Effects of Thai Foot Massage on Balance Performance in Diabetic Patients with Peripheral Neuropathy: A Randomized Parallel-Controlled Trial

Authors' Contribution:
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Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: Peripheral neuropathy is the most common complications of diabetic patients and leads to loss of plantar cutaneous sensation, movement perception, and body balance. Thai foot massage is an alternative therapy to improve balance. Therefore, the purpose of this study was to investigate the effects of Thai foot massage on balance performance in diabetic patients with peripheral neuropathy.

Material/Methods: Sixty patients with type-2 diabetes were recruited and randomly assigned into either the Thai foot massage or control groups. The Thai foot massage group received a modified Thai traditional foot massage for 30 min, 3 days per week for 2 weeks. We measured timed up and go (TUG), one leg stance: OLS), the range of motion (ROM) of the foot, and foot sensation (SWMT) before treatment, after the first single session, and after the 2-week treatment.

Results: After the single treatment session, only the Thai foot massage group showed a significant improvement in TUG. After the 2-week treatment, both Thai foot massage and control groups showed a significant improvement of TUG and OLS (P<0.05); however, when comparing between 2 groups, the Thai foot massage group showed better improvement in TUG than the control group (p<0.05). The Thai foot massage group also showed significant improvements in ROM and SWMT after the 2-week treatment.

Conclusions: The results of this study suggest that Thai foot massage is a viable alternative treatment for balance performance, ROM of the foot, and the foot sensation in diabetic patients with peripheral neuropathy.

MeSH Keywords: Massage • Postural Balance • Sensation

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Background

Peripheral neuropathy (PN) is the most common complication of diabetic patients and leads to loss of plantar cutaneous sensation, movement perception and body balance. Fifty percent of patients with diabetes over 60 years old are affected by PN [1]. The somatosensory deficit in diabetic PN can include loss of muscle spindle function in lower leg, loss of movement perception at the ankle joint and loss of plantar cutaneous sensation [2,3]. PN causes decreased proprioception and/or increased reflex reaction time [4–6]. Limited joint mobility is frequently observed in diabetic patients who have increased stiffness of articular capsule, ligaments and tendons [7–10]. These may lead to postural instability [11] and an increased risk of falls [12]. The sensory system is also important to control balance. Sensations from the bottom of the foot play an important role during dynamic postural response [13,14]. Also, ankle flexibility, foot sensation and strength of toe flexor are important predictors of balance and functional ability in older people [15,16].

Thai foot massage is a form of deep massage using thumb pressure applied along the meridian lines of the foot and the leg combining with toes distraction. Thai massage technique is similar to the acupressure massage [17]. Pressure is applied by using thumb, finger, palm or elbow of practitioner [18]. Each pressure is held for 5–10 seconds at the point when the patient starts to feel some pain and repeated 3-5 times for each point [19]. Plausible mechanism of deep massage pressure might improve of blood flow to enhance skin sensations from the bottom of the feet [20–22]. Combining with joint distraction which may increase joint mobility, Thai foot massage may be one of the alternative therapies to improve balance performance for diabetic patients as a result of increasing range of motion (ROM) and sensation of the foot. It may directly stimulate the nervous system to help the myelin sheath of the nerves [23]. Previous studies show that western foot massage combined with mobilization can stimulate cutaneous sensory and joint sense, improving standing balance in elderly people [24,25]. There is no studies to support the effectives of Thai foot massage on balance performance, ROM of the leg and the foot and the foot sensation in Type II diabetic patients with PN. Therefore, the purpose of this study was to investigate the immediate and short-term effects of Thai foot massage on balance performance, ROM of the leg and the foot and the foot sensation in Type II diabetic patients with PN.

Material and Methods

Subjects

Type II diabetic patients aged 40–70 years and with peripheral neuropathy were recruited and their demographic characteristics and health status were recorded, including duration of diabetes (Table 1). Patients were diagnosed as having an impaired level of diabetic foot [26] as per the following criteria: 1) Peripheral sensory deficit was assessed with the Semmes-Weinstein monofilaments test (SWMT) [27]. The third and fifth toes and the head of the first and third metatarsi can indicate sensory neuropathy [28]. One or more deficits of sensation were indicative of sensibility abnormality or peripheral

Table 1. Demographic characteristics and health status of study participants.

Characteristics	Thai foot massage (FM) n=30	Control group (CON) n=30	Total n=60
Female, n (%)	20 (66.7)	20 (66.7)	40 (66.7)
Age (years)	57.8±6.5	57.6±6.5	57.7±6.4
Height (cm)	157.7±7.4	158.9±8.2	158.3±7.8
Body mass (kg)	63.8±8.0	65.5±10.8	64.2±9.5
BMI (kg/m2)	25.3±2.7	25.9±3.7	25.6±3.3
Occupation, n (%)			
Government officer and employer	9 (30.0)	13 (43.3)	22 (36.7)
Farmers	21 (70.0)	17 (56.7)	38 (63.3)
Duration of diabetes (years)	8.2±3.7	7.1±3.6	7.7±3.6
Fasting blood sugar (mg/dl)	126.0±33.4	132.4±29.2	±31.3
Numbness; SWMT (points)			
Left foot	3.0±2.0	3.9±2.1	3.5±2.1
Right foot	3.8±2.1	3.9±1.8	3.8±1.9

All data are shown as mean ±SD.
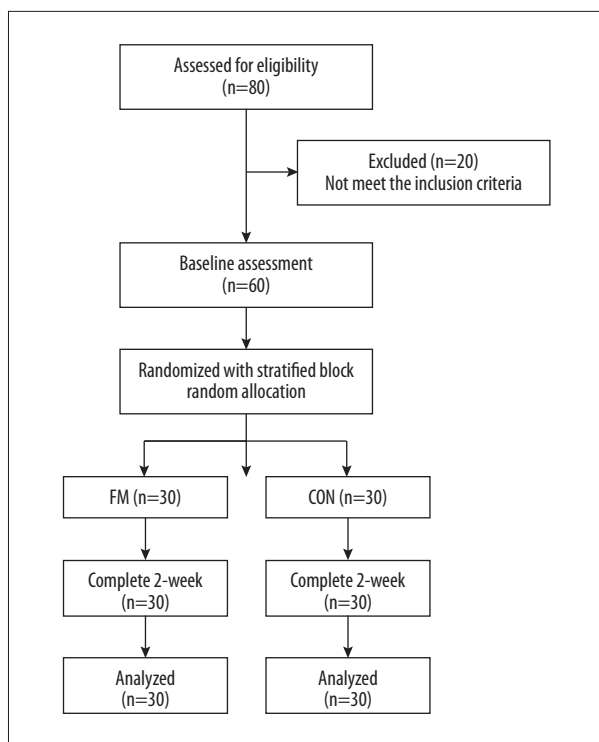
Figure 1. Participant flow and follow-up chart.

Figure 2. Thai foot and leg massage points and lines. At the sole of foot: 4-massage lines from the heel to the base of metatarsophalangeal joints (MTP) (**A**), 5-massage points; 1 point at the base of 3rd MTP (**B**) and 4 points at the head of MTP (**C**). At the dorsum of the foot: 4-massage lines from the ankle to the base of MTP (**D**), 5-massage points at the head of MTP (**E**), and distraction of all joints of toes (**F**). Massage lines at the anterior leg, posterior leg, and knee (**G, H**).

neuropathy [26]. 2) Ability to walk 10 m without a walking aid. Patients with any of the following condition were excluded: 1) Parkinson's disease and stroke, 2) severe cognitive disability, 3) acute illness, unstable hypertension, and angina, 4) myocardial infarction, 5) fracture of the lower limb within the 6 months before the study, 6) foot deformity and neuroarthropathy, 7) foot ulcer, due to the contraindication of Thai massage [17], 8) dependence on alcohol and/or drugs with known effects on the central nervous system, and 9) partial or complete blindness.

Patients who met the inclusion criteria were randomly allocated to either the Thai foot massage (FM) or control (CON) groups using stratified block random allocation with block sizes of 2, 4, and 6. The sex (male or female) and age groups (group 1=40–50 years old, group 2=51–60 years old and group 3=61–70 years old) were also used as stratification variables to achieve an approximate balance of age and sex of patient characteristics. A pre-generated random assignment scheme was made and enclosed in envelopes by the research assistant who was not involved in the process of treatment and outcome assessment. A 2-week prospective, parallel group, randomized, controlled clinical trial was conducted with physical therapists and a traditional Thai massage therapist. The local ethics committee approved the research protocol (HE562152). Written informed consent was obtained from all participants at the start of the study. A detailed summary of patient recruitment, participation, and attrition is shown in Figure 1.
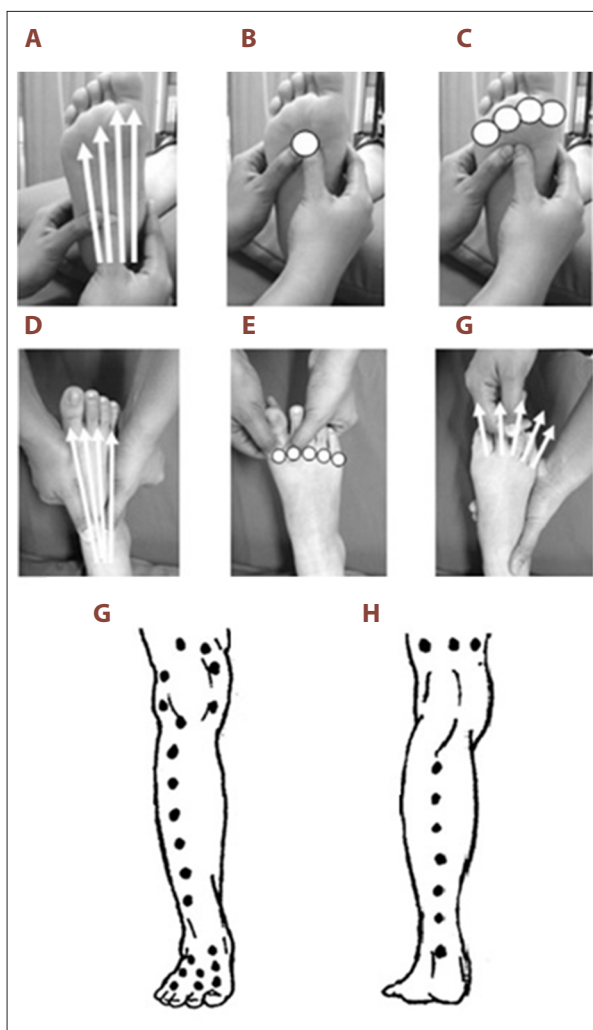
Interventions

Thai foot massage (FM)

A modified FM [17] was applied on the area of the foot, ankle, lower leg, and knee in supine and side-lying positions of the participants (Figure 2). Thumb pressing was used in FM by the massage therapist by applying gentle and gradually increasing pressure along the 3 meridian lines on the feet, named in Thai as Ga-la-ta-ree, Sa-has-rang-see, and Ta-wa-ree. These 3 lines cover the sole and dorsal surface of the feet, tibialis anterior, and gastrocnemius muscles. According to the different

threshold in each individual, each thumb pressure was applied until the participant started to feel some discomfort (below-pressure pain threshold) and maintain the pressure for 5–10 seconds at each massage point [29]. In addition; manipulation using distraction technique in each toe was applied after the massage. This sequence was repeated 3-5 times for each massage line or point, combined with a gentle pulls of all toes. The protocol was used combining massage for 25 min and stretching for 5 min according to the pattern of royal Thai massage [30]. All participants received 30 min per session, 3 sessions per week for the 2-week course with a traditional Thai massage therapist who had more than 5 years of experience.

Control group (CON)

Each patient in the control group received the health education [31] using the 10 guidelines of foot self-care (e.g., washing and checking feet every day, applying skin lotion if skin is too dry, avoid wearing tight shoes, wearing shoes and socks at all times, and refraining from smoking). Patients were encouraged to practice active foot exercise in the direction of ankle dorsiflexion/plantarflexion for 5–10 min every day at home. All activities were done 30 min per session, 3 sessions per week for 2 weeks. These activities were performed at the hospital for the same period but in a different examination room for the intervention group.

Measurements

The outcome measurements were assessed before and after the first single session and re-assessed again after the 2-week treatment (2–3 day after the last treatment). The primary outcome measure was the time up and go test (TUG). The secondary outcome measures included one-leg standing tests (OLS), range of motion (ROM) of first metatarsophalangeal (MTP), ankle and knee joints, and sensation of the foot measured by Semmes-Weinstein Monofilament Test (SWMT). All outcome measures were assessed and the assessor was blinded to treatment of each participant. TUG is an outcome measure to assess functional dynamic balance. Dynamic balance is the ability to maintain total body equilibrium while moving the body and static balance is the ability to maintain total body equilibrium while standing in one spot [32–33]. The intra-rater reliability of TUG is excellent and intraclass correlation coefficient (ICC) is 0.98 (95% CI 0.96 to 0.99) [25]. During measurement, subjects stood up from a standard chair with a command "Go", walked 3 meters, turned at the marked cone, and walked back to the chair as fast as possible. Timing started when the command was given and stopped when the subject was back to the chair again. Each participant performed 3 trials, and the best result of the 3 trials was recorded as the time in seconds [34]. OLS was measured on left and right legs with both eyes open and closed condition. Subjects stood with hands on the hips. The non-stance leg was standardized in a position of 30°

of hip flexion and 90° of knee flexion with the ankle relaxed. The test was finished when the stance foot moved or shifted in any way or the non-stance foot touched the ground [35]. Each participant performed 3 trials, and the best result of the 3 trials was recorded. The active ROM for the 1st MTP, ankle, and knee joints in both legs were measured with a goniometer. Measurements were performed with 3 trials, and the average value of the trials was used for further analysis [36]. SWMT was used to apply a consistent 10-g force on 10 different sites on the plantar surface of the foot. A filament was placed perpendicular to the skin surface avoiding callosity, and the filament was pushed with sufficient force until it bent or twisted. Subjects were asked if they felt anything touching the skin. The examination was repeated 3 times for each site, and included at least 1 sham examination in which the filament was not actually placed on the skin. If the patient gave incorrect answers 2 or more times out of the 3 examinations per site, the site was considered as positive. If an incorrect answer occurred once or less, the site was considered as negative. The examination was conducted at all 10 sites, with random orders. The number of positive points was recorded for each side [37].

Statistical analysis

All data are presented as means ± standard deviations (SD). Estimation of the sample size was based on a previous study [18] done in the healthy elderly. The effect size (0.7) of timed up and go (TUG) in minutes after foot massage of treated and untreated groups was used to calculate the sample size for a statistical power of 80% at a 5% significance level. A drop-out rate of 10% was added for estimating the final sample size of 30 participants per group [38]. This study aimed to analyze each outcome separately at different points of time over the period of treatment to detect the immediate effect (after the first treatment) and short-term effect (after 2-week treatment). Since the randomization method did not guarantee that baseline characteristics would be the same between groups, analysis of co-variance (ANCOVA) was performed to compare post-test data between groups using the pre-test as a covariant. Shapiro-Wilk W test for testing the normality of all variables was performed before the treatment. This analysis was used to compare differences in outcome measures between the 2 treatment groups and to estimate the adjusted mean differences with 95% confidence intervals for each outcome measure in each group. Pearson's correlation coefficient (r) and its 95% confidence interval were used to explore the correlations among parameters. The level of significance was set at p<0.05.
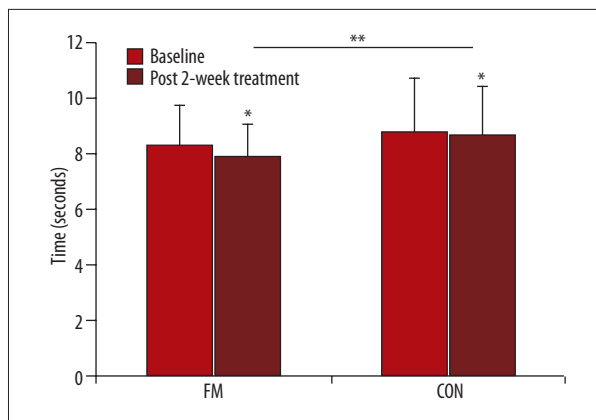
Results

Table 1 shows the details of the demographic characteristics of the subjects in the 2 groups. These variables were not

Table 2. Comparison between group of the adjusted immediate post after the first treatment and adjusted post after 2-weeks treatment of all parameters.

Outcome	Group	Baseline (Mean ±SD)	Immediate post after 1st treatment (Mean ±SD)	Post after 2st week of treatment Mean ±SD)
Timed up and go test; TUG (seconds)	FM	8.31±1.42	7.87±1.18*	7.06±1.14**
	CON	8.80±1.91	8.67±1.75	8.56±1.67*
One leg stance test; OLS opened eyes(seconds): Left	FM	27.4±29.52	28.18±32.74	56.18±52.90*
	CON	25.58±26.97	22.4±22.98	39.98±44.98*
One leg stance test; OLS opened eyes (seconds) Right	FM	33.62±39.45	32.48±37.80	69.3±69.66*
	CON	32.8±39.30	33.46±41.51	48.32±57.25*
One leg stance test; OLS closed eyes(seconds): Left	FM	2.9±2.99	4.68±2.98*	12.24±12.04*
	CON	3.82±4.88	4.7±4.21	8.3±7.33*
One leg stance test; OLS closed eyes (seconds): Right	FM	2.74±1.91	2.88±2.12	9.68±12.73*
	CON	3.44±2.58	3.4±3.15	5.9±3.61*
1st MTP flexion (degree, °): Left	FM	24.97±8.88	26.00±8.65**	28.20±8.03**
	CON	21.63±5.07	22.40±4.93*	24.03±5.35*
1st MTP flexion (degree, °): Right	FM	26.77±8.29	28.33±8.06**	31.50±7.77**
	CON	24.10±4.58	24.93±4.56*	26.90±4.80*
1st MTP extension (degree, °): Left	FM	62.00±12.01	63.60±11.83**	67.17±11.32**
	CON	73.70±7.74	74.40±7.85*	76.23±7.97*
1st MTP extension (degree, °): Right	FM	65.37±11.82	66.70±11.62**	69.63±11.24**
	CON	74.57±7.89	75.23±8.06*	76.93±7.75*
Ankle dorsiflexion (degree, °): Left	FM	10.13±4.28	12.13±3.95*	15.30±4.04**
	CON	10.00±3.71	11.57±3.56*	14.17±3.65*
Ankle dorsiflexion (degree,0): Right	FM	12.63±4.92	14.37±4.90*	16.60±4.55**
	CON	13.23±3.70	14.50±3.56*	16.17±3.92*
Ankle plantarflexion (degree, °): Left	FM	32.50±5.98	34.33±5.70*	38.27±5.25**
	CON	34.17±8.62	35.80±8.21*	38.23±7.93*
Ankle plantarflexion (degree, °): Right	FM	34.53±4.83	35.67±4.61*	38.60±4.80*
	CON	37.07±8.60	37.87±8.19*	40.20±8.01*
Knee flexion (degree, °): Left	FM	119.83±7.37	121.60±7.45*	124.77±7.66**
	CON	122.57±10.99	123.33±10.65*	124.30±10.07*
Knee flexion (degree, °): Right	FM	120.13±6.99	121.40±6.67*	123.93±6.48**
	CON	124.33±10.49	125.20±10.19*	126.83±10.16*
Knee extension (degree, °): Left	FM	−6.17±2.26	−5.37±2.11*	−3.60±2.18**
	CON	−7.43±3.16	−6.83±3.21*	−5.47±2.96*
Knee extension (degree, °): Right	FM	−7.77±1.81	−6.77±1.98*	−4.67±2.09*
	CON	−8.93±2.52	−8.10±2.34*	−6.33±2.40*
Positive of SWMT (number): Left	FM	3.03±2.04	3.03±2.04	1.43±1.52**
	CON	3.93±2.07	3.90±2.02	3.70±2.02*
Positive of SWMT (number): Right	FM	3.77±2.06	3.77±2.06	1.83±1.64**
	CON	3.90±1.81	3.90±1.81	3.60±1.71*

* Denotes statistically different (p<0.05) from baseline; ** indicates statistically different (p<0.05) from baseline and between groups using analysis of covariance (ANCOVA) with adjusted for baselines, FM – Thai foot massage; CON – control; 95%CI – 95 percent confidence interval; statistically significant different defined as a p-value of <0.05.

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Figure 3. Time up and go (TUG) after the 2-week treatment. * Denotes statistically different (p<0.05) from baseline and ** indicates statistically different (p<0.05) between groups.

significantly different between groups. For immediate effects of the first single-session treatment, TUG for FM group was significantly improved from the baseline, while the CON did not change. However, when comparing the 2 groups after adjustment for baseline levels, TUG was not significantly different between the groups (p>0.05) (Table 2). Similar findings were found in OLS on the left leg with closed eyes. ROM in both groups significantly improved from baseline (p<0.01); however, only ROM of 1st MTP in FM was significantly larger than CON (p<0.05). In contrast, SWMT was not significantly different either within or between groups. After the 2-week treatment, both groups significantly improved from baseline in all parameters. When comparing between the 2 groups after adjustment for baseline levels, TUG for the FM group was faster than for CON as 1.13 s (95% CI of 0.76 to 1.50 s, p<0.001) (Table 2 and Figure 3). In terms of the effect size (ES or Cohen's *d*) [39], this effect was evaluated as a large degree (ES=1.00). Similar findings were found for SWMT and ROM, except for ROM in right ankle plantarflexion and knee extension. In contrast, OLS was not significantly different between the 2 groups. Sex differences were not found in any outcome measurements. In addition, TUG was correlated with pre-test variables of both left and right 1st MTP in extension (left; r=0.39, p=0.0023 and right; r=0.35, p=0.0064). OLS with eyes open condition also correlated with SWMT (left; r=0.31, p=0.0116 and right; r=0.32, p=0.0085).

Discussion

This study is the first reported study to show that Thai foot massage using deep pressure and stretching improved TUG performance, ROM of the foot, and foot sensation in type II diabetic patients with PN after a 2-week treatment. TUG after the 2-week treatment was 1.13 s (95% CI of 0.76 to 1.50

s) faster in FM than CON. This was similar to the minimal detectable change of 1–2 s considered as clinically significant and was found in previous studies [40,41]. Vaillant et al. [25] show significant improvement in TUG after 20-min massage and mobilization of the foot and ankle joints in elderly adults, with the different mean change about 0.7 s when compared with the placebo protocol group. Cho et al. [42] also show significant improvement in TUG after ankle joint mobilization for 4 weeks, 3 times a week with 2 min per sessions, with different mean change 2.54 s when compared with the control group. In contrast, Pertille et al. [43] reported non-significant improvement in the TUG after 3 sets of 30-s ankle joint mobilization in elderly women. Although there has been controversy about effects of massage and mobilization on TUG in elderly adults, the combined treatment of massage and joint mobilization of the foot could have better effects for improvement in dynamic balance performance in type II diabetic patients with PN.

The mechanism underling the effects of Thai foot massage on the dynamic balance in diabetic patients with PN remains unclear; however, it may be explained by improvements in ROM and skin sensation of the foot after Thai foot massage using deep pressure and stretching of the foot and the leg. We showed that improvements of ROM and skin sensation of the foot were associated with improved dynamic balance performance. Using direct-deep pressure combined with gentle distraction on the muscle and joints of the foot and lower leg increases local blood circulation and stimulates the somatosensory system, including multiple receptors [25]. These effects may reverse neuropathy by changing pressure distribution, proprioceptive systems, muscle tension, joint angle, and muscle length. These sensory and segmental adjustments play an important role in postural control [14]. Direct-deep pressure technique could increase the extensibility of the non-contractile capsular and ligamentous tissues [13,14] and stimulating the joint mechanoreceptors may enhance the neuromuscular function of joint stabilizing muscles [44]. Joint mobilizations also increase flexibility [45] and may enhance postural control [37]. This was supported by positive relationships between TUG and ROM of 1st MTP. In line with this result, Mecagni et al. [11] showed a correlation between ankle ROM and balance. Therefore, it can be suggested that adequate ROM of the ankle and MTP joints plays an important role in better dynamic balance [15].

The limitation of the study is lack of inter- and intra-reliability of the TUG in diabetic patients. This might be a reason for an improvement of TUG in an active control group, although this result might be explained by the effect of active exercise as a part of the health education program. Also, it is not clear what duration of treatments is long enough to achieve the maximum effects and nor is it clear how long this positive effect can last. Therefore, a further study is needed to

understand the long-term effect of improvement in mobility and balance to confirm the effect of Thai foot massage in diabetic patients with PN.

Conclusions

This study revealed that Thai foot massage using the pressure applied along the Thai meridian lines of the foot and the leg significantly improved dynamic balance performance, ROM of the foot, and foot sensation in diabetic patients with PN. Because Thai foot massage technique is not complex and is easy to perform, it may be a viable alternative treatment for home health care and in clinical settings for diabetic patients.

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