ORIGINAL ARTICLE

Effectiveness of self-massage combined with a health education program using the self-efficacy theory in reducing peripheral neuropathy among diabetes mellitus patients

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ABSTRACT

Diabetic peripheral neuropathy (DPN) is a common complication of diabetes mellitus. It often causes impairment of sensory nerves, which can negatively impact functional mobility and quality of life for patients. Self-massage along with health education is one potential method to reduce the impact of DPN. However, to date there are limited studies on such treatment programs. The present study investigated the effect of self-massage combined with a health education program using the self-efficacy theory in DPN patients, who were recruited from the major District hospital in Pratumrat District, and 8 other local hospitals in Roi Et Province, Thailand. This randomized control trial collected data from February to May, 2022. Seventy DPN patients were randomly assigned into two groups (intervention and control) which contained 35 participants each. The intervention group received 21 sessions of massage and health education (every other day for 6 weeks). The control group received only the normal program from the hospital. The participants were assessed for their peripheral neuropathy using Michigan Neuropathy Screening Instrument (MNSI) at baseline, after 2 weeks, 4 weeks, and 6 weeks. Generalized estimating equations were used to quantify the mean difference of scores of MNSI compared between intervention and control groups for overall post measurement compared to baseline. The results showed that the mean scores of MNSI for intervention and controls at baseline were 11.31 (SD = 1.36) and 11.24 (SD = 1.49), respectively. After receiving the intervention program for 6 weeks, the mean difference of scores of MNSI in the intervention group reduced by 5.49 (95% CI: 5-5.98; p-value <0.001) compared to the control group. This study reveals that the combination of self-massage and a health education program based on self-efficacy theory can reduce peripheral neuropathy in patients with DPN. This outcome could be useful for healthcare professionals in improving the health of DPN patients.

Key words:
diabetes mellitus; diabetic peripheral neuropathy; self-massage; health education program; self-efficacy theory

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INTRODUCTION

Diabetes mellitus (DM) is a group of chronic metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion or insulin action, or both[1]. There are two major types of DM: type 1 DM (T1DM) and type 2 DM (T2DM). T1DM mainly results from autoimmune β-cell destruction of pancreas, usually leading to absolute insulin deficiency, and T2DM is a combination of insulin resistance or relatively insufficient insulin secretion[2]. There are approximately 422 million people worldwide living with DM, with the majority diagnosed with T2DM[3]. In Thailand, there were approximately 4.2 million people living with T2DM in year 2017[4]. DM is a leading cause of death in Thailand[5]. From more than 200,000 deaths annually among the Thai population due to chronic non-communicable diseases, approximately 30,000 are due to DM[6]. Furthermore, DM related chronic hyperglycemia is also associated with long-term complications including retinopathy, nephropathy, genitourinary, cardiovascular dysfunction, and especially diabetic peripheral neuropathy (DPN)[2].

DPN, a debilitating microvascular complication, is the most common complication of DM[7, 8]. In Thailand, 16.8% of DM patients had DPN based on loss of ankle reflexes, vibration perception, and insensitivity to monofilament[9]. Furthermore, 34% of DPN patients attended a primary care service[7]. The patients experience abnormal sensation in the toes, which may extend to involve the feet and legs in a stocking distribution[10], which induces the risk of foot ulcers and amputations[11, 12]. Long-term DPN affects motor fibers and therefore, motor function (i.e., atrophy and weakness) cause progressive dysfunction in distal to proximal parts of the body[13]. DPN invariably leads to several serious health problems, irrespective of age, and physical impairment[11]. Early intervention for DPN patients is very important to reduce numbness and prevent further severe complications.

Previously, the American Diabetes Association published a diabetes position statement stating that non-weight bearing activities in the presence of severe DPN may be the most effective, such as swimming, bicycling, or arm exercises, because of the decreased risk of skin breakdown and infection[2]. The evidence supports massage therapy for improving DPN complaints[14, 15]. Although several previous studies have explored the effect of massage on DPN patients, few studies have investigated the combined effect of self-massage and a health education program in these patients. Self-efficacy for health behaviors refers to the confidence a person has in their capacity to perform certain health behaviors, that may lead to desired outcomes[16]. Thus, the patients' self-management has been recommended as a component of chronic care management[17], in which DPN is most likely to be permanent with chronic conditions. As well, most studies explored the role of self-massage as a rehabilitative tool rather than a preventive intervention[18], especially in DPN patients. Therefore, this study aimed to investigate the effect of self-massage combined with a health education program using self-efficacy theory in patients with diabetic peripheral neuropathy.

METHODS

Study design

This study was a randomized controlled trial with double blind method (participants and assessor were blinded). Participants were male and female T2DM patients with DPN, who were recruited from the major District hospital in Pratumrat District, and 8 other local hospitals in Roi Et Province, Thailand. The data were collected between February and May, 2022. The researcher first requested staff in participating hospitals to inform patients who had been diagnosed with

T2DM by a doctor, and were currently undergoing treatment for the condition, about the study and invite them to participate. Potential participants contacted the research team if they were interested in taking part, and were then screened for inclusion criteria. Research staff who were physical therapists screened potential participants for DPN using the criteria of the Michigan Neuropathy Screening Instrument (MNSI). Participants were classified as having DPN if they had a score of at least 7 out of 13 on the first part (self-administered questionnaire), and a score of at least 2.5 out of 10 on the second part (physical assessment) of the MNSI[19]. To be included in the study participants also needed to understand simple commands for self-massage such as sitting on the table, holding the right hand above the head and moving to the left side, putting both thumbs nested and pressing on the sole of the foot, putting both thumbs nested and pressing on the joint of big toe and so on, and willing to participate in the study. Potential study participants were also excluded if they had polyarthritis and gout, concomitant foot ulcers, severe foot deformity (require custom therapeutic footwear), stroke, and other physical limitations (i.e., can not sit with legs extended or bend the knee for long periods of time, unable to bend over for a long period of massage, or having received another massage program previously).

Variables measurements

Data on the health status of participants such as body mass index (BMI), the information regarding DM status (i.e., duration of DM, level of glucose, and medication used), and frequency of exercise were obtained using interview-based health questionnaires. Prior to the study participants were screened regarding function and DPN condition using the MNSI. MNSI consisted of 2 parts, the first part (subjective part) is a self-administered questionnaire that consisted of 15 yes/no questions based on sensations experienced in participants' legs and feet, in which 13 items represent symptoms of DPN, 1 item assesses peripheral vascular disease, and 1 item assesses general asthenia, then the total score of this part was 13 points. The second part (objective part) is physical assessment, which consists of 5 items including appearance of feet (deformity, dry skin, callus, infection, and fissure), ulceration, ankle reflexes, vibration perception at great toe, and monofilament[20]. One point is given if any of these signs are present. Both feet were evaluated; thus, the total potential score was 10 points[20].

DPN was diagnosed if the participants had an MNSI score of at least 7 out of 13 on the self-administered questionnaire, and a score of at least 2.5 out of 10 on the physical assessment[19]. Furthermore, they were assessed for foot numbness at baseline, 2-week, 4-week and after 6-week of intervention (4 times), using the MNSI. After this initial assessment, 89 potential participants were excluded due to either not meeting the DPN criteria, or because they had wounds in the weight bearing area of the foot.

Sample allocations

The eligible participants were randomly allocated to intervention and control groups. Allocation was concealed by the use of envelopes, which were opened in each community at the time of the randomization visit. There were 35 participants in the intervention group and 35 participants in the control group. Over the course of the study, no participants were lost to follow-up. Figure 1 shows the study flow diagram giving a detailed description of exclusion criteria, allocation, and the number of participants in the analysis process.

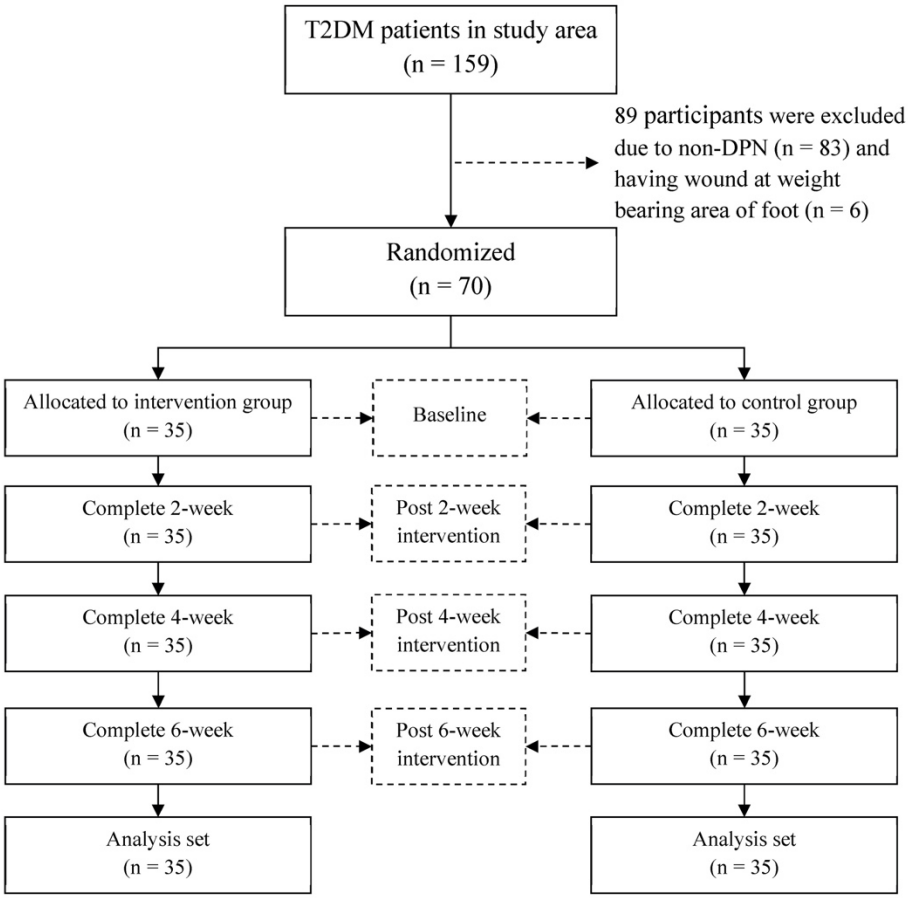

Figure 1 Study flow diagram

Intervention design

Before the intervention program, all participants received training in self-massage for 3 hours by a research assistant (another physical therapist). To control the quality of training, the participants were divided into groups of 5 persons to ensure individual attention could be paid to each participant, then they were trained in the same protocol by a physical therapist using video media of self-massage program developed by Photijuk and colleagues[21]. The intervention group received self-massage combined with a health education program using self-efficacy theory. The intervention group then was asked to use self-massage at their home for 45 to 50 minutes/session every other day for 6 weeks. The self-massage was directed by a researcher and an assistant, who had previously received training in self-massage from a physical therapist with more than 10 years of experience. The details of self-massage consisted of 5 minutes of warm up, followed by circuit training for 45 minutes to 50 minutes. This included 3 parts consisting of lower leg, plantar and instep. Each session was composed of a set of three tasks: counting from 1 to 5 at each point (outside lower leg, plantar, instep). Then, sessions were completed with raised feet on cloth and squat[14]. For self-efficacy theory, the participants received education about diabetes with peripheral neuropathy, and diabetic foot care[22]. The control group received the normal program from the hospital using the 10 guidelines of foot health care (e.g., checking and washing the foot every day, avoiding wearing tight shoes) from the hospital program for 6 weeks.

Statistical analyses

Baseline characteristics of participants were presented as frequency number and percentage for categorical data, and mean plus standard deviation (SD), median, and minimum and maximum range for continuous data. The mean scores of DPN at each step of the intervention (after 2-week, 4-week, and 6-week), were measured and compared for the intervention and control groups adjusted for baseline scores and presented as mean differences and their 95% confidence intervals (CI) obtained by analysis of covariance (ANCOVA). The mean scores of DPN for overall post-intervention measurement were compared again between intervention and control groups adjusted for baseline and all study factors and presented as adjusted mean difference and their 95% CI obtained by generalized estimating equations (GEE) under linear regression framework. A p-value of less than 0.05 was considered statistically significant. All statistical analyses were performed using the STATA program version 15[23].

Ethics approval

The research protocol was approved by the Khon Kaen University Ethics Committee for Human Research, reference number HE642230. All participants gave written informed consent to participate in the study.

RESULTS

Baseline characteristics of sample

The majority of participants in both control and intervention groups were females, with 71.43% in the intervention group and 68.57% in the control group. Mean ages of 65.2 years (SD = 5.05) and 65.57 years (SD = 4.92) were found in intervention and control groups, respectively. Around two-thirds were diagnosed with DM more than 10 years ago in both intervention and control groups (62.86%). There were no statistically significant differences between the groups at the baseline for demographic characteristics, and health status (Table 1).

Table 1. Baseline demographic characteristics of participants

Characteristics	Intervention (n = 35)	Control (n = 35)	Total (n = 70)
	Number (%)	Number (%)	Number (%)
Gender			
Male	10 (28.57)	11 (31.43)	21 (30.00)
Female	25 (71.43)	24 (68.57)	49 (70.00)
Age (years)			
< 60	6 (17.14)	5 (14.29)	11 (15.71)
≥ 60	29 (82.86)	30 (85.71)	59 (84.29)
Mean ± SD	65.2 ± 5.05	65.57 ± 4.92	65.39 ± 4.96
Median (Minimum : Maximum)	65.00 (53 : 70)	68 (52 : 70)	67.00 (52 : 70)
Marital status			
Single	10 (28.57)	15 (42.86)	25 (35.71)
Married	25 (71.43)	20 (57.14)	45 (64.29)
BMI (kg/m^2)			
18.50 - 22.99	10 (28.57)	9 (25.71)	19 (27.14)
≥ 23	25 (71.43)	26 (74.29)	51 (72.86)
Mean ± SD	24.69 ± 3.33	24.91 ± 3.40	24.80 ± 3.35
Median (Minimum : Maximum)	25.00 (18.1 : 31.25)	24.65 (18.73:32.00)	24.99 (18.14 : 32)

Characteristics	Intervention (n = 35)	Control (n = 35)	Total (n = 70)
	Number (%)	Number (%)	Number (%)
Frequency of excercise			
No exercise	5 (14.29)	10 (28.57)	15 (21.43)
1 - 4 times/week	14 (40.00)	17 (48.57)	31 (44.29)
≥ 5 times/week	16 (45.71)	8 (22.86)	24 (34.29)
Duration of DM (years)			
< 10	10 (28.64)	11 (31.36)	21 (30.00)
≥ 10	25 (71.37)	24 (68.63)	49 (70.00)
Mean ± SD	13.26 ± 6.33	12.29 ± 7.04	12.77 ± 6.66
Median (Minimum : Maximum)	11.00 (2 : 30)	12.00 (1 : 25)	11.00 (1 : 30)
FBS (mg/dL)			
≤ 120	4 (11.4)	3 (8.6)	7 (10.00)
> 120	31 (88.6)	32 (91.4)	63 (90.00)
Mean ± SD	164.66 ± 38.57	157.25 ± 38.23	160.96 ± 38.30
Median (Minimum : Maximum)	160.00 (91 : 254)	156.00 (91 : 300)	160.00 (91 : 300)
Using sulfonylurea			
No	23 (65.71)	30 (85.71)	53 (75.71)
Yes	12 (34.29)	5 (14.29)	17 (24.29)
Using GLP-1 receptor agonist			
No	23 (65.71)	15 (42.86)	38 (54.29)
Yes	12 (34.29)	20 (57.14)	32 (45.71)
Insulin (basal)			
No	21 (60.00)	17 (48.57)	38 (54.29)
Yes	14 (40.00)	18 (51.43)	32 (45.71)

SD=Standard deviation; BMI=Body mass index; DM=Diabetes mellitus; FBS=Fasting blood sugar

Michigan neuropathy screening instrument scores over time

Table 2 shows the mean total MNSI score of intervention group members at baseline measurement was 11.31 ± 1.36. This then reduced to 8.09 ± 1.33, 6.20 ± 1.23, and 5.29 ± 1.16 scores after 2-week, 4-week, and 6-week post measurements, respectively. The mean total MNSI score of the control group at baseline was 11.24 ± 1.49, which then increased to 11.56 ± 1.71, 11.71 ± 1.75, and 12.39 ± 1.69 after 2-week, 4-week, and 6-week post measurements, respectively. The baseline MNSI score of the intervention group in the subjective section was 7.43 ± 0.92 scores then reduced to 5.66 ± 1.19, 4.23 ± 1.11, and 3.49 ± 1.09 after 2-week, 4-week and 6-week, respectively. The MNSI score of the intervention group for the objective section at baseline was 3.89 ± 1.15 and then reduced to 2.43 ± 0.82, 1.97 ± 0.70, and 1.80 ± 0.61 after 2-week, 4-week, and 6-week post measurements, respectively.

Table 2. Mean and standard deviation of MNSI scores at baseline and post measurements according to intervention and control groups

Measurements	Intervention group (n = 35)		Control group (n = 35)		Overall (n = 70)	
	Mean ± SD	95% CI	Mean ± SD	95% CI	Mean ± SD	95% CI
Baseline						
Total scores	11.31 ± 1.36	10.85-11.78	11.24 ± 1.49	10.73-11.76	11.28 ± 1.42	10.94-11.62
Subjective part	7.43 ± 0.92	7.11-7.74	7.37 ± 0.65	7.15-7.59	7.40 ± 0.79	7.21-7.59
Objective part	3.89 ± 1.15	3.49-4.28	3.87 ± 1.29	3.43-4.31	3.88 ± 1.21	3.59-4.17

Measurements	Intervention group (n = 35)		Control group (n = 35)		Overall (n = 70)	
	Mean ± SD	**95% CI**	**Mean ± SD**	**95% CI**	**Mean ± SD**	**95% CI**
Post (2-week)						
Total scores	8.09 ± 1.33	7.63-8.54	11.56 ± 1.71	10.97-12.14	9.82 ± 2.32	9.27-10.37
Subjective part	5.66 ± 1.19	5.25-6.06	7.60 ± 0.91	7.29-7.91	6.63 ± 1.44	6.29-6.97
Objective part	2.43 ± 0.82	2.15-2.71	3.96 ± 1.34	3.50-4.42	3.19 ± 1.34	2.87-3.51
Post (4-week)						
Total scores	6.20 ± 1.23	5.78-6.62	11.71 ± 1.75	11.11-12.32	8.96 ± 3.16	8.20-9.71
Subjective part	4.23 ± 1.11	3.85-4.61	7.65 ± 0.94	7.34-7.98	5.94 ± 2.00	5.46-6.42
Objective part	1.97 ± 0.70	1.73-2.21	4.06 ± 1.37	3.59-4.53	3.02 ± 1.50	2.66-3.37
Post (6-week)						
Total scores	5.29 ± 1.16	4.89-5.69	12.39 ± 1.69	11.81-12.97	8.84 ± 3.85	7.92-9.75
Subjective part	3.49 ± 1.09	3.11-3.86	7.94 ± 1.14	7.55-8.33	5.71 ± 2.50	5.12-6.31
Objective part	1.80 ± 0.61	1.59-2.01	4.45 ± 1.33	3.99-4.90	3.13 ± 1.68	2.72-3.52

SD=Standard deviation

Mean difference of Michigan neuropathy screening instrument scores comparison between intervention and control groups

Mean MNSI scores at baseline measurement were 11.31 ± 1.36 and 11.24 ± 1.49 in intervention and control groups, respectively. Mean MNSI scores in the intervention group decreased to 8.09 ± 1.33, 6.20 ± 1.23, and 5.29 ± 1.16 at 2-week, 4-week, and 6-week post-intervention, respectively. While, these scores increased to 11.55 ±1.71, 11.71 ±1.75, and 12.39 ±1.69 in the control group (Figure 2 and Table 3). Table 3 shows the mean difference of MNSI scores comparison between intervention and control groups. Controlling for baseline measurement and other factors such as gender, age, marital status, BMI, frequency of exercise, hypertension, duration of DM, FBS, using sulfonylurea, using GLP-1 receptor agonist as well as using Insulin, this study showed that after 2 weeks, the mean MNSI in the intervention group was reduced by 3.63 (95% CI: 3.10-4.15; p-value <0.001) compared to the control group. After 4 weeks, the mean MNSI in the intervention group was reduced by 5.61 (95% CI: 4.95-6.27; p-value <0.001) compared to the control group. After 6 weeks, the mean MNSI in the intervention group was reduced by 7.22 (95% CI: 6.52-7.92; p-value <0.001) compared to the control group. Overall post measurements, mean of MNSI in intervention group was reduced by 5.49 (95% CI: 5-5.98; p-value <0.001) compared to the control group (Table 3).

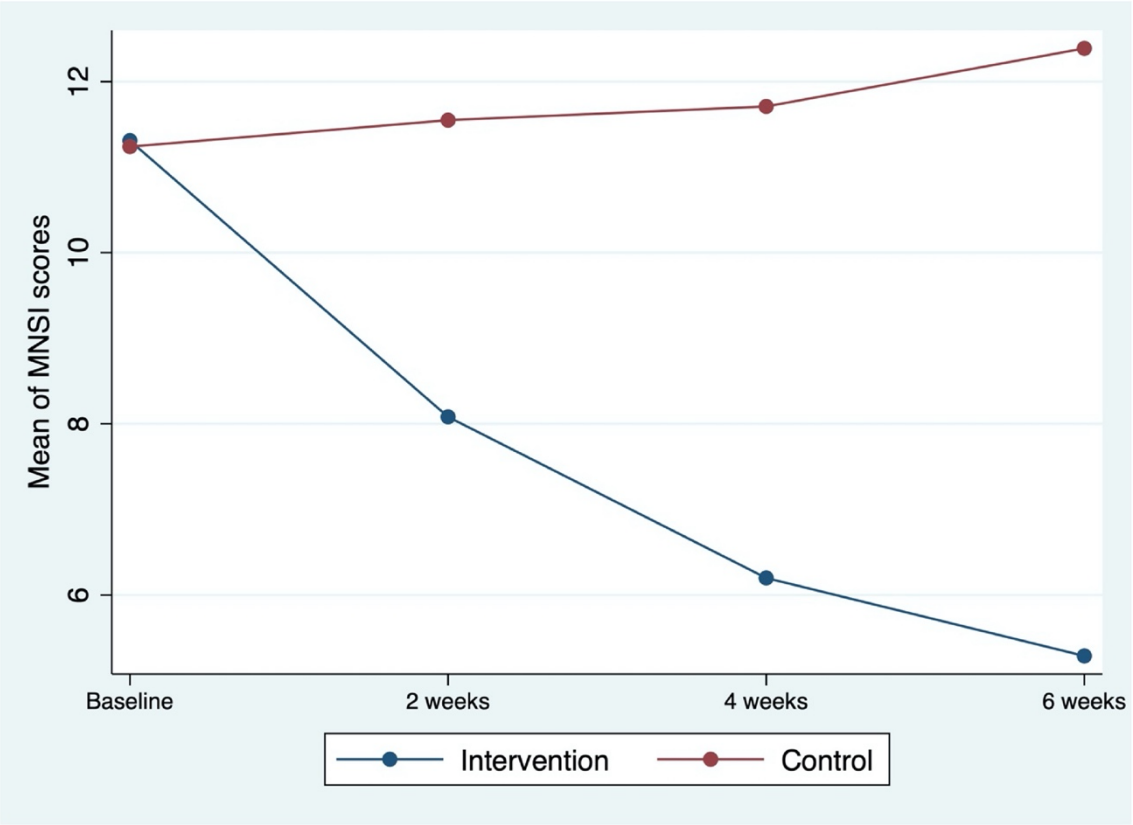

Figure 2. Comparison of control and intervention groups at baseline, 2-week, 4-week and post intervention of outcomes

Table 3 Mean difference of MNSI scores comparison between intervention and control groups

Measurement of MNSI scores	Intervention (n = 35)	Control (n = 35)	Crude mean diff. 95% CI p-value	Adjusted mean diff. 95% CI p-value
	Mean ± SD	Mean ± SD		
Baseline	11.31 ± 1.36	11.24 ± 1.49	N/A	N/A
Post (2-week)	8.09 ± 1.33	11.55 ± 1.71	-3.53 -3.06, -4.00 <0.001	-3.63 -3.10, -4.15 <0.001
Post (4-week)	6.20 ± 1.23	11.71 ± 1.75	-5.56 -4.98, -6.14 <0.001	-5.61 -4.95, -6.27 <0.001
Post (6-week)	5.29 ± 1.16	12.39 ± 1.69	-7.13 -6.52, -7.75 <0.001	-7.22 -6.52, -7.92 <0.001
Overall post measurements	N/A	N/A	-5.40 -4.94, -5.87 <0.001	-5.49 -5.00, -5.98 <0.001

Crude mean diff=Mean difference comparison between intervention and control adjusted for baseline measurement after ignoring other factors; Adjusted mean diff=Mean difference comparison between intervention and control adjusted for baseline measurement and other factors; CI=Confidence interval; N/A=Not available

DISCUSSION

The present study investigated the effect of self-massage combined with a health education program using self-efficacy theory on reducing peripheral neuropathy among DPN patients, compared with a control group who received only standard guidelines from the hospital. The participants were compared for mean MNSI scores with the intervention group experiencing a significant improvement in MNSI compared to the controls.

The study showed that the mean scores of MNSI at 2, 4 and 6-week follow-ups in the control group increased over time, while in the intervention group, the mean scores of MNSI reduced by 8.09 ± 1.33, 6.20 ± 1.23, and 5.29 ± 1.16 at 2, 4, and 6-week post-intervention, respectively. The findings revealed that this intervention program was effective and consistent with a previous study in Thailand in 2015, which found that DPN patients who received a modified Thai traditional foot massage experienced a significant improvement in foot sensation[14]. In line with this finding, Agustini et al. (2019)[24] investigated the effect of foot massage on decreasing DPN complaints when performing foot massage for approximately 15 minutes each session, twice a week for 4 weeks. They found that foot massage is not only effective at reducing the complaints of peripheral neuropathy but it can also provide a comfortable feeling, which may affect stress reduction. However, the prior study was designed as a one group pretest-posttest design without a control group. Similarly, in the pre-test and post-test experimental design by Sunarmi et al. (2022)[15] on DPN patients, electric foot massage for 15 minutes, twice a week for as long as 4 weeks was effective in reducing the complaints of DPN. Evidence suggested that the comparison of experimental treatment with standard care in a randomized controlled trial can aid in maintaining clinical equipoise by assessing benefit, harm, or futility, therefore allowing decisions on continuation or termination of the treatment in clinical practice[25]. Thus, the findings of present study confirmed the utility of self-massage combined with a health education program as an alternative treatment for DPN patients.

Self-massage could significantly improve peripheral neuropathy among DPN patients because its effect can increase blood circulation around the muscles of the lower leg, plantar and instep. However, the present study involved self-massage for a longer duration and more frequently than the previous reports[14, 15, 24] resulting in better blood flow. Self-foot massage caused an increase in peripheral tissue perfusion by increasing blood circulation to the periphery, transporting oxygen, and nutrients to distal areas; moreover, massage can affect blood vessels by dilatation of superficial blood vessels and increase the rate of blood flow[15]. In addition, it resulted in improving peripheral neuropathy and also decreased foot numbness[14, 15]. Foot massage also increased the flexibility of muscles and enhanced the range of motion of joints[26]. Evidence supports that foot massage can improve mobility and reduce the incidence of neuropathic ulcerations in DPN patients, which may occur due to the improvements in the range of motion of the ankle and metatarsophalangeal joints, and enhanced skin sensation of the foot after foot massage[14, 27].

The study design incorporated repeated measures including baseline and 3 post measurements. The findings showed reduction in the mean scores of MNSI after 2 weeks, 4 weeks, and 6 weeks, compared to the baseline measurement. At each measurement, and at the end of the study the mean MNSI scores in the intervention

group were statistically significantly lower than those in the control group. The effect of self-massage combined with a health education program in the present study was able to reduce the MNSI in DPN patients. Another study in Thailand (2019) also found similar results on foot sensation using self-foot massage utilizing a wooden massage device in DM patients[28]. Furthermore, another previous study supported that foot massage could improve functional mobility in DM patients due to the reduction in foot numbness[25]. Thus, foot massage should be added to rehabilitation programs for DPN patients to improve their physical function.

The similar baseline characteristics of participants in the two groups in present study might assist to verify the effect of specific self-massage combined with health education in being able to improve MNSI in DPN patients. However, there were some limitations of the study. A larger sample size is recommended for participants to discover further factors that were associated with peripheral neuropathy. Furthermore, this study was not designed to follow up the improvement of sensation after 6-week training. Thus, the findings could not prove the retention effect of self-massage therapy.

CONCLUSION

The present findings confirmed that using self-massage combined with health education could improve MNSI more than using normal guidelines from the hospital in DPN patients. In addition; the study also revealed that 6 weeks of specific self-massage was an appropriate period and enough to improve peripheral neuropathy in these individuals. This self-massage and health education program, therefore, has the potential to prevent severe complications and promote health status in DPN patients. The findings could assist health practitioners in promoting health status and reducing numbness in these individuals.

RECOMMENDATION

A larger sample size is recommended for participants to discover further factors that were associated with peripheral neuropathy. Moreover, further research should investigate the retention effect of self-massage beyond the 6-week training in order to reduce numbness sustainably. Recommendations regarding the intervention program related to self-massage and health education in DPN patients should be applied by healthcare workers, so that such an intervention program may be available as an alternative treatment for diabetic patients in clinical settings.

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