Appendix A:
Article Analysis Sheets

Articles:

1. Abou-Shady, N. et al. (2017)
2. Dixit, S. et al. (2013)
3. Handsaker, JC. (2015)
4. Kruse, RL. (2010)
5. Mueller, MJ. (2013)
6. Rojhani-Shirazi, Z. (2017)
7. Sartor, CD. (2014)
8. Streckmann, F. (2014)

Intervention – Evidence Appraisal Worksheet- #1

Citation Abou-Shady Nawal Abd El-Raouf, Amira Mohamed El Gohary, Shendy WS, Ahmed Magdy Metwally Abd Al Hamid. Effect of Task Oriented Training on Postural Stability in Patients with Type (II) Diabetic Neuropathy. *Int J Ther Rehabil Res.* 2017;6(1):100-109. doi:10.5455/ijtr.000000227.

Is the purpose and background information sufficient?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if the topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>Yes, the purpose of the study was clearly stated. The researchers of the study wanted to investigate the effect of physical therapy treatment along with task oriented training on postural stability in patients with type two diabetes with neuropathy.</p>
<p>Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study</p>	<p>The authors stated that diabetic peripheral neuropathy can negatively affect nerve function including those involved with sensation, movement, gland/organ function and overall health. As a result, balance can be greatly impacted from diabetic peripheral neuropathy and the risk of falling is greatly increased. The authors of this study explained that task oriented training along with physical therapy may improve balance compared to physical therapy exercises alone.</p>

Does the research design have internal validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>➤ Discuss possible threats to internal validity in the research design. Include:</p> <ul style="list-style-type: none"> ➤ Assignment ➤ Attrition ➤ History ➤ Instrumentation ➤ Maturation ➤ Testing ➤ Compensatory Equalization of treatments ➤ Compensatory rivalry 	<p>Assignment: A total of thirty subjects aged 50-65 years were included in this study. Inclusion criteria consisted of being diagnosed with type II diabetes with peripheral neuropathy, aged 50-65 years old, currently ambulatory, medically stable and had a body mass index between 20-30 Kg/m². The investigators excluded subjects who had musculoskeletal issues, psychiatric disorders or seizures, classified as being obese with a BMI greater than 30 Kg/m², foot ulcers and lower limb operations. Possible threats to assignment include inclusion and exclusion</p>

<p>➤ Statistical Regression</p>	<p>criteria could affect generalization to other subjects who did not meet the criteria.</p> <p>Attrition: Thirty subjects were randomly and equally assigned to either group I (task oriented training + physical therapy treatment) or group II (physical therapy treatment only). All subjects who completed the pretest measurements also completed the posttest assessments.</p> <p>History: All thirty subjects completed the pre- and post-test assessments.</p> <p>Instrumentation: The Biodex balance system was used to assess balance from pre- and post-treatment. Although calibration nor reliability of this system was explained in the study.</p> <p>Maturation: Both groups received treatment for twelve sessions every other day each session for one hour. A possible threat to the study's internal validity could be the familiarity effect. Subjects in the task oriented group could have become accustomed to the procedures of each session therefore impacting the results of the study.</p> <p>Testing: One single investigator evaluated all subjects for pre- and post-test measurements. The measurements included postural stability test, Berg Balance Scale, Functional Reach Test and the Timed Up and Go Test. The pre-test could have familiarized each subject and allowed subjects to learn what to expect for the post test.</p> <p>Compensatory Equalization of treatments: It is unclear if both groups met during the same time of the day or at separate times. If subjects received intervention at the same time there is the possibility that they communicated about the study.</p> <p>Compensatory rivalry: Subjects were recruited from multiple outpatient hospitals and clinics. It is possible that subjects knew one another and discussed details regarding the study.</p> <p>Statistical Regression: There was no information that indicated the presence of outliers.</p>
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Are the results of this therapeutic trial valid?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>1. Did the investigators randomly assign subjects to treatment groups?</p> <p style="margin-left: 20px;">a. If no, describe what was done</p> <p style="margin-left: 20px;">b. What are the potential consequences of this assignment process for the study's results?</p>	<p>1) Subjects were randomly assigned to two equal groups. The process of the randomization was not explained.</p>
<p>2. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</p> <p style="margin-left: 20px;">a. If they were not similar – what differences existed?</p>	<p>2) Yes, there were no significant differences between subjects regarding age, height, weight and body mass index.</p>
<p>3. Did the subjects know to which treatment group they were assign?</p> <p style="margin-left: 20px;">a. If yes, what are the potential consequences of the subjects' knowledge for this study's results</p>	<p>3) It was not state whether subjects were blinded to which group they were assigned to.</p> <p style="margin-left: 20px;">A. If subjects knew they were in the physical therapy treatment only group and after having done the pre-test they may be more inclined to try harder and practice outside of the therapy intervention sessions.</p>
<p>4. Did the investigators know who was being assigned to which group prior to the allocation?</p> <p style="margin-left: 20px;">a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</p>	<p>4) No, the single investigator randomly assigned each group before learning of the subjects characteristics.</p>
<p>5. Were the groups managed equally, apart from the actual experimental treatment?</p> <p style="margin-left: 20px;">a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>5) Yes, each group received physiotherapy treatment for 12 sessions every other day and each session was 1 hour.</p>

<p>6. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>6) The post test was assessed after the completion of the 12th session. This was sufficiently long enough to answer the questions posed by the investigators.</p>
<p>7. Did all the subjects originally enrolled complete the study?</p> <p>a. If not how many subjects were lost?</p> <p>b. What, if anything, did the authors do about this attrition?</p> <p>c. What are the implications of the attrition and the way it was handled with respect to the study's findings?</p>	<p>7) Yes, the thirty subjects who completed the pre-test also completed the post-test.</p>
<p>8. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>8) Yes, although there was no indication that there was intention to treat analysis.</p> <p>a. Statistical analysis was performed using SPSS for windows software. Data was summarized using mean, range, and standard deviation for quantitative variables and percentage for qualitative variable and frequency. In addition, a 2x2 mixed design Multivariate Analysis of Variance was used to compare the variables of interest to different tested groups and measuring periods. Lastly t-tests for qualitative variables was used and chi-square for qualitative data.</p>
<p>Are the valid results of this RCT important?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>

<p>9. What were the statistical findings of this study?</p> <ol style="list-style-type: none"> a. When appropriate use the calculation forms below to determine these values b. Include: tests of differences? With p-values and CI c. Include effect size with p-values and CI d. Include ARR/ABI and RRR/RBI with p-values and CI e. Include NNT and CI <p>10. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>9) Yes, results were presented in tables and graph charts in the study. Group 1= task oriented + Physical therapy treatment Group 2 = Physical therapy treatment only</p> <ul style="list-style-type: none"> • Stability Index <ul style="list-style-type: none"> ➤ Group one % of change 40.04↓ (p<.0001) ➤ Group two % of change 22.34↓ (p<.0001) • Anterior-posterior stability index <ul style="list-style-type: none"> ➤ Group one % of change 45.32↓ (p<.0001) ➤ Group two % of change 16.1↓(p<.0001) • Medial-lateral stability index <ul style="list-style-type: none"> ➤ Group one % of change 47.05↓ (p<.0001) ➤ Group two % of change 22.22↓ (p<.0001) • Berg Balance Scale <ul style="list-style-type: none"> ➤ Group one % of change 29.33↑ (p<.0001) ➤ Group two % of change 23.94↑ (p<.0001) • Functional Reach Test <ul style="list-style-type: none"> ➤ Group one % of change 78.5↑(p<.0001) ➤ Group two % of change 35.2↑ (p<.0001) • Timed Up and Go Test <ul style="list-style-type: none"> ➤ Group one % of change 46.9↓ (p<.0001) ➤ Group two % of change 29.7↓ (p<.0001) <p>10) Physical therapy intervention according from the results of this study help to improve postural stability. More so when physical therapy is combined with task oriented exercises.</p>
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<p>11. Do these findings exceed a minimally important difference? a. If not, will you still use this evidence?</p>	<p>11) Yes, for the Berg Balance scale and for the Timed up and go the findings exceed the minimally important difference.</p>
<p>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>12. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?</p>	<p>12) Yes, the task specific exercises done in this study are feasible to instruct to patients who are similar to this population in any clinical setting. It should be noted that appropriate knowledge of outcome measure testing should be learned to accurately measure each individual.</p>
<p>13. Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?</p>	<p>13) Yes, subjects in this study share the same age, height, weight and BMI to my patient</p>
<p>14. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?</p>	<p>14) Yes, the outcome measures used in this study are commonly used in a variety of physical therapy settings. They have been found to be safe, reliable and valid and would be appropriate to use with my client. My client would benefit from a combination of task oriented training and physical therapy to improve their postural stability.</p>
<p>15. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?</p>	<p>15) Yes, the intervention would be appropriate for my client .</p>
<p>16. Are there any threats to external validity in this study?</p>	<p>16) None</p>
<p>What is the bottom line? What pedro score would you give this trial?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>

<p>17. Summarize your findings and relate this back to clinical significance</p>	<p>17) Overall task oriented training combined with physical therapy treatment can significantly improve balance outcomes in a person with type II diabetes with peripheral neuropathy. The tasks oriented training described in this study can easily be implemented in to therapy sessions to improve balance deficiencies.</p>
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Intervention – Evidence Appraisal Worksheet #2

Citation: Dixit S, Maiya AG, Shastry BA. Effect of aerobic exercise on peripheral nerve functions of population with diabetic peripheral neuropathy in type 2 diabetes: a single blind, parallel group randomized controlled trial. *J Diabetes Complications*. 2014;28(3):332-339. doi:10.1016/j.jdiacomp.2013.12.006.

<p>Is the purpose and background information sufficient?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader’s Comments</i></p>
<p>Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>Yes, the purpose of the study was stated in the abstract “to evaluate the effect of moderate intensity aerobic exercise on diabetic peripheral neuropathy patients.” Aerobic exercise can be advised to patients who come to physical therapy and is a better alternative to medications.</p>
<p>Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic.</p>	<p>Investigators explained that prior research has looked at intervention programs to combat diabetic neuropathy including lifestyle changes, long term aerobic exercises and weight bearing activities in rats who were diabetic. There is no current research examining the efficacy of moderate intensity</p>

Describe the justification of the need for this study	aerobic exercise and its effects on nerve conduction velocity of the peroneal motor nerve and sural sensory nerve in a person with diabetic peripheral neuropathy.
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Does the research design have internal validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<ul style="list-style-type: none"> ➤ Discuss possible threats to internal validity in the research design. Include: ➤ Assignment ➤ Attrition ➤ History ➤ Instrumentation ➤ Maturation ➤ Testing ➤ Compensatory Equalization of treatments ➤ Compensatory rivalry ➤ Statistical Regression 	<p>Assignment: The study consisted of 87 subjects, this could be a threat to the validity due to a greater risk of drop outs in the study. Subjects were randomly assigned using computer program although distribution was unequal resulting in 40 subjects in one group and 47 subjects in the other group. This would have affect the results of the study.</p> <p>Attrition: The researches did not allow for subjects to be replaced in the study. A total of 21 subjects were lost to follow and did not complete the final analysis. The large number of drop out could influence the results of the study.</p> <p>History: Due to reasons unknown to the researchers many (21 subjects) did not follow-up.</p> <p>Instrumentation: Equipment to complete a nerve conduction study was used. Many possible threats can occur with this equipment including user error, not being trained well to interpret results, and picking up on background data. Another instrument used in the study was a surface infrared device to record temperature. The exact calibration and details on the use of this instrument was not explained. Therefore, this could have impacted the results of this instrument.</p> <p>Maturation: The experimental group was instructed to exercise between 150 to 360 mins/week. The researches could not control the subjects if they exercised more than the maximum number of minutes per week. This could influence the end results of this study.</p> <p>Testing: Standard procedures were used for the electrophysiological evaluation although the exact procedure and script during this evaluation was not stated in the study. In addition, intra-rater reliability of performing</p>

	<p>the Michigan diabetic neuropathy score (MDNS) was not stated. Results could have been affected by inconsistent scoring using the MDNS or inconsistent evaluation for the nerve conduction study.</p> <p>Compensatory Equalization: After the study was complete the control group was told to take part in supervised exercise sessions, the extent to what they did during the exercises is unknown. Therefore, the follow up session regarding the control group could have impacted the results.</p> <p>Compensatory Rivalry: Subjects were recruited from an outpatient hospital clinic and given the procedures of the study. Subjects could have knowledge about both groups before the start of the study and influenced their performance in the exercises.</p> <p>Statistical Regression: There was no information that indicated the presence of outliers.</p>
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Are the results of this therapeutic trial valid?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>18. Did the investigators randomly assign subjects to treatment groups?</p> <p>a. If no, describe what was done</p> <p>b. What are the potential consequences of this assignment process for the study's results?</p>	<p>1) Yes, subjects were stratified based on their staging on diabetic peripheral neuropathy on the MDNS. Subjects were divided into two categories mild and moderate peripheral neuropathy. Then randomization was performed to each division to put them in either the experimental or the control group. Randomization was done by a computer program generator using a number table.</p>
<p>19. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</p>	<p>2) No, the subjects were considered to be in various stages of having peripheral neuropathy</p>

<p>a. If they were not similar – what differences existed?</p>	<p>a. Categorized as either having mild or moderate peripheral neuropathy.</p>
<p>20. Did the subjects know to which treatment group they were assign? a. If yes, what are the potential consequences of the subjects’ knowledge for this study’s results</p>	<p>3) Yes, Subjects were not blinded to which group they were in. a. This could impact the motivation levels of each group, the experimental group could be highly motivated to complete the study while the control group could put in little effort. Both situations could impact the results of this study.</p>
<p>21. Did the investigators know who was being assigned to which group prior to the allocation? a. If they were not blind, what are the potential consequences of this knowledge for the study’s results?</p>	<p>4) Yes, the subjects were initially stratified in to a mild or moderate group then randomized. The investigators had great sense of knowing who would be in each group due to the initial categorization. a. The researches could have given the experimental subjects more encouragement, advise, and tips while exercising.</p>
<p>22. Were the groups managed equally, apart from the actual experimental treatment? a. If not, what are the potential consequences of this knowledge for the study’s results?</p>	<p>5) Yes, both groups received information for foot care, and diet. In addition, all subjects received information regarding the complete procedure of the study.</p>
<p>23. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? a. If not, what are the potential consequences of this knowledge for the study’s results?</p>	<p>6) Yes, follow up time was sufficiently long to answer the questions posed by the research?</p>
<p>24. Did all the subjects originally enrolled complete the study? a. If not how many subjects were lost? b. What, if anything, did the authors do about this attrition? c. What are the implications of the attrition and the way it was handled with respect to the study’s findings?</p>	<p>7) No a. 21 subjects were lost to follow-up b. Authors concluded that this was limitation to the study. c. Could greatly impact finding from this study. There was intention to treat analysis.</p>
<p>25. Were all patients analyzed in the groups to which they were</p>	<p>8) All subjects were analyzed in the groups and there was an intention to treat analysis.</p>

<p>randomized (i.e. was there an intention to treat analysis)?</p> <ul style="list-style-type: none"> a. If not, what did the authors do with the data from these subjects? b. If the data were excluded, what are the potential consequences for this study's results? 	
Are the valid results of this RCT important?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>26. What were the statistical findings of this study?</p> <ul style="list-style-type: none"> a. When appropriate use the calculation forms below to determine these values b. Include: tests of differences? With p-values and CI c. Include effect size with p-values and CI d. Include ARR/ABI and RRR/RBI with p-values and CI e. Include NNT and CI <p>27. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>9) Significant findings include a significant difference seen in nerve conduction velocity of the distal peroneal nerves between groups after eight weeks (DF1,62 F=5.14 p=.03). In addition, sural sensory nerve was found to a significant difference in the two groups for conduction velocity (DF1,60 F=10.16 and p=.001). Lastly a significant difference was observed when comparing MDNS in between both groups at eight weeks with a p-value <.05.</p> <p>10) Overall, the effect of aerobic exercise according to the authors of this study suggested that aerobic exercise has the effect to halt or disrupt the process of diabetic peripheral neuropathy. In addition, when the authors discussed the use of medication including insulin to slow the process of DNP they concluded that aerobic exercise along with medication can yield greater benefits in combating neuropathy. Lastly, this relates to my client because I would categorize him the mild group according to the MDNS which if we were to follow the aerobic exercise recommendation my patient could see positive benefits and reduce progression of DNP.</p>
<p>28. Do these findings exceed a minimally important difference?</p> <ul style="list-style-type: none"> a. If not, will you still use this evidence? 	N/A

Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
29. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	12) Yes, this treatment option is available to perform in the clinic. Activity watches that display heart rate could be used to exercise in the 40-60% of heart rate reserve while in the clinic or at home.
30. Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?	13) Yes, the subjects in the study were similar to my patient. Similar characteristics to my patient and subject in the study including having diabetic peripheral neuropathy, using drugs and alcohol, and current medication use. Also, my patient would tolerate the exercise threshold of this current study.
31. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	14) Yes, aerobic exercise in this study has been found to increase conduction velocity in one motor and sensory nerve. In addition, aerobic exercise has many more benefits that are not described in the study.
32. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	15) Yes, my patient previously used to be an avid runner, this type of exercise would motivate my patient to change their current lifestyle habits to more a healthier one.
33. Are there any threats to external validity in this study?	16) Study was done in India, could the population studied relate to a US population
What is the bottom line? What pedro score would you give this trial?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
34. Summarize your findings and relate this back to clinical significance	Overall, the study's results reveal that aerobic exercise within 40-60% of heart rate reserve can disrupt the progression of diabetic peripheral neuropathy in patients with type II diabetes. Significant finding regarding conduction velocity in the types of nerves studied shows that aerobic exercise along with medication can halt the progression of diabetic peripheral neuropathy.

Intervention – Evidence Appraisal Worksheet #3

Citation: Handsaker JC, Brown SJ, Bowling FL, Maganaris CN, Boulton AJM, Reeves ND. Resistance exercise training increases lower limb speed of strength generation during stair ascent and descent in people with diabetic peripheral neuropathy. *Diabet Med.* 2016;33(1):97-104. doi:10.1111/dme.12841.

Is the purpose and background information sufficient?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>Yes, the investigators of this study wanted to examine the effects of a resistance exercise training intervention on the speed of ankle and knee strength generation during stair ascent/descent in subjects with diabetes with and without peripheral neuropathy. They proposed that if improvements in speed strength were observed it could reduce the risk of falling in this population</p>
<p>Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study</p>	<p>The authors of this study explained that previous research has examined various types of exercise to improve postural sway in standing and gait impairments during level ground walking in the same population. However, the authors explained that there is evidence still absent regarding resistance exercise training that examines factors including unsteadiness during the “physically challenging and dangerous task of climbing up and down stairs”. The authors stated research from another study revealed that 605 of all fall related deaths occur while walking down stairs making this task ten times more dangerous than walking on level surfaces.</p>

Does the research design have internal validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>➤ Discuss possible threats to internal validity in the research design. Include: ➤ Assignment ➤ Attrition ➤ History ➤ Instrumentation ➤ Maturation</p>	<p>Assignment: A total of 43 subjects were included in this study. The subjects consisted of the following nine subjects with diabetes and peripheral neuropathy, thirteen subjects with diabetes without neuropathy, and twenty-one healthy control subjects. Subjects were excluded from the study if they had any open ulcers, required a walking aid, history of disorder that would affect gait or vision.</p>

<ul style="list-style-type: none"> ➤ Testing ➤ Compensatory Equalization of treatments ➤ Compensatory rivalry ➤ Statistical Regression 	<p>Subjects who had a diagnosis of diabetes and peripheral neuropathy had to have been tested by two clinical tests including the Modified Neuropathy Disability Score (≥ 6), and the vibration perception threshold (≥ 25).</p> <p>Attrition: All subjects who enrolled in the study finished all requirements of the study.</p> <p>History: All subjects who completed the pre-test completed the post-test as well.</p> <p>Instrumentation: Use of the Michigan Neuropathy Disability Score outcome measure could have influenced the scoring and categorization of each subject. In addition to the vibration perception threshold testing the exact procedure of this was not documented and could impact the results of this study.</p> <p>Maturation: Ascending and descending the same stair case could have influenced the results, subjects could have become accustomed to climbing up and down the standardized steps.</p> <p>Testing: The exact protocol including how subjects were instructed to ascend and descend was not provide in this study.</p> <p>Compensatory Equalization of treatments: Healthy control subjects may have been given more motivation or less motivation which could have negatively impacted the results of this study.</p> <p>Compensatory rivalry: The study did not explain how they recruited people for the study. Therefore, subjects may have known each other and possible communication was possible.</p> <p>Statistical Regression: There was no information that indicated the presence of outliers.</p>
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Are the results of this therapeutic trial valid?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>35. Did the investigators randomly assign subjects to treatment groups?</p> <p>a. If no, describe what was done</p> <p>b. What are the potential consequences of this assignment process for the study's results?</p>	<p>Yes, there were a total of 43 subjects, the 16 subjects with diabetes with and without peripheral neuropathy were randomly allocated in to an intervention group or a non-exercising control group. The remaining subjects were also randomly assigned to respective groups. Randomization was used by a random number generator.</p> <p>b) potential consequences could arise from this assignment process by having too many subjects with diabetes with peripheral neuropathy in the intervention group which could have skewed the results of the study.</p>
<p>36. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</p> <p>a. If they were not similar – what differences existed?</p>	<p>The researchers stated that there were no significant differences between the groups at the start of the trail. The demographics of the study groups were reported in a table.</p>
<p>37. Did the subjects know to which treatment group they were assign?</p> <p>a. If yes, what are the potential consequences of the subjects' knowledge for this study's results</p>	<p>Yes, the subjects were aware which group they were assigned.</p> <p>Potential consequences of this result in the control group performing exercises on their own outside of the study.</p>
<p>38. Did the investigators know who was being assigned to which group prior to the allocation?</p> <p>a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</p>	<p>The investigators did not know who was being assigned to which group before the allocation. This was done at random.</p>
<p>39. Were the groups managed equally, apart from the actual experimental treatment?</p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>Yes, each group received the same pre- and post- measurements and a follow up 1 month from the last intervention session.</p>
<p>40. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</p> <p>a. If not, what are the potential consequences of this</p>	<p>Yes, after the 16-week intervention a month later they conducted a follow up post intervention test. The timeframe was long enough to answer the question posed by the investigators.</p>

<p>knowledge for the study's results?</p>	
<p>41. Did all the subjects originally enrolled complete the study?</p> <p>a. If not how many subjects were lost?</p> <p>b. What, if anything, did the authors do about this attrition?</p> <p>c. What are the implications of the attrition and the way it was handled with respect to the study's findings?</p>	<p>No</p> <p>a. Five subjects were lost by the end of the study.</p> <p>b. The authors of this study did not discuss what they did in regard to attrition.</p> <p>c. The authors should have explained if anything was done to account for the loss in subjects. The authors stated that the resulting smaller group numbers represented a limitation to their study.</p>
<p>42. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>Yes. It was unclear if the researchers used an intention to treat analysis. Pre- and post- intervention differences for all variables were tested using a repeated measures Student's t-test. Pre- and post- results for the diabetes groups were tested for differences using a one-way ANOVA and Bonferroni's post hoc test.</p>
<p>Are the valid results of this RCT important?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>43. What were the statistical findings of this study?</p> <p>a. When appropriate use the calculation forms below to determine these values</p> <p>b. Include: tests of differences? With p-values and CI</p> <p>c. Include effect size with p-values and CI</p> <p>d. Include ARR/ABI and RRR/RBI with p-values and CI</p> <p>e. Include NNT and CI</p> <p>44. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>In the subjects with diabetes (with and without peripheral neuropathy) the group was found to have significantly higher strength generation in their knees while ascending and descending stairs after the intervention who completed the resistance exercise training ($P < 0.05$).</p> <p>During stair descent in subjects with diabetes, the speed of ankle and knee strength were significantly higher after the intervention compared to before with a ($p < 0.01$).</p> <p>A resistance exercise training program can improve speed of ankle and knee strength generation during stair ascend and descent in patient with diabetes with peripheral neuropathy.</p>

	Having an increased speed of strength generation of the ankle and knee can improve a person's stability while walking up and down stairs. Ultimately decreasing the risk of falls in this population.
45. Do these findings exceed a minimally important difference? a. If not, will you still use this evidence?	Not applicable to variables tested
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
46. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Yes, the exercise equipment can be found in most physical therapy facilities or the exercise can be modified. The three exercises included leg extensions, leg press, and ankle press.
47. Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?	Yes, subjects selected for the study were similar in age, diagnosis of diabetes, and having peripheral neuropathy. In addition, the severity of peripheral neuropathy studied in was similar to my client.
48. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, with supervised skilled therapy this type of intervention is beneficial for those with diabetes and peripheral neuropathy who want to improve their speed of strength generation to ultimately decrease their risk of falling.
49. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	Yes, client expectations were to improve in all ways possible most importantly with their strength.
50. Are there any threats to external validity in this study?	None
What is the bottom line? What pedro score would you give this trial?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
51. Summarize your findings and relate this back to clinical significance	Overall, fall risk in this population is high due to sensory and motor deficits. This study revealed that improvements in speed of strength generation improves muscle strength. Ultimately neural damage can be reversible and improve a stability and balance

	in people with diabetes and peripheral neuropathy.
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Intervention – Evidence Appraisal Worksheet #4

Citation: Kruse RL, LeMaster JW, Madsen RW. Fall and balance outcomes after an intervention to promote leg strength, balance, and walking in people with diabetic peripheral neuropathy: “feet first” randomized controlled trial. *Physical Therapy*. 2010;90(11):1568-1579.doi:10.2522/ptj.20090362.

Is the purpose and background information sufficient?	
<i>Appraisal Criterion</i>	<i>Reader’s Comments</i>
<p>Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>The purpose of this study was to clarify the effects of weight bearing exercise on foot ulceration and increased risk of falls in people with diabetes and peripheral neuropathy. In addition to assessing the effects of a walking intervention on balance, lower extremity exercise and overall fall incidence in this population.</p> <p>The findings of this study will provide me with a safe evidence based approach to my client who has similar characteristics.</p>
<p>Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study</p>	<p>Yes, in patients with diabetes and peripheral neuropathy it has been discouraged to participate in any weight bearing exercises due to common symptoms of having sensory impairments. These impairments increase the risk of falling. Therefore, this study wanted to assess if lower extremity exercise and balance training improve balance and decrease the risk of falling in people with diabetes and peripheral neuropathy. These types of exercises have been shown to have benefits in elderly patients and the researchers of this study wanted to assess if the same is true for people in this population.</p>

Does the research design have internal validity?	
<i>Appraisal Criterion</i>	<i>Reader’s Comments</i>
	<p>Assignment: Subjects only 50 years and older were included in this study. Investigators did not assess those who were younger who had</p>

<ul style="list-style-type: none"> ➤ Discuss possible threats to internal validity in the research design. Include: ➤ Assignment ➤ Attrition ➤ History ➤ Instrumentation ➤ Maturation ➤ Testing ➤ Compensatory Equalization of treatments ➤ Compensatory rivalry ➤ Statistical Regression 	<p>diabetes and peripheral neuropathy. This could effective validity due to not capturing a larger age range.</p> <p>Attrition: 79 subjects were enrolled originally although 5 were loss for various reasons. They did not allow for subjects to be replaced.</p> <p>Instrumentation: Information regarding accuracy and details for the use of the following instruments (biothesiometer, handheld dynamometer, and computerized accelerometer) were not reported in the study.</p> <p>Maturation: Subjects were older patients which strength has been shown to decrease. The study could have included a wider age range of subject to test their hypothesis.</p> <p>Testing: The original script for investigators to follow for each subject was not documented in this study.</p> <p>Compensatory Equalization of treatments: Both subjects and physical therapist were not blind to group assignment. Control group received phone calls, this could have motivated them to perform more exercises to skew results.</p> <p>Compensatory Rivalry: Acquired knowledge of being in the control group could have changed their behavior. For example, the control group to participate in exercise.</p> <p>Statistical Regression: Not reported in study.</p>
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Are the results of this therapeutic trial valid?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>52. Did the investigators randomly assign subjects to treatment groups?</p> <p>a. If no, describe what was done</p>	<p>Yes, randomization blocks were used and subjects were stratified into a control group or intervention group. 42 subjects in the</p>

<p>b. What are the potential consequences of this assignment process for the study's results?</p>	<p>intervention group and 38 in the control group.</p>
<p>53. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? a. If they were not similar – what differences existed?</p>	<p>Yes, there were no significant differences in baseline demographics. Demographics assessed were age and gender.</p>
<p>54. Did the subjects know to which treatment group they were assign? a. If yes, what are the potential consequences of the subjects' knowledge for this study's results</p>	<p>Yes, could motivate control group to participate in exercises to improve their own balance, and strength.</p>
<p>55. Did the investigators know who was being assigned to which group prior to the allocation? a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</p>	<p>Yes, the physical therapist providing treatment may have not followed the protocol or may have provided additional intervention strategies.</p>
<p>56. Were the groups managed equally, apart from the actual experimental treatment? a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>Yes, both groups received the same evaluations (prior to, 3 months, 6 months, and 12 months and weekly telephone calls.)</p>
<p>57. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>Yes, a year was sufficient time. Although one subject died during this timeframe and another subject dropped out due to cognitive decline within the year.</p>
<p>58. Did all the subjects originally enrolled complete the study? a. If not how many subjects were lost? b. What, if anything, did the authors do about this attrition? c. What are the implications of the attrition and the way it</p>	<p>No, 5 subjects were lost during the study. They did not allow for subjects to be replaced. Results could have been affected.</p>

<p>was handled with respect to the study's findings?</p>	
<p>59. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>Yes, researchers performed an intention to treat using SAS for Windows to compare both groups.</p>
<p>Are the valid results of this RCT important?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>60. What were the statistical findings of this study?</p> <p>a. When appropriate use the calculation forms below to determine these values</p> <p>b. Include: tests of differences? With p-values and CI</p> <p>c. Include effect size with p-values and CI</p> <p>d. Include ARR/ABI and RRR/RBI with p-values and CI</p> <p>e. Include NNT and CI</p> <p>61. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>There was no statistical finding between the groups during follow up. At 12 months, there was a small improvement in the amount of time that subjects in intervention group could stand on 1 leg with their eyes closed compared to the control group.</p> <p>The results of this study revealed that the training program that was implemented in the study had little effect on the subject's balance and lower extremity strength. In addition, increasing weight bearing exercises did not affect the rate of falling. Also, people with diabetes and peripheral neuropathy who are sedentary can increase their physical activity without increasing their rate of falling.</p> <p>Overall, this study emphasized the need for a balance and strength exercise program to be individualized and challenging for each subject.</p>
<p>62. Do these findings exceed a minimally important difference?</p> <p>a. If not, will you still use this evidence?</p>	<p>No</p>
<p>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>

63. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	No, I would use a more individualized approach to improving balance and strength in my client.
64. Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?	Yes, the study subjects fit within the same age and diagnosis as my client.
65. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	No, this intervention did not appear to have a benefit over the control group.
66. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	No, this research article demonstrates the need for an individualized approach to my client's impairments.
67. Are there any threats to external validity in this study?	No
What is the bottom line? What pedro score would you give this trial?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
68. Summarize your findings and relate this back to clinical significance	Overall, this study appeared to have no significant findings. Although it shed light into developing a treatment plan that is appropriate for each individual. It also pointed out that increasing weight bearing activities did not increase the risk of falls Therefore inferring that with the right about of specialized treatment from a physical therapist and progression of patient with diabetes it is possible to improve balance and strength.

Intervention – Evidence Appraisal Worksheet #5

Citation: Mueller MJ, Tuttle LJ, Lemaster JW, Strube MJ, McGill JB, Hastings MK, Sinacore DR. Weight-bearing versus nonweight-bearing exercise for persons with diabetes and peripheral neuropathy: a randomized controlled trial. *Arch Phys Med Rehabil.* 2013;94(5):829-838.

Is the purpose and background information sufficient?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you.	The purpose was clearly stated in the abstract. "Determine the effect of a weight bearing exercise program compared with a non-weight bearing exercise program outcome measures including the 6 minute walk test and daily step counts."

<p>Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>This study was conducted from the program of Physical Therapy from the Washington University School of Medicine. This article relates to the PICO question because it addresses physical therapy intervention for a person with diabetes who is experiencing peripheral neuropathy.</p>
<p>Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study</p>	<p>Investigators explained that prior research has looked at the effects of weight bearing exercise as a contraindication for patients with diabetes who experience peripheral neuropathy. Therefore, this study wanted to look at possible positive effects from WB exercises in the same population. In addition, recently in 2010 an article “Feet first, RCT” revealed people with DM and PN have positive effects after participating in a low-intensity intervention. This current study wanted to provide a more progressive and intensive intervention compared to the “Feet first RCT” looking at a WB vs. NWB program in similar subjects. Overall, investigators wanted to incorporate common outcome measures to assess the effects of physical therapy intervention in subjects with DM who have PN.</p>

Does the research design have internal validity?	
<i>Appraisal Criterion</i>	<i>Reader’s Comments</i>
<ul style="list-style-type: none"> ➤ Discuss possible threats to internal validity in the research design. Include: ➤ Assignment ➤ Attrition ➤ History ➤ Instrumentation ➤ Maturation ➤ Testing ➤ Compensatory Equalization of treatments ➤ Compensatory rivalry ➤ Statistical Regression 	<p>Assignment: Research investigators included 29 subjects with DM and with a peripheral neuropathy sense of 5.07 Semmes-Weinstein monofilament on at least 1 spot on the plantar foot and inability to sense vibration at the plantar great toe from a biothesiometer at <25V, in addition to having a step count of 2000-9000 steps/day, and exercising less than 3 days/week with less than 20 mins per session.</p> <p>Possible threats to assignment include not including more severe deficits greater than 5.07 PN sense, in addition including people who had greater than 25 V vibration sense, and those who patients who were already</p>

exercising above the current exercise amount. Exclusion criteria could have influenced internal validity due to the fact that this study only allowed subjects less than 299.83 lbs, pt. with no current severe foot deformity, comorbidity, and those who were taking medication. This could have limited the inclusion of more severe patients.

Lastly the small sample size is a threat to the studies internal validity it makes it less generalizable.

Attrition: The final count of subjects was 12 in the Wb group and 10 in the NWB group. Investigators stated recruiting subjects who met the criteria was challenging and investigators did not allow for subjects to be replaced in the study.

History: From the original 29 subjects a total of 4 were lost to follow up and 2 subjects died resulting in a sample size of 22. This affected the study protocol because there were 12 subjects in the WB group and 10 in the NWB group. This was beyond the researchers control and could have affected the results of the study.

Instrument: StepWatch Activity Monitor was used to gather the number of strides each subject took in a day. This was then used to determine steps per day. This could threaten the validity due to the use of a determined stride length measurement for every subject rather than measuring each subjects stride length. Subjects could have had a shorter or longer stride length compared to a set stride length determined from the StepWatch Activity Monitor. Also, a Biodex isokinetic dynamometer was used to assess ankle muscle strength, the exact calibration and details of this piece of equipment was not stated in this study. Also, a post survey was given to each subject, subjects could have given misunderstood the questions or they may have filled it inaccurately. Lastly a handheld infrared thermometer was used for recording foot skin temperature, there was a

	<p>high rate of false positive which interfered with the studies validity.</p> <p>Maturation: The weight bearing group was told to increase their center-based step count by 24% on the three days they participated in the exercise program with the goal of increasing 10% every 2 weeks, it is likely that the correct percentage by which to increase was not completely accurate and may have influence the outcome of the study. Also, if subject's diabetes became uncontrolled this could have interfered with the study's results.</p> <p>Testing: Outcome measures were conducted by a single physical therapist of which the PT did not indicate a specific script to show how subjects were taken through the outcome measures.</p> <p>Compensatory Equalization: Appendix of exercise intervention regarding WB and NWB exercises were given. Although there was no indication of how the physical therapist talked to each patient. For example, the physical therapist could have motivated the weight bearing group and not the non-weight bearing group.</p> <p>Compensatory Rivalry: Subjects were recruited from a database or previous participants, a research participant registry, TV commercials, newspaper, and posters. There is a possibility that some of the subjects knew each other from previous studies and exposed to which of the groups they were put into for the study.</p> <p>Statistical Regression: There was no information that indicated the presence of outliers.</p>
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Are the results of this therapeutic trial valid?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>69. Did the investigators randomly assign subjects to treatment groups?</p> <p>a. If no, describe what was done</p> <p>b. What are the potential consequences of this assignment process for the study's results?</p>	<p>1) Subjects were randomly allocated. This was done by a computer program called statistician a prearranged schedule generation.</p> <p>a. The computer program could put subject's unequally (baseline characteristics) in groups.</p>
<p>70. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</p> <p>a. If they were not similar – what differences existed?</p>	<p>2) There were no significant differences between groups in any of the categories including sex, age, duration of DM, BMI, NP, # of comorbidities.</p>
<p>71. Did the subjects know to which treatment group they were assign?</p> <p>a. If yes, what are the potential consequences of the subjects' knowledge for this study's results</p>	<p>3) Subjects were not blinded to which group they were in due to the weight bearing or non-weight bearing exercises.</p>
<p>72. Did the investigators know who was being assigned to which group prior to the allocation?</p> <p>a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</p>	<p>4) Research coordinator was the only person who the details regarding the allocation. The physical therapist was not blind to subject groups due to intervention requirements.</p>
<p>73. Were the groups managed equally, apart from the actual experimental treatment?</p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>5) Both groups were seen for baseline measurements, 3x a week during study, and at the 12 week post intervention measurement session.</p>
<p>74. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>6) Follow up was at 15.5 months after completion of subject's intervention. The investigators stated that they had limited follow ups (86%) they concluded with stating that they would like to have a longer follow up with a larger sample size.</p> <p>This amount of time in my opinion is too long, the study had 1 participant die within this time and 5 others who did not respond to the survey. Overall, a shorter follow up</p>

	would have possibly given them a greater response.
<p>75. Did all the subjects originally enrolled complete the study?</p> <p>a. If not how many subjects were lost?</p> <p>b. What, if anything, did the authors do about this attrition?</p> <p>c. What are the implications of the attrition and the way it was handled with respect to the study's findings?</p>	<p>7) Of the 265 contacts 29 met the inclusion/exclusion criteria. Only 22 completed the entire study.</p> <p>a. 7 subjects did not complete the study, 2 died and 5 lost to follow-ups</p> <p>b. Authors stated attrition was low and did not comment further.</p> <p>c. The could threaten the results of the experimental groups which the 7 subjects were apart of for the study.</p>
<p>76. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>8) Yes, there was an intention to treat performed using the Statistical Package for the Social Sciences software.</p>
Are the valid results of this RCT important?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>77. What were the statistical findings of this study?</p> <p>a. When appropriate use the calculation forms below to determine these values</p> <p>b. Include: tests of differences? With p-values and CI</p> <p>c. Include effect size with p-values and CI</p> <p>d. Include ARR/ABI and RRR/RBI with p-values and CI</p> <p>e. Include NNT and CI</p> <p>78. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>The study found significant differences in the WB group in the 6MWD and average daily step count ($P < .05$). The mean between-group difference over time was 29 meters (95% CI, 6-51) for the 6MWD and 1178 steps (95% CI, 150-2205) for average daily step count. In addition, the non-weight bearing group had better improvements in hemoglobin A1c compared the weight bearing groups with a P value of $< .05$. The mean-group difference over time was .50% with a 95% confidence interval .03-.96.</p> <p>10) This study was meaningful in many ways including providing information regarding my pico question and patient case. The results proved that weight bearing exercise can be beneficial to people with DM who have NP. In addition, the study provided the</p>

	<p>exercises used in the study protocol, which can be extrapolated and used in my clinical setting for the same population. Overall, the benefits of both weight bearing and non-weight bearing exercises in this population had positive effects and should be used instead of contraindicated for physical therapy intervention</p>
<p>79. Do these findings exceed a minimally important difference? a. If not, will you still use this evidence?</p>	<p>The MCID in a normal population for the 6MWD is considered to be 54-80 meters. So, a mean difference of 29 meters seen in this population would be reliable for this population studied. I would use still use the evidence gathered from this study.</p> <p>Regarding the step count the author's stated that this population tends to walk slower and the study protocol underestimated the number of additional steps needed for a 10% increase each week. I would reconsider the step per day recommendations. I would rather take in to consideration the patient and their existing comorbidities and progress the amount of steps a day according to their individual needs.</p>
<p>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>80. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?</p>	<p>The intervention was done with equipment readily available in most clinical settings. In addition, most of the exercises in the protocol used the subjects body weight which could be accomplished with every patient.</p>
<p>81. Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?</p>	<p>Yes, study consisted of 10 males who had a diagnosis of diabetes and peripheral neuropathy. Also, my patient is currently exercising only 1-2 times per week which fit into one aspect of the study's inclusion criteria.</p>

82. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	The benefits outweigh the potential risks. Each patient was given individual care from a physical therapist and assistant which could be the case in the clinic setting.
83. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	Yes, my patient is highly motivated to start exercising and eager to gain improvements in current symptoms.
84. Are there any threats to external validity in this study?	Yes, subjects were given money for transportation and a completion stipend. This could have been the reason for subjects completing the protocol.
What is the bottom line? What pedro score would you give this trial?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
85. Summarize your findings and relate this back to clinical significance	There were significant differences found between the weight bearing and non-weight bearing groups regarding the 6MWD, average daily step count and hemoglobin HA1c. The weight bearing groups was found to have greater improvements in the 6MWD and average daily step count. Overall, these two forms of outcome measures are widely used in the physical therapy setting and the exercise protocol would be feasible in any outpatient setting.

Intervention – Evidence Appraisal Worksheet #6

Citation: Rojhani-Shirazi Z, Barzintaj F, Salimifard MR. Comparison the effects of two types of therapeutic exercises Frenkele vs. Swiss ball on the clinical balance measures in patients with type II diabetic neuropathy. *Diabetes Metab Syndr.* 2017;11 Suppl 1:S29-S32. doi:10.1016/j.dsx.2016.08.020.

Is the purpose and background information sufficient?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you.	Yes, the purpose of this study was to examine two different types of therapeutic approaches (Fenkel vs. Swiss ball exercises) for improving balance in subjects with diabetes and peripheral neuropathy against a control group.

<p>Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>This study incorporated therapeutic exercises in to the design. It is relevant to physical therapy to determine if there is evidence that supports these approaches to improve balance for this specific population. My patient fits this population category.</p>
<p>Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study</p>	<p>The authors described that diabetes is a common problem in many countries and peripheral neuropathy is a common symptom. The authors also explained that peripheral neuropathy can lead to somatosensory dysfunction which can ultimately lead to difficulties with balance. Peripheral neuropathy according to this study can lead to weak neuromuscular reactions which could lead to falling. Currently, there is not enough evidence that supports the use of specific exercises to improve balance in this population. Therefore, this study wanted to compare two different therapeutic exercises approaches on clinical balance measures in patients with type two diabetes with peripheral neuropathy.</p>

Does the research design have internal validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<ul style="list-style-type: none"> ➤ Discuss possible threats to internal validity in the research design. Include: ➤ Assignment ➤ Attrition ➤ History ➤ Instrumentation ➤ Maturation ➤ Testing ➤ Compensatory Equalization of treatments ➤ Compensatory rivalry ➤ Statistical Regression 	<p>Assignment: A total of 60 patients age 45 to 65 years old with a diagnosis of diabetes with peripheral neuropathy were included into the study. They had to have been referred by physicians and received >2 scores in the Michigan Neuropathy Screening Instrument and have a body mass index between 18-30. Subjects were excluded if they any lower extremity complications including fractures, experienced dislocation, surgical operations in muscles, joints or bones of their lower extremities. In addition, subjects who were experiencing musculoskeletal disorders, vestibular impairments, lower extremity contractures, and two consecutive day interruptions of intervention sessions. Possible threats to assignment include not</p>

capturing subjects below or above the selected age range and BMI range. In addition, the subjects were recruited only by referral from a physician which leaves out those who did not have referrals.

Attrition: Subjects were placed in three groups, 20 subjects in an intervention group that received ball training exercises, 20 subjects in another intervention group that received Frenkel training exercise and 20 subjects in a control group.

History: From the original 60 subjects, all subjects finished the study to its entirety.

Instrumentation: Swiss ball was used in the study for the balling training exercises. The ball could threaten the internal validity of this study by not being an appropriate size for each subject.

Maturation: Subjects in the intervention group performed the exercises for three weeks, a possible threat would be that subjects performed exercises in routine perhaps they could have just improved on the specific exercises which effected the results.

Testing: Outcome measures were assessed by therapist who performed the measurements and analyzed the data. This could greatly impact the study's internal validity.

Compensatory Equalization of treatments: It is not stated that there was a specific protocol that each therapist followed to train each subject. This could threaten the validity because the therapist could have given more guidance and motivation to both of the intervention groups.

Compensatory rivalry: Subjects were recruited from referrals from physicians although it is not clear if the physicians worked at the same facility. It is possible subjects in the control and intervention groups knew each other.

Statistical Regression: There was no information that indicated the presence of outliers.

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Are the results of this therapeutic trial valid?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
86. Did the investigators randomly assign subjects to treatment groups? a. If no, describe what was done b. What are the potential consequences of this assignment process for the study's results?	1) Subjects were randomly allocated into three different groups. Details of the allocation were not described in the study.
87. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? a. If they were not similar – what differences existed?	2) The groups showed no significant difference between each other regarding age, height, sex, weight, body mass index, and duration of diabetes involvement. In addition, there were no differences in the study variables before the administration of intervention.
88. Did the subjects know to which treatment group they were assign? a. If yes, what are the potential consequences of the subjects' knowledge for this study's results	3) It can be inferred that the subjects knew to which treatment group they were assigned due to the exercises in each intervention group and control group only receiving information regarding diabetes.
89. Did the investigators know who was being assigned to which group prior to the allocation? a. If they were not blind, what are the potential consequences of this knowledge for the study's results?	4) No, allocation was done at random .
90. Were the groups managed equally, apart from the actual experimental treatment? a. If not, what are the potential consequences of this knowledge for the study's results?	5) Yes, pre- and post-tests were administered to all subjects.
91. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?	6) Three weeks was sufficiently long enough to see if subjects improved in their balance capabilities.

<p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	
<p>92. Did all the subjects originally enrolled complete the study?</p> <p>a. If not how many subjects were lost?</p> <p>b. What, if anything, did the authors do about this attrition?</p> <p>c. What are the implications of the attrition and the way it was handled with respect to the study's findings?</p>	<p>7) Yes, all 60 subjects completed the study's pre- and post-test measurements.</p>
<p>93. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>8) Yes, statistical analysis was done by SPSS statistical software. Normal distribution of the data was confirmed by using Levene Test and One-way Analysis of Variance (ANOVA) was used to assess differences between groups.</p>
<p>Are the valid results of this RCT important?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>94. What were the statistical findings of this study?</p> <p>a. When appropriate use the calculation forms below to determine these values</p> <p>b. Include: tests of differences? With p-values and CI</p> <p>c. Include effect size with p-values and CI</p> <p>d. Include ARR/ABI and RRR/RBI with p-values and CI</p> <p>e. Include NNT and CI</p> <p>95. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>9) Outcome measures and results</p> <ul style="list-style-type: none"> • One Leg Stance Test <ul style="list-style-type: none"> - Eyes open <ul style="list-style-type: none"> ➤ Left significant difference from pre- to post- in both interventions groups (P <.001) - Eyes closed <ul style="list-style-type: none"> ➤ Right significant difference from pre- to post- in both interventions groups (P <.001) ➤ Left significant difference from pre- to post in both ball training group (P<.001) & Frenkel training group (P=.03) • Berg Balance Scale

	<ul style="list-style-type: none"> ➤ Significant difference from pre- to post test in ball training group ($p < .001$) and Frenkel training group ($p = .01$) • Star Excursion Balance Test <ul style="list-style-type: none"> ➤ Significant difference in both intervention groups in the anterior direction from pre- to post- test ($p < .001$) ➤ Significant difference in posteromedial direction from pre- to post-test with the ball training group ($p < .001$) and Frenkel training group ($p < .01$) ➤ Significant difference in posterolateral direction from pre- to post- test seen in the ball training group ($p < .001$) and Frenkel training group ($p = .02$) <p>Control group: no significant differences found regarding all outcome measures from pre- to post- test.</p> <p>10) Both intervention exercises can positively improve a person's balance with the same characteristics presented in this study. This study proved evidence for the use of these exercises in people with diabetes with peripheral neuropathy.</p>
<p>96. Do these findings exceed a minimally important difference?</p> <p>a. If not, will you still use this evidence?</p>	<p>11) Minimally important difference for the Berg Balance scale is considered to be 8 points to truly have a functional change, the results from both intervention groups revealed 2.64-point difference from pretest in the ball training group and 3.34-point difference in the Frenkel training group from pretest measurements. This was taken after three weeks it would be interesting to see what the change would be after a longer period of time. I would still use this evidence due to the short follow up time.</p>

Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
12) Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	12) The intervention would be appropriate for clinical use as these exercises are feasible in various physical therapy settings.
13) Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?	13) Yes, the subjects in the study are similar to that of my patient, similar age, gender, BMI, and symptom of neuropathy.
14) Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	14) Yes, the benefits outweigh the potential risk using both interventions described in this study with my patient.
15) Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	15) Yes, the exercises would be feasible for my patient as they require little equipment and can be done at a home setting as well.
16) Are there any threats to external validity in this study?	16)none
What is the bottom line? What pedro score would you give this trial?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
17) Summarize your findings and relate this back to clinical significance	17) Both intervention exercises including the ball training and Frenkel training showed significant differences from pre-to post-test measurements. This study was done with a three week follow up which provides good projection for outcome measurements if done for a longer period of time. Overall, these exercises have strong evidence that they can help improve balance in a person with type two diabetes with peripheral neuropathy.

Intervention – Evidence Appraisal Worksheet #7

Citation: Sartor CD, Hasue RH, Cacciari LP, Butugan MK, Watari R, Pássaro AC, Giacomozzi C, Sacco ICN. Effects of strengthening, stretching and functional training on foot function in

patients with diabetic neuropathy: results of a randomized controlled trial. *BMC Musculoskeletal Disord.* 2014;15:137. doi:10.1186/1471-2474-15-137.

Is the purpose and background information sufficient?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>Yes, the purpose of this study was to evaluate the effects of stretching, functional training and strengthening on foot rollover process during gait in patients with diabetic poly neuropathy.</p> <p>This study is relevant to my client as these possible strategies could be implemented in to a physical therapy intervention plan.</p>
<p>Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study</p>	<p>In patients with diabetes and peripheral neuropathy there is an increased risk for plantar ulcerations. Due to loading patterns from worsening foot-ankle musculature, joint function and nervous function deficits. Previous studies have looked at the effectiveness of various off-loading techniques. Although it has been challenging to study due to standardization, and application of the appropriate techniques. The investigators in this study wanted to examine the possible effects of exercises on foot rollover process in the diabetic neuropathy population in a randomized control trial.</p>

Does the research design have internal validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>➤ Discuss possible threats to internal validity in the research design. Include:</p> <ul style="list-style-type: none"> ➤ Assignment ➤ Attrition ➤ History ➤ Instrumentation ➤ Maturation ➤ Testing 	<p>Assignment: Subjects 45-65 years of age were included in this study who were diagnosed with either type I or II DM and who had been diagnosed for seven years. This could impact the results because they did not include those who may have been diagnosed for less than 7 years.</p> <p>Attrition: According to the researchers 46 subjects was enough to detect a moderate effect difference assuming a 10% loss, although the study had a 15% loss therefore</p>

<ul style="list-style-type: none"> ➤ Compensatory Equalization of treatments ➤ Compensatory rivalry ➤ Statistical Regression 	<p>they recruited 55 subjects to “warrant sample power.”</p> <p>History: From original pool of subjects during the allocation process from the intervention group a total of 9 subjects were loss for several reasons including loss of contact, broken ribs after falling, treatment for lower limb edema, distance problems, and suffering from a heart attack. From the control group a total of 8 were also loss due to several reasons including did not complete period, treatment for sciatic pain, gallbladder surgery, moved to a different city, and disenrolled without out giving reason.</p> <p>Instrumentation: The Pedar X system was used to record plantar pressure. The validity of this instrument was not discussed. The use of six infrared cameras were used to record ground reaction force data from subjects. Discussion regarding regular maintenance of each camera was not discussed in the study. The physiotherapist who performed the manual functional testing, did not provide the exact procedure of how this testing was performed.</p> <p>Maturation: The intervention group was given physical therapy treatment along with exercises to be completed at home. This could impact the results because appropriate monitoring by a physiotherapist was not done at the home site. The control group was given foot care instructions and pharmacological treatment for diabetes only. This could have impacted the results because the subjects could have exercised outside of the study’s request.</p> <p>Testing: Primary outcome of the study assessed peak pressure under the lateral forefoot according to the researchers this area is to prone to alterations from diabetes peripheral neuropathy. Secondary outcomes were also assessed including center of pressure, time to peak pressure, pressure-time integral, sagittal range of motion during stance phase, joint angle at the conclusion of the propulsion phase, and peak</p>
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	<p>extensor/flexor moments at two points in the stance phase of gait. In addition, clinical outcomes were assessed including foot and ankle muscle function, scores from the Michigan Neuropathy Screening Instrument, functional test for foot and ankle and score for the Activities-specific Balance Confidence.</p> <p>Compensatory Equalization: The intervention protocol was included with the study. Along with examples of the exercises used in the study. The physiotherapist was blinded to the groups, although it is unclear if there was a script they had to follow while guiding subjects through each exercise and only one group received therapy so blinding was questionable. Motivation to the intervention group could have impacted results.</p> <p>Compensatory rivalry: Subjects were recruited from three settings from the National Association of Diabetes, a diabetes mellitus ambulatory medical center and a primary care center at the school of medicine (University of Sao Paulo, Brazil).</p> <p>Statistical Regression: There was no information that indicated the presence of outliers.</p>
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Are the results of this therapeutic trial valid?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>97. Did the investigators randomly assign subjects to treatment groups?</p> <p>a. If no, describe what was done</p> <p>b. What are the potential consequences of this assignment process for the study's results?</p>	<p>1. Yes subjects were randomly allocated. Randomization was done with Clinstat software by an independent researcher not aware of group coding.</p> <p>b. The independent researcher could have manipulate the randomization process.</p>
<p>98. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</p>	<p>2. Baseline characteristics including diabetes, demographic information, and foot characteristics did not differ from one group</p>

<p>a. If they were not similar – what differences existed?</p>	<p>to the other. Peak pressure at the heel and medial forefoot, muscle function and muscle function were different between groups at baseline.</p>
<p>99. Did the subjects know to which treatment group they were assign? a. If yes, what are the potential consequences of the subjects’ knowledge for this study’s results</p>	<p>3. Yes, each subject knew if they were in a treatment group or non-treatment group. a. Subjects in the non-treatment group could drop out an effect results.</p>
<p>100. Did the investigators know who was being assigned to which group prior to the allocation? a. If they were not blind, what are the potential consequences of this knowledge for the study’s results?</p>	<p>4. No, they were unaware or who was being assigned to which group prior to the allocation. An independent researcher was the one individual who knew the details of the allocation.</p>
<p>101. Were the groups managed equally, apart from the actual experimental treatment? a. If not, what are the potential consequences of this knowledge for the study’s results?</p>	<p>5. Both groups were seen at baseline and after 12 weeks. The intervention group was seen again after 24 weeks for a follow-up period.</p>
<p>102. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? a. If not, what are the potential consequences of this knowledge for the study’s results?</p>	<p>6. Yes 24 weeks was a sufficient amount of time to follow up on the intervention group although the researchers did report a limitation was there decision to follow only the intervention group.</p>
<p>103. Did all the subjects originally enrolled complete the study? a. If not how many subjects were lost? b. What, if anything, did the authors do about this attrition? c. What are the implications of the attrition and the way it was handled with respect to the study’s findings?</p>	<p>7. No, 46 subjects were originally calculated to be in the study. a. 15.% were loss after the basis of the primary outcome. b. The researches recalculated and a total of 55 subjects were recruited to the study after the original 46. c. Researcher’s realized the need to add more subjects to their study in order to justify a sample power from the study.</p>
<p>104. Were all patients analyzed in the groups to which they were</p>	<p>8. An intention-to-treat analysis was performed.</p>

<p>randomized (i.e. was there an intention to treat analysis)?</p> <ul style="list-style-type: none"> a. If not, what did the authors do with the data from these subjects? b. If the data were excluded, what are the potential consequences for this study's results? 	<p>b. According to the authors of this study the missing data was analyzed as missing completely at random. This could have greatly impacted the end results.</p>
<p>Are the valid results of this RCT important?</p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>105. What were the statistical findings of this study?</p> <ul style="list-style-type: none"> a. When appropriate use the calculation forms below to determine these values b. Include: tests of differences? With p-values and CI c. Include effect size with p-values and CI d. Include ARR/ABI and RRR/RBI with p-values and CI e. Include NNT and CI <p>106. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>9. There were no statistically significant change under the six foot areas. Although intention to treat analysis revealed softening of heel strike with a delayed heel time to peak pressure with a p-value equal to .03, decrease in ankle extensor amount $p < .01$, increase in function of ankle dorsiflexion $p < .05$, time to peak pressure earlier on lateral forefoot compared to medial forefoot, and increased peak pressure/pressure time integral from increase participation of hallux and toes (medium effect size) when comparing the intervention group to the control group. An increase in overall foot and ankle function resulted in $p < .05$ and slower center of pressure velocity p-value equal to .05 in the intervention group compared to the control group. In addition, all subject values returned to baseline after the follow-up p-value $< .05$.</p> <p>10. The true significant findings from this study including an improvement seen in foot and ankle function and slower center of pressure velocity at midfoot revealed that these exercises can be done before a person's diabetes progresses to help improve foot rollover. The exercises performed in the protocol can be easily implemented in any therapy department as they require equipment widely used in various therapy settings.</p>
<p>107. Do these findings exceed a minimally important difference?</p> <ul style="list-style-type: none"> a. If not, will you still use this evidence? 	<p>11. The foot and ankle function finding did exceed the minimally important difference.</p>

Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
108. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	13. Yes, Theraband was the only therapy equipment one would need to appropriately perform the exercises from this protocol. This can be easily implemented in a plan of care for a patient who is presenting this difficulty in foot roll over.
109. Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?	13. Close in similarity regarding age, diagnosis of diabetes and experiencing peripheral neuropathy. a. Although the patient I was seeing did not have diabetes for more than 7 years like the subject in this study.
110. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	14. Yes, after professional physical therapy instruction on an exercise program the benefits outweigh the potential risks.
111. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	15. Yes, the patient I was seeing was highly motivated to improve his current state. The patient would have capability to routinely complete these exercises.
112. Are there any threats to external validity in this study?	16. None
What is the bottom line? What pedro score would you give this trial?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
113. Summarize your findings and relate this back to clinical significance	17. Overall, there were significant differences found between the intervention group compared to the control group regarding ankle/foot function and loading variables. The study assessed many forms of outcome measures and used very detailed software to show loading variables. The exercises presented in the study's protocol can be easily implemented in to a variety of physical therapy settings.

Systematic Review- Evidence Appraisal Worksheet #8

Citation: Streckmann F, Zopf EM, Lehmann HC, May K, Rizza J, Zimmer P, Gollhofer A, Bloch W, Baumann FT. Exercise intervention studies in patients with peripheral neuropathy: a systematic review. *Sports Med Auckl NZ*. 2014;44(9):1289-1304. doi:10.1007/s40279-014-0207-5.

Does the design follow the Cochrane method?	
Appraisal Criterion	Reader's Comments
<p>Step 1-formulating the question</p> <ul style="list-style-type: none"> • Do the authors identify the focus of the review • A clearly defined question should specify the types of: <ul style="list-style-type: none"> • People (participants), • Interventions of exposures • Outcomes that are of interest • Studies that are relevant to answering the question 	<p>The purpose of this systematic review was to evaluate the effectiveness of several exercise interventions (e.g. balance training, gait training, whole body vibration, Tai Chi, endurance training, strength training, and flexibility training) in patients with peripheral neuropathy. Several origins of PNP were examined in this study including diabetes, chemotherapeutic agents, genetics, autoimmune disorders, infections, nutritional deficiencies, and idiopathic factors. With a majority of them being patients with diabetes. Overall, the goal of the review was to generate recommendations for exercise in this population, improve quality of life, justify therapeutic treatment and improve future research.</p>
<p>Step 2- locating studies</p> <ul style="list-style-type: none"> • Should identify All relevant literature • Did the include multiple databases? • Was the search strategy defined and include <ul style="list-style-type: none"> - Bibliographic databases used as well as hand searching - Terms (key workds and index terms) - Citation with 'experts' to identify 'grey' literature (body of materials that cannot be found easily through conventional channels such as publishers) - Sources for 'grey literature' 	<p>To be eligible, studies had to have been ranked high quality according to the Oxford center for evidence or meet the search goal. In addition, the studies had to examine exercise interventions in patient with peripheral neuropathy. The following electronic databases were used: PubMed, MEDPILOT, Cochrane, and relevant reference lists. Terms used included: peripheral neuropathy, CIPN, chemotherapy, induced PNP, diabetic NP, combined with using AND physical activity, exercise etc.. 18 studies were selected for review from an original pool of 9837 articles.</p>
<p>Step 3- Critical Appraisal/Criteria for Inclusion</p> <ul style="list-style-type: none"> • Were criteria for selection specified? 	<p>The systematic review restricted review studies that involved animal studies, expert opinions without critical appraisal, fewer than 10</p>

<ul style="list-style-type: none"> • Did more than one author assess the relevance of each report • Were decisions concerning relevance describe; completed by non-experts, or both? • Did the people assessing the relevance of studies know that names of the authors, institutions, journal of publication and results when they apply the inclusion criteria? Or is it blind? 	<p>subjects, no control group, therapeutic footwear, combing exercise and nutrition, and medication for peripheral neuropathy. There was a total of three reviewers searching online databases from August 2013 to December 2013. Articles were chosen based on grade, study design, quality, results, and the ten gradations of quality which resulted in the overall grade recommendation according to the Oxford levels of evidence. Two reviewers graded each article in a case of doubt the third reviewer would grade the same article.</p>
<p>Step 3- Critically appraise for bias:</p> <p>Selection-</p> <ul style="list-style-type: none"> • Were the groups in the study selected differently? • Random? Concealed? <p>Performance-</p> <ul style="list-style-type: none"> • Did the groups in the study receive different treatment? • Was there blinding? <p>Attrition-</p> <ul style="list-style-type: none"> • Were the groups similar at the end of the study? • Account for drop-outs? <p>Detection-</p> <ul style="list-style-type: none"> • Did the study selectively report the results? • Is there missing data? 	<p>The details regarding selection, performance, attrition and detection were not reported in this systematic review.</p>
<p>Step4- Collection of the data</p> <ul style="list-style-type: none"> • Was a collection data form used and is it included? • Are the studies coded and is the data coding easy to follow? • Were studies identified that were excluded & did they give reasons why (i.e. which criteria they failed) 	<p>Collection data form was not included. RCTs were appraised on the following criteria but not mentioned if a specific form was used. Inclusion/Exclusion criteria listed in SR article. RCTs reviewed according to Oxford level of evidence based on quality of study, study design, its results, creating ten gradation of quality which are translated into four grades of recommendation. Studies were excluded due to not having a control group, additional interventions, other reviews, only examined electrotherapy, expert opinions, no exercise intervention described.</p>

Are the results of this SR valid?

<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>114. Is this a SR of randomized trials? Did they limit this to high quality studies at the top of the hierarchies?</p> <p>a. If not, what types of studies were included?</p> <p>b. What are the potential consequences of including these studies for this review's results?</p>	<p>Yes, this systematic review consisted of 10 randomized controlled trials and 8 controlled clinical trials.</p> <p>a. Researches sought to gather only high- quality studies. Twelve studies had a high-quality grade (Level 1 &2). While six studies had a poor-quality grade (Level 4).</p> <p>b. The poor-quality studies could influence overall recommendations given by the authors.</p>
<p>115. Did the study follow the Cochrane methods selection process and did it identify all relevant trials?</p> <p>a. If not, what are the consequences for this review's results?</p>	<p>Authors did not state if they followed the Cochrane methods selection process.</p> <ul style="list-style-type: none"> - articles are not appraised following specific criteria
<p>116. Did the methods describe the process and tools used to assess the quality of individual studies?</p> <p>a. If not, what are the consequences for this review's results?</p>	<p>RCTs were graded according to the Oxford level of evidence.</p>
<p>117. What was the quality of the individual studies included? Were the results consistent from study to study? Did the investigators provide details about the research validity or quality of the studies included in review?</p>	<p>This SR included 10 RCTs high quality, and 6 poor quality. Details were provided for each study regarding the quality and limitations to each study.</p>
<p>118. Did the investigators address publication bias?</p>	<p>No</p>
Are the valid results of this SR important?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>119. Were the results homogenous form study to study?</p> <p>a. If not, what are the consequences for this review's results?</p>	<p>Seven studies reviewed balance training as a primary variable with results that were homogenous from study to study. 4 studies reviewed aerobic exercise as a primary variable which also had homogenous results from study to study. The remaining studies looked at variety of variable including strengthening, stretching, gait, and functional</p>

	exercises the results were more heterogeneous from study to study. The consequences of this could make it challenging to derive recommendations for exercise in this population.
120. If the paper is a meta-analysis did they report the statistical results? Did they include a forest plot? What other statistics do they include? Are there CIs?	No.
121. From the findings, is it apparent what is cumulative weight of the evidence is?	The systematic review found that balance training is the most effective form of exercise intervention. Aerobic training plays an important role in metabolically derived neuropathies. Exercise interventions consisting of strengthening, or a combination or strengthening and endurance tend to have a low impact in providing benefits to people with peripheral neuropathy.
Can you apply this valid, important evidence about this SR in caring for your patient/client? What is the external validity?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
122. Is your patient different from those in this SR?	No, the patient is similar to those included in this SR, as this SR focused on exercises as an intervention for peripheral neuropathy in several populations including diabetes.
123. Is the treatment feasible in your setting? Do you have the facilities, skill set, time, 3rd party coverage to provide this treatment?	Yes, exercise plays an important role in physical therapy and can be easily introduced in the orthopedic setting.
124. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	Yes, the patient would benefit from supervised treatment session to treat symptoms associated with peripheral neuropathy.
What is the bottom line?	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
125. Summarize your findings and relate this back to clinical significance	Overall, the evidence of this systematic review suggest that supervised therapeutic exercise intervention should be done twice a week for 12 weeks focusing on balance and aerobic training. These kinds of exercises can be easily integrated into clinical practice and

	have been shown to have successful outcomes, although much more research is needed for further recommendations regarding this population.
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