



REFLEXOLOGY AND QUALITY OF LIFE IN DIABETIC PATIENTS: RANDOMIZED CLINICAL TRIAL

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ABSTRACT **BACKGROUND:** The chronic nature of diabetes mellitus and the complexity of its treatment interfere with the patient's quality of life (QOL). Reflexology is one of the most popular complementary therapies in the world. It is a systematic practice in which applying some pressure to any particular points on the feet gives impacts on the health of related parts of the body. The current study aimed to evaluate the effects of feet reflexology on the quality of life of diabetic patients.

METHODS: Randomized, controlled and single-blind clinical trial performed at a diabetes educational center, in Brazil. Sixty two type 2 diabetic patients were randomized to receive self-care guidelines with feet and 12 sessions of feet reflexology (TG; n=32), and only self-care guidelines with feet (CG; n=30). Before starting reflexology therapy and after four consecutive weeks were applied the instruments for QOL (SF-36), and the Stanford Health Assessment Questionnaire Disability Index (HAQ-DI), for assessment of functional capacity. This research was conducted in accordance with the ethical recommendations of the Declaration of Helsinki.

RESULTS: After feet reflexology therapy the SF-36 scores, functional capacity (FC), role-physical (RP), pain (P), role-emotional (RE), and HAQ-DI were better in TG group, when compared with CG group, (FC: TG=90,8±10,7 vs CG=83,5±5,0, $p=0,01$; RP: TG=95,3±7,6 vs CG=85,3±85,3, $p=0,01$, P: TG=80,2±7,2 vs CG=67,3±12,2, $p=0,01$; RE: TG=95,0±7,2 vs CG=81,5±15,1, $p=0,01$; HAQ-DI: TG=93,7% vs CG=66,7%, $p=0,01$).

CONCLUSION: Feet reflexology therapy has improved the patient's quality of life (QOL), in functional capacity, role- physical, pain, role-emotional aspects.

KEYWORDS : diabetes complication; complementary therapy; massage; quality of life; disability evaluation.

INTRODUCTION

World Health Organization defines quality of life as individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns¹. Quality of life as reported by the patients is the patient's perspective on health, disease, which is easily missed in a clinical scenario. Studies have found that health-related quality of life (HRQOL) is an independent marker of mortality², and even, lower physical and mental HQOL are found to be associated with higher rates of overall mortality and cardiovascular-related mortality in type 2 diabetes³.

The chronic nature of diabetes mellitus (DM), the complexity of its treatment, the severity of its complications and its social impact affect the patients' quality of life, negatively⁴.

In public health and in medicine, the concept of health related quality of life refers to a person's or group's perceived physical and mental health over time. Physicians have often used HRQOL to measure the effects of chronic illness in their patients to better understand how an illness interferes with a person's day-to-day life. Similarly, public health professionals use health-related quality of life to identify subgroups with poor physical or mental health and this can help guide policies or interventions to improve their health. The HRQOL deficits reported by patients with DM are generally attributed to the disease itself, its restrictive treatment regimens and its associated comorbidities. Complications of DM affect quality of life more than the overall treatment intensity⁵.

Reflexology is a systematic practice in which applying some pressure to any particular points on the feet give impacts on the health⁶. Studies

in other countries have shown that the reflexology and foot massage influenced the symptoms of some clinical conditions such as decreasing stress and tension in menopause⁷, postural regulation in neuropathy⁸, and decreasing pain in women with multiple sclerosis⁹.

In diabetic patients, a study showed that the massage applied to the plantar region led to an improvement in balance, timed performance, functional mobility level, functional reach values, and improving quality of life¹⁰. There are many potential benefits of reflexology for people with DM, particularly relaxation massage such as physical and emotional comfort. Living with DM is inherently stressful. Fluctuating blood glucose levels cause significant short- and long-term complications. The practical demands of balancing food intake with insulin or oral medications, monitoring blood glucose and regulating exercise, as well as undertaking usual life activities, can be a daunting task for many people. Worry about developing DM complications or anxiety relating to work or interpersonal relations, can add to the stress of self-care. Reflexology can reduce stress and improve well-being, which has a secondary effect on blood glucose and lipid levels, and therefore may play a role in preventing complications¹¹.

Sofar, no studies have evaluated the effects of reflexology on quality of life and functional capacity in diabetic patients. We therefore designed a prospective, randomized, and controlled clinical trial to compare the effects of feet reflexology in quality of life and functional capacity of diabetic patients.

METHODS

This is a randomized, controlled and blind clinical trial performed at the Centro Municipal de Educação em Diabetes, Pouso Alegre (MG), Brazil, between January 2016 and March 2017.

The target population consisted of people diagnosed with type 2 diabetes mellitus (DM), aged 18 years or more, and registered in the Centro Municipal de Educação em Diabetes, Pouso Alegre, state of Minas Gerais, Brazil. As exclusion criteria, it was considered: presence of ulcer in the foot, amputation of the lower limb, and cognitive deficits.

A pilot test was conducted with eight diabetic patients, who met the eligibility criteria, for the calculation of the sample size. The sample size was calculated considering the 36-Item Short Form Survey (SF-36) total score as the primary outcome variable. With anticipated mean ± SD of SF-36 total score, in control group, as 76.2 ± 7.3 and expecting 10% more improvement in reflexology group, the sample size was calculated to be 30 samples per group with 95% confidence level and 90% power.

A number of 70 subjects were screened to meet with the eligibility criteria of the clinical trial and a sample size of 68 subjects, diagnosed with type 2 DM and aged 18 years or more was selected for recruitment in the trial. Six patients were excluded from the trial due to their refusal to receive reflexology therapy. Sixty two type 2 diabetic patients were randomized, into two groups: reflexology therapy group, which received self-care guidelines with feet and 12 sessions of feet reflexology therapy (TG; n=32), and control group, which received only self-care guidelines with feet (CG; n=30). The details of the study subjects recruitment procedure are presented in a consort flow diagram as shown in Figure 1.

Before starting reflexology therapy and after four consecutive weeks were applied the Brazilian version of instruments SF-36, and the Stanford Health Assessment Questionnaire Disability Index (HAQ-DI), by a trained researcher who did not know the patient's group.

Blinding was at a single level, the first evaluator determined the eligibility criteria and evaluated the patients for outcome measures at baseline, and the other evaluator independently assessed the outcome measures.

SF-36 is an instrument of easy administration that has been globally used to evaluate the health-related quality of life (HRQOL) in healthy, elderly participants and also in patients with chronic diseases¹². SF-36 is a multidimensional instrument, composed of 36 items, being one item related to changes in health over time and 35 items grouped into eight dimensions: physical functioning (ten items), role limitations caused by physical problems (four items), bodily pain (two items), general health perceptions (five items), vitality (four items), social functioning (two items), role limitations caused by emotional problems (three items) and mental health (five items). Each item presents from two to six answer possibilities and the final score ranges from 0 to 100, being 0 representing the worst HRQOL and 100 the best HRQOL¹³. The physical components scales are: physical functioning, role-physical, pain, general health perceptions, and vitality. The emotional components scales are: social functioning, role-emotional and mental health. The measurement properties, such as reproducibility, validity and sensitivity to change have already been reported as adequate¹⁴.

Stanford Health Assessment Questionnaire Disability Index (HAQ-DI) is a 20-item disease specific questionnaire with eight subscales including dressing & grooming, arising, eating, walking, hygiene, reach, grip, and activities. A four-point Likert scale ranging from 0 (without difficulty) to 3 (with much difficulty) is used for scoring each item. The total score ranges from 0-3 where 0 indicates no disability and 3 indicates the most disability. The total score is calculated by summing the greatest item scores in relevant subscales divided by eight¹⁵.

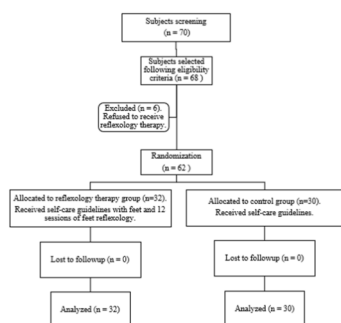


Figure 1: Consort diagram for subjects' recruitment and follow up.

After participants had given written informed consent, they completed SF-36 and HAQ-DI. Then they were given the reflexology therapy, by trained physiotherapist, in the relaxed supine on an examination couch, in separate rooms, covered by a blanket above the ankles leaving the feet exposed. To maintain uniformity and standardization of the technique, the left foot was massaged first and then the right one and an order of pressure points has been established, first the points located on the toes, then the points located in the lateral and medial portions and, finally, in the plantar surface of feet, according to the technique of Lourenço¹⁶. Three therapy sessions a week, during 15 minutes, were performed, totaling 12 sessions over a period of 30 days. After the last therapy session the patients responded again to the SF-36 and HAQ-DI.

Statistical analyses were performed using the Bioestat® 5.3 software version 5.3 (Mamirauá Institute, Brazil). Descriptive values of the obtained data were calculated as mean ± standard deviation (SD), number, and percentage frequencies. Statistical tests such as Mann-Whitney, and Fisher's least significant difference were used to analyze the data. P-value adopted was smaller than 5%.

To ensure the blinding, the study included an interventionist enabled for application of feet reflexology and a trained evaluator to apply the questionnaires. The evaluator did not know to which group each participant belonged.

This study was registered in the Protocol Registration and Results System Clinical Trials (NCT03280524) and has been previously approved by the Ethics Committee (CAAE: 30795814.8.0000.5102). This research was conducted in accordance with the ethical recommendations of the Declaration of Helsinki.

RESULTS

Socio-demographic, economic and clinical characteristics of diabetic patients of the CG and TG are shown in Table 1. There was no difference between the two groups, showing the homogeneity of the sample.

TABLE 1 - Socio-demographic, economic and clinical characteristics of diabetic patients of the control group (CG) and reflexology therapy group (TG).

CHARACTERISTICS	CG (n=30)	TG (n=32)	p
Age (years; X±SD)	60,8±15,3	61,9±17,4	0,6
Years of DM (X±SD)	15,89±5,3	16,35±6,9	0,4
Female sex n (%)	16 (53,3)	17 (53,1)	0,8
Ethnicity, white n (%)	9 (30,0)	10 (31,2)	0,7
Marital status, single n (%)	19 (63,4)	20 (62,5)	0,5
Less than 4 years of education n (%)	16 (53,3)	17 (53,3)	0,6
Unemployed or retired n (%)	16 (53,3)	18 (56,2)	0,7
Household income < US\$ 300* n (%)	10 (33,3)	11 (34,4)	0,7
Urban resident n (%)	12 (40,0)	13 (40,6)	0,8
Physically inactive n (%)	7 (23,3)	8 (25,0)	0,6
Alcohol drinking n (%)	4 (13,3)	5 (15,6)	0,7
Current smoking n (%)	2 (6,6)	2 (6,2)	0,7
Psychotropic drugs n (%)	3 (10,0)	4 (12,5)	0,6
Obesity n (%)	12 (40,0)	12 (37,5)	0,5
X±SD: mean ± standard deviation; DM:diabetes mellitus; * monthly			

TABLE 2- Comparison between the control group (CG) and reflexology therapy group (TG), of the SF-36 scales, on the first and on the 30th day of reflexology therapy.

SF-36 SCALES	FIRST DAY OF REFLEXOLOGY THERAPY			30 th DAY OF REFLEXOLOGY THERAPY		
	CG (n=30)	TG (n=32)	p	CG (n=30)	TG (n=32)	p
Physical Functioning (X±SD)	81,8±16,7	80,6±20,8	0,9	83,5±8,2	90,0±10,7	0,01
Role-Physical (X±SD)	86,5±10,8	87,2±8,1	0,9	85,3±5,0	95,3±7,6	0,01

Pain (X±SD)	66,6±14,4	62,7±10,9	0,7	67,3±12,2	80,2±7,2	0,01
General Health (X±SD)	73,7±23,6	72,5±23,2	0,1	70,3±21,4	73,1±22,3	0,5
Vitality (X±SD)	63,5±2,3	61,6±3,9	0,9	61,8±14,8	60,0±8,5	0,3
Social Functioning (X±SD)	96,7±10,3	96,9±10,0	0,9	97,3±6,9	96,7±7,8	0,5
Role-Emotional (X±SD)	84,6±8,6	86,6±7,9	0,6	81,5±15,1	95,0±7,2	0,01
Mental Health (X±SD)	83,2±13,0	85,8±13,7	0,9	82,9±20,0	84,8±8,3	0,5
X±SD: mean ± standard deviation						

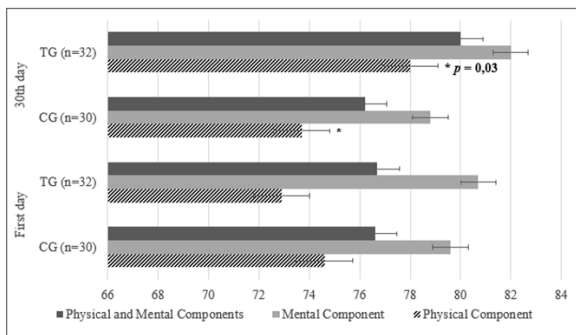


FIGURE 2- Comparison between the control group (CG) and reflexology therapy group (TG) of SF-36 components Physical and Mental scores, on the first and on the 30th day of reflexology therapy.

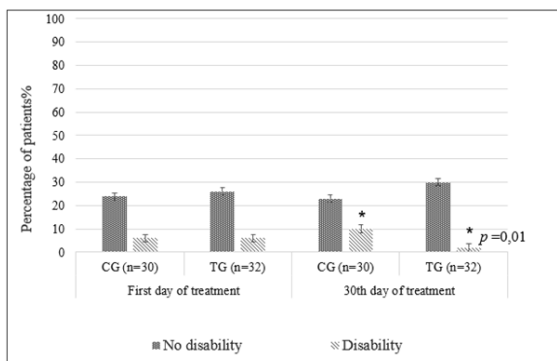


FIGURE 3- Comparison between control group (GC) and reflexology therapy group (GT) of Stanford Health Assessment Questionnaire Disability Index (HAQ-DI), on the first and on the 30th day of reflexology therapy.

DISCUSSION

The current study aimed to evaluate the effects of feet reflexology therapy on the quality of life of diabetic patients. There is no difference between the groups in socio-demographic, economic and clinical characteristics. Before the start of the feet reflexology therapy, the scores of SF-36 scales showed no differences between reflexology therapy and control groups. According to the protocol used for feet reflexology, there was improvement in some scales of quality of life and HAQ-DI, in patients receiving the therapy, after 30 days of treatment. Functional capacity, role-physical, pain, role-emotional, and HAQ-DI scores were better in patients treated with reflexology, when compared with untreated patients. However, we observed no difference in general health, vitality, social functioning and mental health scales. One concern with this is the method for assessing HRQOL. When using a generic HRQOL instrument such as the SF-36 it is possible that it could be insensitive to detect differences in HRQOL. A factor of possible importance is the ceiling effect, i.e. the mean score on a certain scale is already rather high and makes an improvement hard or impossible to detect¹⁷. This is the only study, to our knowledge, using a feet reflexology therapy that has shown improvement in these aspects of quality of life in diabetic patients.

The limitation of this study is that the recruited subjects were those that

presented no ulcer in the foot, no amputation of the lower limb, and no cognitive deficits, than the results cannot be extended to those patients with these comorbidities.

CONCLUSION

Feet reflexology has improved the quality of life of diabetic patients, in functional capacity, role-physical, pain, role-emotional aspects.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

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