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Research Article

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Improving Planter Pressure Distribution Could Reduce the Risk of Fall in Patients with Diabetic Neuropathy

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Abstract

Objective: This study aimed at assessing the effectiveness of a task specific training guided by visual biofeedback in improving plantar pressure distribution to decrease risk of fall in individuals with Diabetic Peripheral Neuropathy (DPN).

Methods: Thirty-four patients with DPN were included in the study and were randomly assigned into two equal groups. The study group received task specific training and 3-Dimensional terminal biofeedback. The control group received traditional strength training. Three sessions of assessments (pre, post and follow-up after a month) were done for all participants. Training was three times per week for 10 weeks. Berg Balance Scale (BBS) and Functional Reach Test (FRT) were used to assess the dynamic and anticipatory balance in addition to the risk of fall. E-med pedography was used to quantify the Planter Pressure (PP) beneath the hind and forefoot during walking.

Results: Significant differences were noted in the BBS and FRT indicating a reduced risk of fall in the study groups. PP has been significantly changed in the study group and between the groups. Post-hoc test showed non-significant differences between the second and third measurements of the BBS, FRT and PP within the study group indicating along lasting effect of the applied treatments ($p < 0.05$).

Conclusions: Task specific training and biofeedback may reduce the risk of fall by improving planter pressure distribution in individuals with DPN.

Keywords

Diabetic peripheral neuropathy, Planter pressure, Exercises, Biofeedback, Risk of fall

Introduction

Diabetic peripheral neuropathy (DPN) is a frequent and devastating complication of diabetes mellitus type II, with multiple clinical manifestations. The prevalence of peripheral neuropathy in type 2 diabetes is approximately 30% based on the clinical examination [1]. Sensory diabetic polyneuropathy which is typically distal more than proximal is the standard presentation of neuropathy in diabetes, and up to 50% of patients may have symptoms as burning or deep aching foot pain, electrical sensations and paraesthesia [2]. Intrinsic foot muscles and ankle flexors/extensors weakness was also reported by Salsich and colleagues who considered it as an independent risk factor for a less effective plantar pressure distribution [3]. Proximal weakness and wasting were also found in patients with distal sensory neuropathy [4]. These symptoms often lead to a decline in the individual's ability to perform daily living activities [5]. Other reports showed that DPN may undermine balance during functional activities. Five times increased risk of falling was found among patients with DPN with an annual incidence of 39% and consequences include reduction in mobility, isolationism, hospitalization and death [6].

Previous studies reported that patients with DPN showed higher overall dynamic plantar pressure especially below the forefoot compared to patients without DPN [7, 8]. This high planter pressure could be due to foot pain [9, 10], limited joint mobility [11] or muscle imbalance [12]. High plantar pressures produced during walking may cause an increased risk of falls [10, 13]. Wang and colleagues found that the individuals with abnormal pressure distribution have higher fall risk than other individuals [14]. Moreover, studying the correlation between plantar pressure and the risk of falls in old women showed that the higher the plantar pressure, the higher the number of falls, given the fact that proprioception and sensory feedback from the plantar surface of the feet are the most important factors for maintaining balance in the usual conditions [15].

A substantial effort has been done in the theme of decreasing the number of falls among patients with DPN. Studies on the relation between the risk of falls in individuals with DPN and different therapies have showed contradictory results. These varying findings may be due to the existence of diabetic complications, long duration of illness, sex and age differences or the design of the study. These studies did not also recommend the type, frequency and duration with which exercises should be prescribed. Moreover, conventional passive stretching and strengthening exercises may not always be appropriate for DPN patients due to their high risk of fall, loss of joint perception and decreased range of motion (ROM) [16]. Many factors need to be contemplated during the recommendation and application of exercise for DPN patients including the compensation of lost deep sensations, and the management of exercise programs intensity to prevent overloading.

Biofeedback is a therapeutic technique uses external information provided along with the perception of the mover. It could be visual, auditory, verbal or, tactile provided concurrently, directly following, or after the action [17]. Earlier researches revealed that terminal visual feedback was significantly effective because it accentuated the internalization of task-relevant aspects [18]. Moreover, Schween et al., examined the effect of visual biofeedback on motor learning processes and concluded that it enhances implicit adaptation [19].

Recently, studies in physical rehabilitation followed motor learning principles to overcome motor deficits [20, 21]. Motor learning exercise intervention was more effective than impairment-oriented exercise intervention in improving gait, balance performance and participation outcomes in older adults with mobility limitations. Motor learning exercise intervention in rehabilitation specifically focuses on the improvements in gait and balance performance through goal-directed practices with high number of repetitions [20, 21].

Given that abnormal planter pressure distribution increases the risk of fall among patients with DPN, the current study evaluated the effectiveness of a task specific exercise program guided by terminal visual biofeedback in improving planter pressure distribution and decreasing risk of fall in DPN patients. We hypothesize that task specific exercise training guided by visual terminal biofeedback could improve planter pressure distribution decreasing risk of fall in DPN patients.

Subjects and Methods

For this study, fifty-seven individuals with age ranged between 45-55 years old and a diagnosis of DPN were recruited. Each individual has a history of fall during the past three months. All individuals signed informed consent after detailed explanation about the procedures of the study to make sure that they understand and welling to participate before enrollment. International physical activity questionnaire (IPAQ) was used to evaluate the total level of physical activities performed during daily life. Subjects were found to be either low or moderate levels of physical activity. Michigan neuropathy screening instrument was used to assess distal symmetrical peripheral neuropathy. Subjects were screened to fulfill the Michigan neuropathy screening instrument. Michigan neuropathy screening instrument is fifteen items assessment with a higher score indicating severe peripheral neuropathy [22]. Foot inspection was done by a one examiner to recognize any foot deformities. Tactile sensitivity was also tested as part of the inclusion criteria using (5.07) 10 g Semmes-Weinstein monofilaments (6.65 model, A83522, Germany) on both feet in plantar surface of the hallux, metatarsal heads, midfoot, and the rearfoot [23]. Individuals with DPN were excluded from this study if they have retinopathy, scars at planter surface of the foot, flat feet, hallux valgus, shoulder dysfunctions, not able to stand independently for at least 30 seconds, autonomic neuropathy, any upper motor neuron, extrapyramidal, cerebellar syndromes or any orthopedic disorders that could affect the ability to walk. After Initial evaluation which was conducted one week before baseline measurement, 34 participants (12 females and 22 males) were eligible and welling to participate in the study. All participants were included in three sessions of assessments: Pre-training (week 0), Post-training (week 10), and Follow-up (week 14). Participants were randomly assigned into to two equal groups (17 each) using online randomization software to achieve balance among groups in terms of subjects' baseline characteristics including gender. During the time of the study, none of the participants changed, or ceased their medical prescriptions (oral hypoglycemic medications) due to therapy applied in this study. All participants completed the training to the end of the study. This study was approved by the College of Applied Medical Sciences, University of Hail, KSA ethical review board.

After initial data collection, BBS was used to evaluate the dynamic balance and detect the risk of fall by assessing the performance of functional tasks. Fourteen functional tasks are included in the BBS. Each task is scored on a scale of 0 to 4, for a total possible score of 56. The score of 0 is assigned if a person is unable to perform a task and a score of 4 is gained when the task is independently performed. The highest score is indicating no balance difficulties. FRT was also used to assess the anticipatory balance. A score of 6 or less is an indication of a high risk for falls. A score between 6 - 10 inches indicates a moderate risk for falls.

A pressure platform (emed-q100, GmbH, Novel Munich, Germany) was used for measuring the arch index and the planter pressure distribution. The procedures of measuring planter pressure distribution were demonstrated to each participant before starting. At a usual walking speed, participants were asked to walk across the platform while concentrating on rounded stickers fixed on both directions of walking at the same level to keep gaze away from the pressure platform during measurement. Successful five passes of each foot were needed to complete the procedure of measuring the planter pressure. A trial was repeated if a foot is placed near to or on the edges of the platform. The data obtained from an average of the five steps of each foot was used to represent the individual's dynamic pressure distribution. Novel's foot report (Novel, Munich, Germany) was used to provide foot arch index and numerical measurement of the planter pressure in addition to colored graphs simulating foot placement. These reports were created instantly after the data collection.

Participants in both groups received instructions about the safety of the foot. Participants in the control group (G_2) received 60 minutes of passive stretching for the Hamstrings, Quadriceps, hip adductors, hip flexors, ankle plantar flexors, subtalar invertors. Graduated active exercises applied for the hamstring, hip abductors, knee extensors, ankle dorsi-flexors and foot evertors which were practiced two sets of 10 repetitions in addition to 10 minutes bicycle ergometer three times a week for 10 weeks.

For participants in the study group (G_1), an exercise program based on the principles of motor learning in addition to a terminal visual biofeedback technique was applied. Training session lasted 60 min with two to five minutes rest in-between tasks were allowed for a good performance. Treatment frequency was three times a week for 10 weeks.

The exercise program included: dynamic stretching of lower extremity muscles including the hamstrings, quadriceps, hip adductors, hip flexors, ankle plantar flexors, subtalar invertors and toes long flexors. Stretching was applied for each muscle group five repetitions with hold for 20-30 seconds. In addition to that, heel/toes raise, hamstring curls, hip abduction and knee extension exercises were practiced two sets of 10 repetitions. Maintaining single-leg stance while moving other foot to targets in a circle, maintaining single-leg stance while stepping backwards with the other leg, shin balances on Bionic Oscillatory Stabilization Unit (BOSU) ball, athletic standing on BOSU ball with hand tracking, lateral walk over on the BOSU ball, stepping forward, sideways and backward, stepping forwards to reach for an object, walking between lines, Heel/toe walking on a line (tandem walking), Walk and kick a ball to hit cans, and walking up/down stairs were also practiced 3 minutes for each exercise. The proposed tasks were reinforced to be done correctly through sensory and/or short, clear, verbal guidelines with care not overload the participant with excessive or long-winded tips. As initial practice progresses, the participants were requested to self-examine their performance and recognize what difficulties exist, what could be done to overcome these difficulties, and what movements could be omitted or refined.

The functioning of the e-med system and the biofeedback information were explained to the patient first. This information included 3-Dimensional graphical representation, created by the system, (Figure 1) of plantar pressure with colors showing the areas of high pressure and the safe zones on a large screen connected to the main computer. Before starting the exercise program each session, every patient was instructed to walk as naturally as possible on the platform. After each walking sequence and data processing, participants received information related to the relationship between the local planter pressure under the high-pressure zone (pink colors) and the safe zones. The system also allowed a comparison between different measurements to show the how the planter pressure changed for each successful measurement.

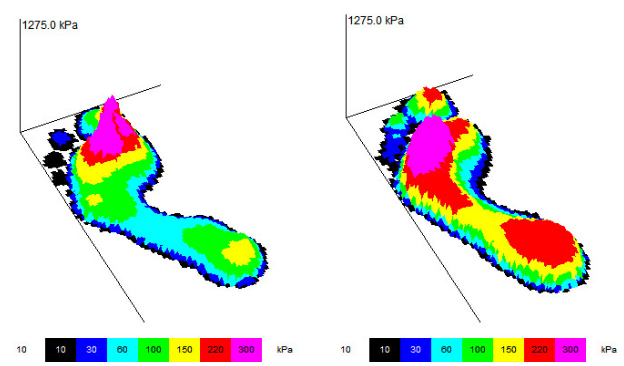

Figure 1: 3-Dimensional graphical representation of plantar pressure (left foot) with colors showing the at-risk zone and the safe zones. The pink colors show areas of highest pressure.

Statistical Analysis

Descriptive statistics were done to quantitatively describe the demographic characteristics of the sample and all outcome measures. T-test ($p < 0.05$) was used to compare the demographic data between groups. Interaction effects which represent the communal effects of the applied treatments on the outcome measures were studied by the two ways ANOVA (2 x 3). With level of significance set at $p < 0.05$, the effects of the applied interventions were compared between groups using t-test. Within group comparison, baseline measurements (1st measurement: week 0), post (2nd measurement: week 10), and follow-up (3rd measurement: week 14) was done using repeated measures of ANOVA at probability level less than 0.05. In addition, post-hoc pairwise comparisons were used to study the differences between measurements ($p < 0.05$).

Results

The demographics of the participants are outlined in table 1. The two-way ANOVA (Figure 2) was conducted to study the effect of applied interventions on each group and BBS and FRT. There were a highly significant interactions between the effects of groups and measurements on BBS: $F (5, 96) = 15.641, p < 0.01$ and FRT: $F (5, 96) = 30.419, p < 0.01$. On the same theme, there was a statistically significant interaction between the effects of the applied treatment on each group and pressure (PP) underneath the hind foot: $F (5, 96) = 10.315, p < 0 .01$ and forefoot: $F (5, 96) = 7.090, p < 0.01$.

Non-significant differences between the study and the control groups at the baseline measurements of all dependent variables including BBS ($p = 0.321$), PP hind-foot ($p = .869$) and PP forefoot ($p = .889$) were recorded. On the other hand, there were statistically significant differences between the post-treatment (2nd) measures (Table 2) of the BBS ($p = .001$), PP forefoot ($p = .021$); and PP hind-foot ($p =. 033$). For the post-one month follow up (3rd), there were statistically significant differences between the two groups in the BBS ($p = .001$), PP forefoot ($p = .028$) and PP hind-foot ($p = .034$).

The null hypothesis of no change in BBS and FRT scores within G_1 measured before, after and one month follow up was tested through the application of the repeated measures of ANOVA. The results indicated a significant time effects (Wilks' Lambda = 0.19, $F (2, 32) = 30.26, p < 0.01$) and (Wilks' Lambda = 0.14, $F (2, 32) = 45.77, p < 0.01$). Thus, there is an evidence to reject the null hypothesis. On the other hand, non-significant time effect on participant of G_2 (Wilks' Lambda = .826, $F (2, 32) = .239, p = .520$) and (Wilks' Lambda = .857, F

Table 1: Participants demographic characteristics and duration of illness

Variables	Mean ± SD		p
	$G_{1(n=17)}$	$G_{2(n=17)}$	
Age (years)	49.35 ± 4.72	48.88 ± 3.25	0.684
Sex (males/females)	11/6	11/6	1
Weight (kg)	66.11 ± 8.06	67.41 ± 7.88	0.646
Height (m)	1.58 ± .059	1.59 ± .084	0.67
BMI (kg/m²)	26.25 ± 1.79	26.22 ± 3.02	0.975
DOI (years)	10.23 ± 2.99	9.70 ± 3.23	0.628
Arch index	0.28 ± 0.01	0.30 ± 0.02	0.531
MDNS questionnaire scores	6.88 ± 2.15	6.47 ± 2.13	0.503
MDNS foot examination scores	4.35 ± 2.37	4.72 ± 2.22	0.664

*G1: group 1 (study group), G2: group 2 control group, DOI: duration of illness, BMI: Body mass index, MDNS: Michigan diabetes neuropathy score.

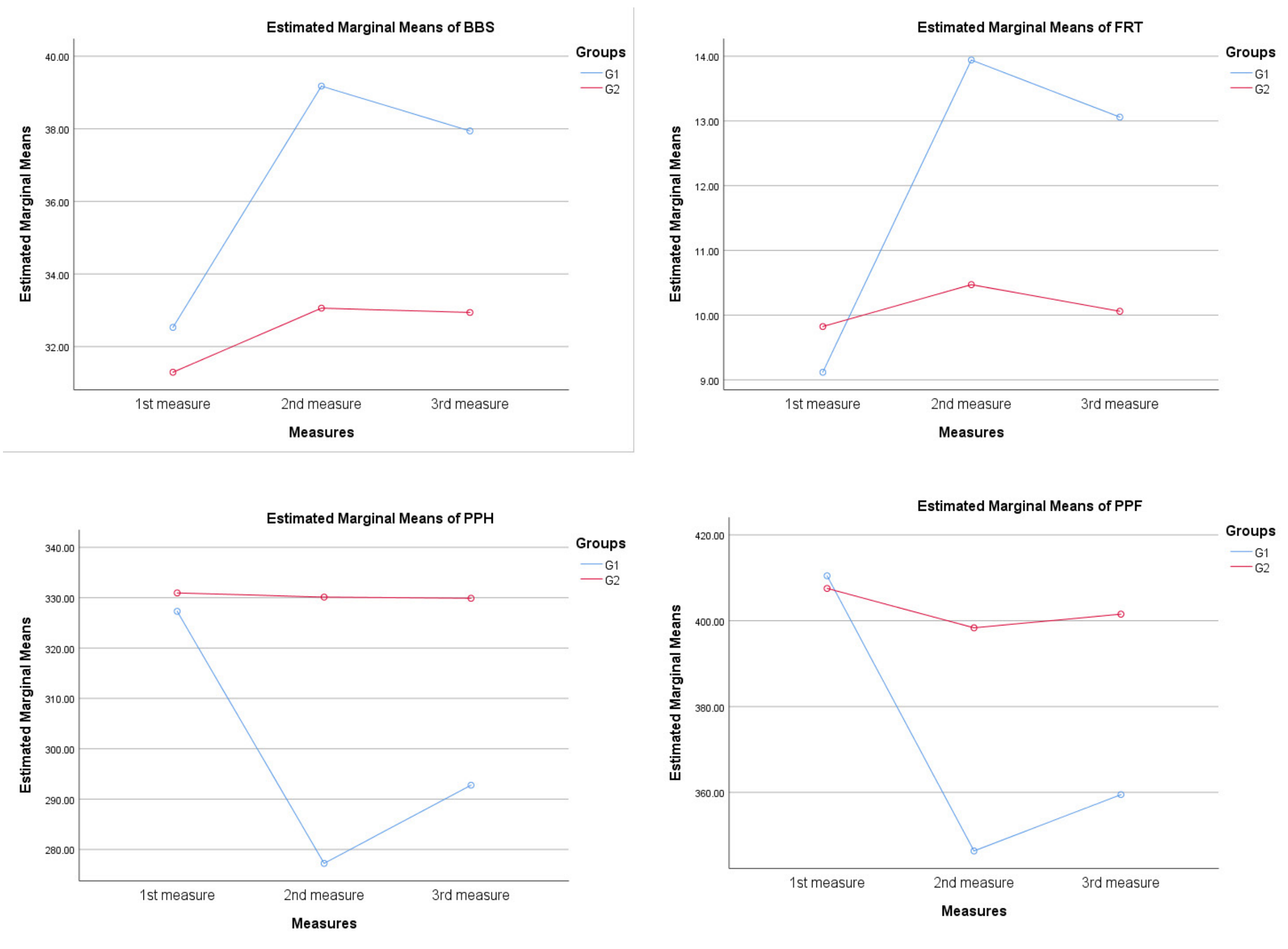

Figure 2: The plot of the mean of (a) BBS, (b) FRT (c) PP hind foot (d) PP forefoot for measurements and treatment applied on each group are plotted in a line graph.

(2, 32) = .1.525, p =.314).

Table 2: Comparison between groups: all outcome measures including planter pressure which presented in kilopascal

Variables	Measures	Group 1 Mean ± SD	Group 2 Mean ± SD	t	P
BBS	1st	32.53 ± 3.06	31.29 ± 4.57	1.025	0.321
	2nd	39.18 ± 2.50	32.23 ± 3.59	5.79	0.001
	3rd	37.94 ± 3.01	32.94 ± 2.74	5.831	0.001
FRT	1st	9.12 ± 1.65	9.82 ± 1.87	1.102	0.001
	2nd	13.94 ± 1.19	10.47 ± 1.23	8.606	0.001
	3rd	13.06 ± 1.08	10.05 ± 1.52	9.35	0.001
PPH	1st	327.29 ± 52.54	330.94 ± 49.46	-0.168	0.869
	2nd	277.24 ± 55.09	330.12 ± 43.14	-2.553	0.021
	3rd	292.76 ± 55.55	329.88 ± 35.54	-2.425	0.028
PPF	1st	410.47 ± 61.22	407.53 ± 57.52	0.142	0.889
	2nd	346.35 ± 57.95	398.35 ± 60.03	-2.336	0.033
	3rd	359.47 ± 54.39	401.53 ± 54.12	-2.324	0.034

*BBS: Berg balance scale, FRT: Functional reach test, PPH: Planter pressure hindfoot, PPF: Planter pressure forefoot, P is significant at $P \leq 0.05$.

In the study group (G_1) pairwise comparison between 2nd and 3rd measurement indicated that difference was not significant, $P > .05$ suggesting that the effect of the interventions lasted for one month after cessation of treatment. Similarly, PP hind-foot and PP fore-foot showed significant change in G_1 (Wilks' Lambda = .06, F (2, 32) = 115.73, p =.001 and Wilks' Lambda =.16, F (2, 32) = 39.235, p=.001 respectively) and non-significant change in G_2 (Wilks' Lambda = .997, F (2, 32) = .24, p = .978 and Wilks' Lambda = .844, F (2, 32) = 1.387, p =.280 respectively). In G_1, post-hoc test showed significant differences between the first and second or third measurements ($p < 0.05$) but not between the 2nd and 3rd measures (p = .130 and .290 respectively). Post hoc tests showed that participants of G_1 have a significant difference among first and the follow up measures ($p < .05$) but it showed a non-significant difference between the 2nd and 3rd measures (p = .335 and .062 respectively). The non-significant difference found between the 2nd and 3rd measurements of the outcome measures indicates that the exercise programs based on the motor learning principles have significant lasting effects.

Discussion

In the present study, we studied the effects of task specific training and biofeedback on plantar pressure distribution and risk of fall in participants with DPN. Biofeedback and task specific training led to decreased risk of fall by improving planter pressure distribution. This is consistent with Mickle et al., who concluded that high plantar pressures produced during walking may lead to an increased risk of fall. Reduction of falls risk could be accomplished through providing therapeutic interventions to people with high plantar pressures [9].

Scores of BBS and FRT showed a significant improvement in dynamic and anticipatory balance between task specific training group indicating a decreased risk of fall. The task specific training has significant effects on improving balance and reducing risk of fall because such approach is goal oriented, allows high number of meaningful repetitions and focus on activities which are directly related to the execution of daily activities. Our results are consistent with the results of Sisupadol et al., who reported that balance training should be done with a set of instructions and attention focused on the balance task [24]. This appears to be necessary to improve coordination and management of multiple tasks to optimize stability during the performance of daily activities [25]. The results of this study are also in close agreement with other studies which reported that task specific balance training is effective in improving the dynamic, anticipatory balance and attenuated risk of falling [26, 27]. It was also reported that balance training has the potentials to improve balance and reduce the risk of fall among individuals with diabetes as a result of improved proprioception and muscle strength [28]. Consistently, in a study by Allet et al, significant improvement of balance and decreased fear of falling which was sustained for a period of six months [26].

The results from this study showed that the mean planter pressure (PP) recorded under the hind foot and forefoot have been decreased after application of the task specific exercises. This may be attributed to changes in sensorimotor information and enhanced muscle abilities in addition to the modifications foot mechanics during walking as a result of increased foot muscle flexibility and strength. This is consistent with Barnett et al. who reported that foot rollover and planter pressure distribution during gait can be improved by balance and gait training and foot and ankle exercises [29]. Our results are in close agreement with Zhang et al., and Van deursen et al., [28, 30]. The authors reported that gait training could greatly improve the plantar pressure distribution and its related kinematic analysis. The deviation value of peak plantar pressure on each foot region has decreased to a much smaller range, and the load distribution becomes more homogeneous. Additionally, strengthening ankle joint musculature may contribute to proper control of the foot as the heel strikes the ground, resulting in a reduced supinatory moment [31]. Enhanced ankle ROM may improve eversion of the foot to ultimately decrease peak plantar pressures [32, 33].

The biofeedback applied in this study was task specific, provided precise and consistent scanning of the foot placement during walking with easy, understandable information for the patient to correct foot placement. The non-significant differences between the second and third follow up measures is an indication that the biofeedback reduces PP without adding more pressure at any other areas of the feet. This is particularly needed for avoiding new foot ulcer formation due to the recently acquired walking pattern which was observed with other interventions including exercises [34, 35].This is consistent with De León and colleagues who concluded that foot off-loading by biofeedback leads to homogenous plantar pressure distribution without developing any new 'hot spot' potentially at-risk for ulceration [27]. It was also reported that terminal augmented feedback training could positively affect motor learning in diabetic patients with DPN and could possibly lead to appropriate foot offloading [18].

The effects of the applied interventions persisted at third measure which is an indication that the process of motor relearning has been completed with improved neuromuscular coordination including progression, timing and dexterity of movement. This can be attributed to the effect of high number of repetitions of specific motor tasks with visual/auditory–motor co-activation provided during task specific training. This is consistent with Geiger et al., who stated that motor learning interventions should be relevant, task-specific, and adapted to the person's abilities and aims and provide adequate repetition and challenge to persuade training effects [32]. This is also consistent with Thomas et al. who suggest that exercises play an important role in the consolidation phase (Phase 3 of motor relearning) following motor skill learning to augment off-line effects and strengthen procedural memory [36]. It is also consistent with the Assal et al., who reported that the majority of lower extremity complications could be prevented through different educational programs for patients [37].

In this study, we have limitations of one-to-one manual interactions with patients, treatment protocols entail daily one-to-one therapy for several weeks. Nevertheless, we could show the lasting effect of task specific training and biofeedback on the risk of fall and foot ulceration among patients with DPN. Our results warrant further study with a larger sample size.

Conclusion

Task specific training and biofeedback showed a lasting effect on reducing the risk of fall by improving planter pressure distribution.

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