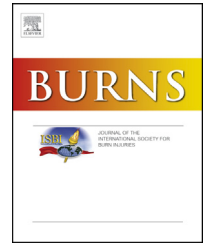


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# Potential efficacy of sensorimotor exercise program on pain, proprioception, mobility, and quality of life in diabetic patients with foot burns: A 12-week randomized control study

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## ABSTRACT

**Background:** Both diabetes mellitus (DM) and burn injuries lead to physical and psychological impairments. Foot burns are still a challenging health condition because of its important sensory role. No previous studies have assessed the physical therapy intervention on diabetic patients with foot burns. Therefore, this study aimed to assess the potential efficacy of sensorimotor exercise on pain, proprioception, mobility, balance, and quality of life in diabetic patients with foot burns.

**Methods:** Between July 2019 and February 2020, thirty-three diabetic patients with foot burns, aged 32 to 46yrs, were enrolled in this randomized control study, and randomized consecutively into two groups, study group ( $n=16$ ) and control group ( $n=17$ ). The study group underwent a sensorimotor exercise program thrice a week for 12 consecutive weeks, however the control group did not undergo the exercise intervention. Both groups were instructed to conduct home exercises. Visual analogue scale (VAS), proprioceptive responses, time-up and go (TUG) values, and short form-36 (SF-36) have been assessed prior and subsequent to the study intervention.

**Results:** No significant differences were observed between groups regarding baseline data ( $p>0.05$ ). Subsequent to 12wk intervention, the study group showed significant improvements in outcome measures (proprioceptive responses,  $p<0.05$ , VAS,  $p<0.001$ , TUG,  $p=0.003$ ,

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and SF-36,  $p < 0.001$ ) and the control group exhibited significant changes in VAS and SF-36 ( $p = 0.004$ ,  $p = 0.043$  respectively) however, no significant changes were found in proprioceptive responses and TUG values ( $p > 0.05$ ). Between groups, the post-intervention comparison demonstrated statistical differences with tending toward the study group (proprioceptive responses,  $p < 0.05$ , VAS,  $p < 0.001$ , TUG,  $p = 0.013$ , and SF-36,  $p = 0.046$ ).

**Conclusions:** Sensorimotor exercise training may improve, pain, proprioceptive responses, mobility, balance, and quality of life in diabetic patients with foot burns. Physiotherapists and rehabilitation providers should include the sensorimotor exercise in their protocols in the treatment of diabetic patients with foot burns.

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## 1. Introduction

Egypt is one of the 21 international locations and regions of the International Diabetes Federation (IDF) in the Middle East and North Africa (MENA) locale. In the world, 463 million persons have diabetes mellitus (DM), and 55 million are in the Middle East and North Africa (MENA) region; by 2045 this is projected to be 108 million people. DM is a fast-growing health problem, affecting 15.2% of the Egyptian adults (8,850,400 millions) among 58,091,500 total adults [1].

DM leads to delay of wound healing, vascular damage, immune dysfunction, metabolic disturbances, high risk of infection and vascular injury [2]. Therefore, burned patients with uncontrolled diabetes are at risk for detrimental results [3]. Healthy people with burns additionally develop stress-induced hyperglycemia because of endocrinal complications from their injury [4]. In the meantime, people with pre-existing DM are at a higher risk for burns and wound healing complications [5].

DM has a less understood complication on the vestibular system, which is responsible for balance in static and dynamic conditions. DM affects the structures and functions of vestibular system in animals and clinical studies [6–8]. Therefore, physiotherapists have to consider the effect of DM on vestibular system due to the risk of falls during assessment, planning and treatment. Physiotherapy can improve diabetic control, physical function, gait and balance by exercises either aerobic, resistive or a combination of them in diabetic patients [9–12].

Foot burns are a critical health problem that could lead to physical and psychological disabilities [13]. Although the foot has a small surface area (approximately 3.5% of the total body surface area), it has an important and specialized role in function that could lead to a serious morbidity. Because of the location, burns to the feet may prolong bedrest, delay return to work, and burn-related complications could give rise to emotional and financial effects [14,15].

Usually, foot burns occur in patients with DM and disability in different ages such as elderly, adults, and children [13,15]. Soft tissue loss subsequent to foot burns is considered a difficult problem as a result of poor vascularization of lower limbs, reasonably tensed skin tissues, and restricted local flutters [16].

Sensorimotor exercise training is an unusual form of proprioceptive and stability exercises that is used for the chronic musculoskeletal pain. It depends on the concept that instead of emphasizing the isolated muscle group strength

around a joint, we must recognize the importance of the central nervous system (CNS) in motion regulation to achieve desirable patterns for preserving joint stability [17,18]. It has been reported that sensorimotor exercise training is characterized by regeneration of neuromuscular structures [19], the reduced occurrence of injuries [20,21], and by functional adaptations of the neuromuscular system [22,23], leading to proprioception improvement [23], balance control and coordination [24] and improving mobility.

Although previous studies confirmed the beneficial effects of exercise on diabetics and burn patients separately [17,25–27] or in combination [28], our current study is the first to assess the potential efficacy of sensorimotor exercise on pain, proprioception, mobility, balance, and quality of life in diabetic patients with foot burns theorizing that this type of exercise may improve pain, proprioception, mobility, balance, quality of life in those patients.

## 2. Materials and methods

### 2.1. Study design

This study was a single-blind randomized control clinical study. It was conducted at the physiotherapy outpatient clinic of the tertiary Kasr-Al-Aini hospital between July 2019 and February 2020. It was approved by the local Institutional Ethical Committee of the Physical Therapy Department at Cairo University Hospitals in accordance with ethical standards and guidelines of Helsinki Declaration, and each patient was instructed to sign a written informed consent before starting the study.

### 2.2. Participants

Thirty-four diabetic patients with foot burns, aged 32–46yrs, were recruited from the Department of Surgery and Burns, and randomized consecutively into two equal groups ( $n = 17$ ), study group (SG) and control group (CG). Patients were included in the study according to the following criteria; (1) diagnosed with type 2 diabetes mellitus (T2DM), (2) more than 6-month post foot burns, (3) total body surface area (TBSA)  $\leq 30\%$ , (4) flames or scalds burn, (5) partial to full-thickness burn, (6) skin graft or none, (7) visual analogue scale (VAS)  $\leq 8$ . However, the exclusion criteria were cognitive or mentality dysfunctions, psychiatric conditions, fractures, pregnancy, cancer, severe vascular complications, inability to walk.

### 2.3. Randomization and blindness

After assessing the patients for eligibility, they were randomized using sealed envelopes to two groups, equal in number ( $n=17$ ). The study group (SG) underwent the sensorimotor exercise program plus home exercise program, and the control group (CG) underwent the home exercise program only without conducting the sensorimotor exercise program. Before starting the study, a simple randomization was performed by a blinded physiotherapist using opaque sealed envelopes contained a specific code for each group.

### 2.4. Intervention

The two study groups were recommended and encouraged frequently to conduct the home exercise program regularly through the twelve weeks of the study in the form of stretching and walking exercise at least twice weekly. Each patient was informed about the benefits of adherence to home exercise program and encouraged to conduct it. One of the family members confirmed patient adherence to the recommended home exercise program.

The study group underwent a sensorimotor exercise program plus home exercise program. The sensorimotor exercise program was performed three times per week for twelve consecutive weeks in the outpatient physiotherapy clinic under the professional supervision of physiotherapists. Each training has been started with 10min warming-up of moderate-intensity aerobic exercise (50–60% of maximal heart rate) using a treadmill or cycle ergometer. The sensorimotor exercise has consisted of core and balance exercises and wall slides on unstable surfaces using soft Thera-Band stability trainers (TheraBand<sup>®</sup>, Richmond, Texas, USA), and different patterns of gait training including side to side, forward, and backward walking exercises. The session was ended with 5–10min cooling-down of deep breathing and mild-stretching exercises. The exercise session was adapted, delayed, or discontinued in accordance with the standards of medical care in diabetes reported by the American Diabetes Association [29]. The level of exercise increased gradually every six sessions if endured.

The control group was recommended to regularly undergo the home exercise program only without conducting the sensorimotor exercise program through the twelve weeks of the study.

### 2.5. Outcome measures

The main measure of the study was a proprioceptive assessment, while secondary measures were pain severity, mobility, balance, and quality of life. All measures were assessed pre- and post-intervention by blinded physiotherapists who were not included in the study interventions.

### 2.6. Proprioception assessment

Proprioceptive response was assessed using Pedalo-balance equipment (Pedalo<sup>®</sup> Sensamove. Balance Test with Sensor, Sport-Thieme AG, Gallen, Switzerland). It is a reliable device, used to assess the differences between baseline and adaptable

stimuli [30,31]. All patients were informed about the test procedures before undergoing the test. Each patient was instructed for a maximal tilting from standing position in left, right, forward, and backward directions. The maximal tilt angle was measured as a center of pressure. The patient was then instructed to shift the center of pressure to the colored mark presented on the monitor with pointer assistance and to keep this mark in mind, and after that reaching the mark on the monitor without pointer assistance. The changes in the maximal tilt angle between the baseline and adaptable stimuli were assessed in all directions.

### 2.7. Pain severity assessment

Pain severity was assessed using the visual analogue scale (VAS). It is a widely used, validated and reliable 10-cm instrument [32]. Each patient was asked to draw a perpendicular line on the VAS at the point that signifies the pain severity. The score of VAS ranged 0–10, 0 suggests no pain and 10 suggest severe pain [33].

### 2.8. Mobility and balance assessment

Mobility and balance were assessed using Time Up and Go (TUG) test. The reliable TUG test was validated to assess the function of lower limbs in burned patients [34]. Each patient was asked to stand from the chair, to walk 3 meters, and come back to the chair. The time spent was recorded in sec and the differences between pre- and post-intervention were assessed.

### 2.9. Quality of life assessment

Quality of life (QOL) was assessed using the short form-36 questionnaire (SF-36). This 36-item self-reported questionnaire comprises 8 domains including general health, mental health, role emotion, role physical, body pain, social function, physical function, and vitality. SF-36 consists mainly of physical and mental components [35]. It is a valid and reliable instrument used in the assessment of burned survivors [36]. Total score ranges from 0 to 100, 0 indicates the poor quality of life and 100 indicates the best quality of life.

### 2.10. Sample size computation

Sample sized computation was based on VAS changes utilizing G\*Power for window (Version 3.1.9.2, Dusseldorf, Germany) aiming to identify a mean difference of 2 and a standard deviation of 1.6 depending on preliminary study findings. Using a two-sided t-test and  $\alpha$ -error of 0.05, 14 patients per each group were required to achieve 90% power. A total sample of 34 patients was included in the study considering the maximal dropout rate is 20%.

### 2.11. Statistical analysis

Demographic and baseline data were examined for normality using the Shapiro–Wilk test. Descriptive analysis was conducted to assess the differences between and within groups. Continuous data were analyzed using Students' t-test

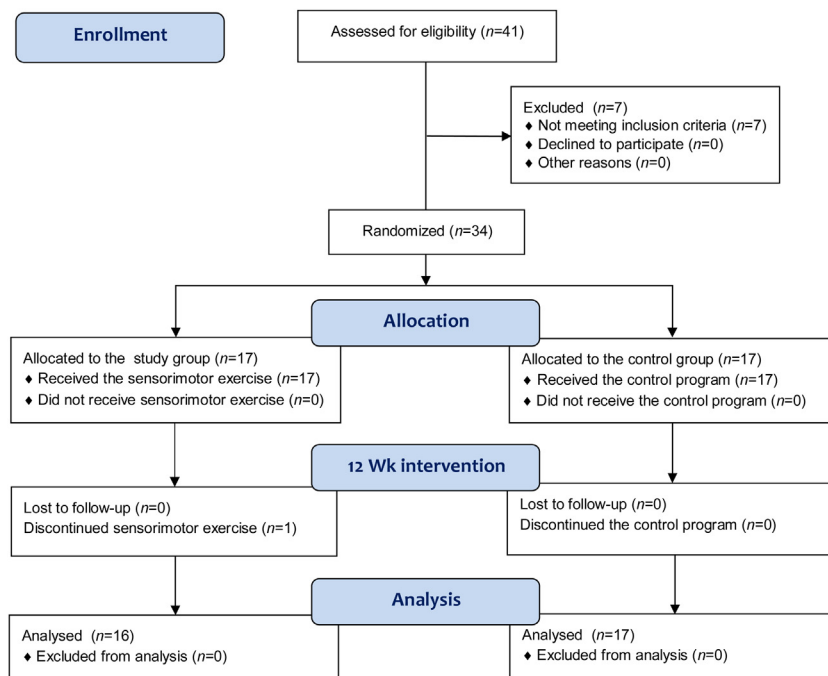


Fig. 1 – The CONSORT flow diagram of the study.

(independent between groups and dependent within each group), however categorical data were analyzed using Mann–Whitney *U* test and Chi-square test. SPSS for windows (V.25, IBM Corp., Armonk, NY, USA) was used for all statistical analysis and the level of significance was set at  $p$ -value  $< 0.05$ .

### 3. Results

Forty-one patients were assessed for eligibility for the study. Thirty-four of them were eligible and included in the study procedures. One patient discontinued the SG treatment and has been excluded from the data analyses. The CONSORT flow diagram of the study is displayed in Fig. 1. Patient baseline characteristics are displayed in Table 1. No significant differences were observed between groups regarding baselines such as age, sex, BMI, duration post-burn, duration of hospital stay, TBSA, etiology, depth of burns ( $p > 0.05$ ).

The mean differences in the baseline outcome measures showed no significant differences between SG and CG groups as displayed in Table 2 ( $p > 0.05$ ). The maximal tilt angle between the baseline and adaptable stimuli showed significant reduction in the SG in all directions (forward,  $p = 0.024$ , backward,  $p = 0.006$ , right,  $p = 0.002$ , left,  $p = 0.001$ ) however no significant changes were found in the CG (forward,  $p = 0.503$ , backward,  $p = 0.562$ , right,  $p = 0.491$ , left,  $p = 0.464$ ). Between groups, the post-intervention comparison has demonstrated statistical significant differences (forward,  $p = 0.047$ , backward,  $p = 0.016$ , right,  $p = 0.008$ , left,  $p = 0.009$ ) as demonstrated in Table 2.

Regarding pain severity, VAS has significantly improved in the SG and CG groups ( $p < 0.001$ ,  $p = 0.004$  respectively). Between groups, the post-intervention comparison has demonstrated

statistically significant differences in favor of SG ( $p < 0.001$ ). For TUG, there were significant changes in the SG ( $p = 0.003$ ) however no significant change was found in the CG ( $p = 0.429$ ), and between groups comparison showed a significant difference in favor SG ( $p = 0.013$ ). For the quality of life, the total score of SF-36 showed significant changes in the SG and CG groups ( $p < 0.001$ ,  $p = 0.043$  respectively). SF-36 showed a greater

Table 1 – Baseline characteristics of the study.

	SG (n=16)	CG (n=17)	p-Value
Age, yr	38.6±7.1	39.2±6.7	0.804
Sex, M/F	10/6	9/8	0.578
BMI, kg/m <sup>2</sup>	25.7±3.5	26.1±3.8	0.755
HbA1c, %	7.4±1.6	7.2±1.8	0.738
Duration post burns, m	8.7±1.7	8.3±1.5	0.478
Duration of hospital stay, days	42.3±7.2	41.5±6.6	0.741
Affected side, uni/bilateral	9/7	11/6	0.619
TBSA, %	24.3±3.8	23.9±4.2	0.776
Burn depth, n (%)			
Partial thickness	11 (68.75)	13 (76.47)	0.618
Full thickness	5 (31.25)	4 (23.53)	
Skin graft, n (%)			
Yes	10 (62.5)	12 (70.6)	0.622
No	6 (37.5)	5 (29.4)	
Etiology of burn, n (%)			
Scald	11 (68.75)	11 (64.7)	0.805
Flame	5 (31.25)	6 (35.3)	

Significant at  $p$ -value  $< 0.05$ . Data showed as means±SD and frequency (percentages), SG: study group, CG: control group, BMI: body mass index, HbA1c: glycated hemoglobin, TBSA: total body surface area.

**Table 2 – Mean pre- and post-intervention changes between and within groups.**

Measures	SG (n=16)	CG (n=17)	p-Value
Proprioception, MTA			
Forward, degrees			
Pre-	7.68±3.64	7.72±3.68	0.975
Post-	5.32±1.7	6.96±2.8	0.047*
p-value	0.024*	0.503	
Backward, degrees			
Pre-	9.85±4.32	9.96±4.52	0.943
Post-	6.17±2.51	9.11±3.92	0.016*
p-value	0.006*	0.562	
Right, degrees			
Pre-	8.75±3.83	8.82±3.79	0.958
Post-	5.02±2.13	7.94±3.56	0.008*
p-value	0.002*	0.491	
Left, degrees			
Pre-	8.61±3.68	8.78±3.75	0.896
Post-	4.93±2.06	7.84±3.63	0.009*
p-value	0.001*	0.464	
VAS			
Pre-	6.5±1.4	6.6±1.2	0.827
Post-	3.2±0.8	5.4±1.1	<0.001*
p-value	<0.001*	0.004*	
TUG, s			
Pre-	10.5±1.4	10.7±1.6	0.706
Post-	9.2±1.1	10.3±1.3	0.013*
p-value	0.003*	0.429	
SF-36, total score			
Pre-	44.8±9.5	48.3±10.7	0.329
Post-	63.5±8.3	56.3±11.4	0.046*
p-value	<0.001*	0.043	

\* Significant at p-value < 0.05. Data showed as means ± SD, SG: study group, CG: control group, MTA: maximal tilt angle, VAS: Visual analogue scale, TUG: time up & go, SF-36: short form-36.

improvement in the SG than CG ( $p=0.046$ ) as demonstrated in [Table 2](#).

#### 4. Discussion

The current study assessed the effects of sensorimotor exercise on diabetic patients with foot burns theorizing that this type of exercise may improve pain, proprioception, mobility, balance, quality of life in those patients. The study contributes to the literature by showing that 12wk sensorimotor exercise may improve VAS, proprioception, TUG, and SF-36.

Treatment of diabetic patients with foot burns has to focus on eliminating subsequent deformities, reducing post-burn pain, improving proprioception and balance, restoring mobility, and improving the quality of life, whether surgical or non-surgical interventions were performed.

Burns are generally related to numerous serious physical and psychological complications in healthy subjects that lead to an increase in morbidity and mortality rates [37]. DM is also associated with serious health problems such as axons and neuronal deficit through inflammatory influences which could lead to peripheral neuropathy [38]. DM has been identified as an important risk factor that affects burn injury because of sensory and vision impairments such as diabetic neuropathy and retinopathy. As a result, diabetic patients are

more susceptible to severe complications of burn injury that oblige specific modalities of the rehabilitation program [39].

Foot burns are still a challenging health condition because of the important sensory role of the feet [40]. It constitutes an imperative sensory component in the physiological control of body posture. As an explicit and overwhelmingly unique mediator between humans' body and the ground, feet allow the body to feel and react with indoor and outdoor environments [41]. Sensation inputs supplied by cutaneous and muscular receptors in the feet provide the capability of upright standing, and posture sway is required to reveal body position and movement in the space. The sensitivity of foot skin declines in aging and other neural dysfunctions such as diabetes-related neuropathy [41]. This impairment of foot sensitivity consequently affects body posture and body balance, and increases the risk of falling among diabetic patients with foot burns.

Our study showed that sensorimotor exercise plays an important role in interventional physiotherapy and rehabilitation modalities for diabetic patients with foot burns. Through undergoing a 12wk sensorimotor exercise program, there were improvements in pain, proprioception, mobility, and quality of life. Therefore, diabetic patients with foot burns who undertake this type of exercise may have less pain and better proprioception, mobility, balance, and quality of life. Moreover, sensorimotor exercise may improve static and dynamic balance [42], and thereby declines the risk of falls among those patients.

In conformity with our findings, previous studies have concluded that exercise training reduces musculoskeletal pain in diabetic patients [43]. Exercise training has analgesic influences through enhancing the release of endogenous opioids [44]. An earlier study supported the analgesic responses to exercise training in healthy individuals, and reported that both high and moderate intensity exercises have potential analgesic effects in healthy individuals [45].

For proprioception, 12-week of sensorimotor exercise shows that the errors of position imitation have reduced in forward, backward, right and left directions. Additionally, it was reported that 8-week of balance training has improved the proprioceptive responses in diabetic neuropathy patients [46]. Since the decline of proprioception leads to posture instability in diabetic patients, improvement in proprioception responses may enhance posture stability and balance in diabetic patients with foot burns.

Similarly, prior articles reported that mobility and balance have been improved following six to twelve weeks of balance exercise through assessment of TUG, function reaching test, and walking over the beam in older adults with diabetic neuropathy [46–48]. Conversely, one study observed non-significant changes following a 3-week balance exercise [49]. The TUG value ranged from 8.7 to 13.5s most study patients. TUG > 14 signifies high falling risk while < 10 signifies low falling risk [50].

Consequently, quality of life has been enhanced subsequent to improvements in pain, proprioceptive feedback, and mobility. In harmony with these findings, prior studies stated that high physical activities are associated with high scores of quality of life [51,52]. In addition, our previous study found that exercise training improves quality of life in diabetic burned patients [25].

The major strength of the current study was that 12-week of the sensorimotor exercise was safe and tolerable for diabetic patients with foot burns. Another strength was the homogenized study sample that allows generalizing the findings to those patients. One more strength was the objective assessment used to determine proprioception and mobility. In contrast, some limitations were reported. The major limitation was the selected specific sample for the study by focusing only on foot burns which affect the generalizability of other areas of burns in diabetic patients. Also, the study lacked long-term assessment post-intervention. One more limitation was that the home exercise program was not supervised. Further studies are necessary to include diabetic patients with different burned areas of lower extremities with long-term assessment (six-month to one-year post-intervention).

## 5. Conclusion

Sensorimotor exercise training may improve, pain, proprioceptive responses, mobility, balance, and quality of life in diabetic patients with foot burns. Physiotherapists and rehabilitation providers should include the sensorimotor exercise in the rehabilitation program for diabetic patients with foot burns.

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## Conflicts of interest

No competing interests to disclose.

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