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Reflexology treatment relieves symptoms of multiple sclerosis: a randomized controlled study

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Objective: *To evaluate the effect of reflexology on symptoms of multiple sclerosis (MS) in a randomized, sham-controlled clinical trial.* ***Methods:*** *Seventy-one MS patients were randomized to either study or control group, to receive an 11-week treatment. Reflexology treatment included manual pressure on specific points in the feet and massage of the calf area. The control group received nonspecific massage of the calf area. The intensity of paresthesias, urinary symptoms, muscle strength and spasticity was assessed in a masked fashion at the beginning of the study, after 1.5 months of treatment, end of study and at three months of follow-up.* ***Results:*** *Fifty-three patients completed this study. Significant improvement in the differences in mean scores of paresthesias ($P = 0.01$), urinary symptoms ($P = 0.03$) and spasticity ($P = 0.03$) was detected in the reflexology group. Improvement with borderline significance was observed in the differences in mean scores of muscle strength between the reflexology group and the controls ($P = 0.06$). The improvement in the intensity of paresthesias remained significant at three months of follow-up ($P = 0.04$).* ***Conclusions:*** *Specific reflexology treatment was of benefit in alleviating motor, sensory and urinary symptoms in MS patients*
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Key words: *complementary medicine; multiple sclerosis; paresthesia; reflexology; spasticity*

Introduction

Multiple sclerosis (MS) is the commonest human demyelinating disease with a general prevalence rate of 50–100 per 100 000 population in northern Anglo-Saxon communities. This autoimmune disorder is characterized by repeated occurrence of demyelinating lesions within the central nervous system and, similarly to other chronic illnesses, can profoundly affect quality of life and activities of daily living. Among major symptoms caused by MS are spasticity, paresthesias and bladder dysfunction.[1–3] Medical treatment of MS patients has emphasized both pharmacological and rehabilitation approaches.[3–5]

New pharmacotherapeutic agents are targeted mainly to reduce demyelination by modifying the immune response (beta interferons), to enhance remyelination (growth factors) and to improve conduction in demyelinated fibres.[3,6] Unfortunately, some current and investigational therapies are associated with considerable adverse effects, or are of limited efficacy.[2,7]

MS patients, similarly to patients with other chronic diseases, frequently apply to complementary ('alternative') therapies,[8] yet the data concerning their effectiveness, safety or costs is limited.

Reflexology is also known as 'zone therapy' and involves manual stimulation of reflex points on the feet that correspond somatotopically to specific areas and organs of the body. It is based on the theory that all organs are represented by various points on the feet, forming a map of the whole body, and that massaging specific areas of feet can affect corresponding target organs. Although the technique was already well known to ancient Chinese physicians, it was introduced to the west by Dr W Fitzgerald in 1913. Since then, reflexology became one of the most popular treatment modalities in complementary medicine.[9,10] However, only one randomized controlled study was performed until now, demonstrating that specific reflexology treatment is superior to nonspecific massage in treating symptoms of premenstrual syndrome.[11]

Our clinical experience indicated that paresthesias and spasticity in MS and in patients with other disorders could be alleviated by reflexology.

We therefore designed a prospective, randomized, sham-controlled clinical trial to compare the effect of reflexology treatment versus non-specific massage on MS patients with spasticity, sensory and urinary symptoms.

Methods

Planned study population

All patients who were treated at the MS Center, Sheba Medical Center, Tel Hashomer, Israel.

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Inclusion criteria Patients with a definite diagnosis of MS, suffering from paresthesias and/or spasticity, or both.

Exclusion criteria Exclusion criteria were:

- acute relapse of the disease three months preceding or during the study period;
- recent onset or discontinuation (less than one month) of physiotherapy or any other manual treatment (e.g., massage therapy).

This criterion was applied in order to eliminate changes in the muscle tone unrelated to reflexology treatment or to the basic disease.

For the same reason, patients were required to report about any change in their medical treatment during the study.

Protocol

Planned interventions

Patients were randomized by block randomization. Every patient that was found to be eligible to the study was assigned a sealed envelope with the group allocation (study/control). Each patient received 11 weeks of treatment once a week, for 45 minutes. The study was performed at the Clinic of Complementary Medicine, Sheba Medical Center, Tel-Hashomer, Israel, with the participation of 36 reflexologists. Each reflexologist treated one study and one control patient. Patients in the study group received full reflexology treatment which included manual pressure on specific points of foot soles and massage of the calf area, while patients in the control group received sham treatment of nonspecific massage of the calf, providing control for touch therapy and general relaxation. The patients in both groups were therefore exposed to the same therapists. All patients received equal number and duration of treatment sessions. The treatment protocol was designed and supervised by two senior reflexologists.

Patients were informed that they are going to receive reflexology treatment targeted mainly either to the sole (study) or to the calf area (controls), while the efficacy of each is yet to be determined. The reflexololgists were instructed not to discuss the efficacy of either treatment with the patients.

Clinical assessment was performed in a masked fashion before, at the onset, after six weeks of treatment, upon completion of the treatment period and after additional three months.

Outcome measures

a) The intensity of paresthesias was assessed by the Visual Analogue Scale (VAS). As the majority of the patients suffered from paresthesias in several locations, the intensity, location and duration (hours/week) of each paresthesia were recorded. Evaluation of VAS at each time point of the follow-up included the information concerning the locations reported prior to the commencement of the trial, as well as inquiry about appearance of additional locations. An average was taken for each patient's scores at each time point of the study. This approach was applied in order to avoid an overload of information.

b) Urinary symptoms were not a part of primary inclusion criteria, but were assessed in all patients by the American Urological Association (AUA) symptom score.[12]

c) Proximal lower extremities muscles (iliopsoas, quadriceps, hamstrings and adductor muscles) of the patients were evaluated as follows: muscle tone-by Ashworth score, and muscle strength-by British Medical Research Council (BMRC) scale.[14] The evaluations were performed by the same physiotherapist in a masked fashion, under supervision of a senior neurologist. Since the same muscle groups were measured in all patients, we evaluated an average score for each patient at each time point of the study.

Sample size calculation

In order to evaluate the possible effect of reflexology treatment on MS patients (which was not yet reported) an open trial was conducted.

Twenty MS patients suffering from paresthesias were recruited and treated for a period of 1.5 months. The intensity of paresthesias was evaluated prior to treatment and at the end of the treatment period. An improvement was noted in seven of 20 patients.

Sample size for the current clinical trial was calculated based on expected improvement of 30% exposed to reflexology treatment and 5% among the controls. A ratio of 1:1 (exposed: controls) was chosen with $\alpha = 0.05$ and $1-\beta = 80\%$.[13] The study population was calculated as 70 patients, equally allocated to treatment and control groups.

Data analysis

Statistical analysis was performed using SPSS-PC software for windows (Version 8.0, SPSS, Chicago, 1997). Probability of < 0.05 was considered statistically significant. Due to the small number of observations in both the study and control groups, normal distribution was not evident. Therefore, nonparametric analysis was performed.

Two related samples Wilcoxon signed Ranks test was performed to calculate for significance of differences within the study and the control groups at various time points of the trial. Mann–Whitney *U*-test for two independent samples was performed for the significance of differences between the study and the control groups.

Trends over time were evaluated between the differences from baseline values at six weeks following commencement of the trial, at completion of the trial and at three months of follow-up.

Only patients who completed the trial were analysed.

The local ethical committee and Israeli Ministry of Health approved the study and written informed consent was obtained from all patients.

Results

Out of 71 patients recruited, 53 (75%) completed this study: 27 patients in the study and 26 in the control group. The demographic variables of the patients are demonstrated in Table 1. There was no statistically significant difference between the study and the control group in any of the following parameters: age, sex, duration of the disease, or in the initial severity of the evaluated symptoms.

There were no statistically significant differences between the intention-to-treat patients and the completers, as well as between the dropouts and the completers.

The outcome measures of clinical symptoms: (I) mean intensity of parasthesias, evaluated by VAS score; (II) urinary symptoms, evaluated by AUA scale; (III) muscle strength, presented as sum of proximal muscle group on BMRC scale, and (IV) spastisity, assessed by Ashworth scale, are presented in Table 2.

Not all patients suffered from the same or all symptoms. No statistically significant differences in the intensity of symptoms was observed at baseline.

Table 3 presents the outcome measures for both the reflexology and the control groups before and after the intervention. Statistically significant improvement for each evaluated outcome measure was demonstrated in the reflexology group, while none of them appeared to be significant in the control group. Comparison of the outcome measures between the two groups (reflexology and control) demonstrated statistically significant differences for scores of paresthesias, urinary symptoms and spasticity, while muscle strength revealed only borderline improvement ($P = 0.06$).

The differences from baseline of both groups were compared over time: beginning of the study, after six weeks of treatment, end of treatment, and after additional three months of follow-up (Table 4). The improvement in the intensity of paresthesia remained significant at three months of follow-up ($P = 0.04$).

An attempt was made to locate the dropouts and invite them for the follow-up. However, the patients refused to do so.

All patients (in both the study and control groups) received physiotherapy prior to the trial and continued to do so throughout the follow-up period.

During the treatment and the follow-up period no changes in medication or physiotherapy were recorded, except for the patients who developed an acute attack of the disease or infectious diseases and thus were excluded from the study.

Discussion

In the present randomized controlled trial we have demonstrated significant decreases in intensity and duration of paresthesia and of urinary symptoms as well as a significant improvement in spasticity, and an improvement of borderline significance in muscle strength in the reflexology group by the end of the treatment period. No improvement could be observed in the control group. The improvement in both spasticity and in muscle strength is quite remarkable, as some of the pharmacological agents for treatment of spasticity are associated with muscle weakness.[14,15]

Critics of complementary therapies often present the argument that placebo effects comprise most of their therapeutic effect, partly due to patient's expectations, the compassion of the therapist and to the relaxing atmosphere of private clinics.[16] In order to overcome this obstacle, we performed all treatments in the facility of a hospital clinic. A design of control treatment has been also given a careful consideration. We considered the difficulty presented to reflexologists to avoid touching specific points of the feet. Therefore, a nonspecific massage of the calf (rather than of the feet area) was chosen as sham therapy, providing control for touch therapy and general relaxation. Another point in evaluation of trials of complementary therapies is related to the fact that the skills of the practitioners are not uniform and thus positive results might not be reproducible. This point was addressed in this study by enrolling 36 reflexologists that provided both verum and control treatment under supervision of two experienced reflexologists.

Table 1 Demographic characteristics of the patients

Variable	*Reflexology (n = 27) (mean ± SD)*	*Control (n = 26) (mean ± SD)*
Sex (female/male)	17/10	17/9
Age	46.2 ± 9.3	49.2 ± 11.0
Duration of the disease	11.9 ± 9.2	13.4 ± 9.1
Intention to treat	36	35
Completed the trial	27 (75.0%)	26 (74.3%)
Reasons for discontinuation:		
Acute attack	3 (8.3%)	3 (8.6%)
Hospitalization unrelated to MS	1 (2.8%)	1 (3.0%)
Inconvenience of time table	3 (8.3%)	2 (5.7%)
Transportation difficulties	2 (5.6%)	3 (8.6%)

The data presents demographic characteristics of the patients within the two groups after randomization procedure (intention-to-treat and completers): age, sex, duration of the disease, the initial severity of the evaluated symptoms and the reasons for discontinuation of treatment.

Table 2 Characterization of symptoms at baseline

Symptom	*Study Group (n = 27)*		*Controls (n = 26)*	
	Number of patients	*Intensity of symptoms*	*Number of patients*	*Intensity of symptoms*
Paresthesia	23	5.62±1.5	20	4.72±2.2
Urinary symptoms	21	4.07±6.4	18	16.25±7.6
Muscle strength	27	15.33±5.4	26	13.77±5.2
Spasticity	11	5.09±4.5	16	3.25±2.1

The data represents distribution and characterization of symptoms at baseline, since not all patients suffered from the same symptoms.

Table 3 Comparison of outcome measures at entry and upon completion of the study in patients treated with reflexology and non-specific massage (control)

Outcome measures	*Reflexology*	*P**	*Control*	*P**	*P***
I. Intensity of paresthesia (mean±SD)					
No. of patients	23		20		
Before treatment	5.62±1.5		4.71±2.2		
Post treatment	4.12±2.3		4.88±2.2		
Mean difference	−1.49±2.1	0.002	0.16±2.1	0.736	0.01
II. Urinary symptoms (mean±SD)					
No. of patients	21		18		
Before treatment	14.07±6.4		16.25±7.6		
Post treatment	9.90±4.9		16.08±8.5		
Mean difference	−4.17±6.32	0.013	−0.34±4.43	0.697	0.03
III. Muscle strength (mean±SD)					
No. of patients	27		26		
Before treatment	15.33±5.4		13.77±5.2		
Post treatment	16.23±5.2		13.99±5.9		
Mean difference	0.96±1.3	0.002	−0.3±1.7	0.646	0.06
IV. Spasticity (mean±SD)					
No. of patients	11		16		
Before treatment	5.09±4.5		3.25±2.1		
Post treatment	3.00±4.2		3.40±2.2		
Mean difference	−2.09±3.01	0.044	0.2±1.72	0.726	0.03

No. of patients in each group of symptoms indicate the number of patients who presented with particular symptoms.
*P** Two related samples Wilcoxon Signed Ranks test.
*P*** Mann–Whitney *U*-test for two independent samples.

An additional difficulty inherent to such study pertains to the treatment modality: reflexology similarly to other complementary therapies, treats patients on individual basis and not according to medical diagnosis. Evaluation of the effect of massaging of fixed points on the feet is therefore not always relevant or possible. For that reason, we evaluated the effect of reflexology (as an intervention procedure) on outcome measures rather than investigating the effect of specific pressure points on the feet.

Previously reported study that examined the effect of reflexology on MS, demonstrated positive results (subjective clinical improvement in 45% of the patients), though contained several methodological flaws such as: i) no randomization was performed to treatment and control groups; ii) the control group received no intervention at all.[17]

Another randomized study that tested the effect of reflexology treatment in women who underwent an abdominal operation, demonstrated positive effect of foot reflexology on voiding during post-operative period.[18]

The effect of neural therapy (a form of acupuncture) was also evaluated in MS patients in a randomized controlled study, which demonstrated short and long-term beneficial effects on functional assessments of the patients.[19]

The mechanism by which reflexology (or acupuncture) may affect sensory, motor and urinary symptoms in MS in not fully understood. A study that tested the hypothesis whether reflexology is associated with specific target organs, demonstrated that massaging the kidney area was followed by an increase of kidney blood perfusion.[20] It is also possible that similarly to the effect of acupuncture,[21] reflexology may influence the release of endogenous opiates that have important role in reduction of pain and regulation of immune functions.[21,22] Both of these techniques are based on traditional Chinese philosophy of healing. While acupuncturist uses specific points along body meridians, reflexologist applies pressure upon end points of these meridians on the feet.

Although the effect of stress on the immune system is well acknowledged,[22] patients in both groups reported that the treatment was pleasant and relaxing, and that they would recommend it to other patients.

A search for new treatment modalities aimed to improve disturbing symptoms in MS continues. It is of interest to

Table 4 Trends over time-differences from baseline at six weeks after the commencement of the trial, at the end of the trial and at three months of follow-up

	Outcome measures	*Study*	*Control*	*P-Value**
I.	*Intensity of paresthesias*			
	Baseline	5.42±1.3	4.71±2.2	NS
	Mean difference after 6w	−1.25±1.8	0.2±1.8	0.04
	Mean difference at completion	−1.49±1.6	0.16±2.1	0.01
	Mean difference at follow-up	−1.25±1.3	0.23±2.3	0.04
II.	*Urinary symptoms*			
	Baseline	14.07±6.4	16.25±7.6	NS
	Mean difference after 6w	−2.69±6.3	−0.47±4.94	0.20
	Mean difference at completion	−4.17±6.32	−0.34±4.43	0.03
	Mean difference at follow-up	−2.77±6.94	−0.91±4.87	0.21
III.	*Muscle strength*			
	Baseline	15.33±5.4	13.77±5.2	NS
	Mean difference after 6w	0.44±1.3	0.28±1.8	NS
	Mean difference at completion	0.96±1.3	−0.3±1.7	0.06
	Mean difference at follow-up	0.48±1.3	0.23±1.3	NS
IV.	*Spasticity*			
	Baseline	5.09±4.5	3.25±2.1	NS
	Mean difference after 6w	−2.11±2.4	−0.46±1.3	0.03
	Mean difference at completion	−2.09±3.01	0.2±1.72	0.03
	Mean difference at follow-up	−1.67±3.2	0.15±2.03	0.06

NS = non significant.
P-value* = Mann–Whitney *U*-test for two independent samples.

note such positive effect of single intervention on a broad range of symptoms. This may possibly stem from the holistic approach of the reflexology (similarly to other complementary therapies), that treats the whole person rather than specific symptoms.

To the best of our knowledge, this is the first randomized controlled study of reflexology treatment in MS patients. We conclude that the treatment was safe, as the patients reported no adverse effects. Moreover, reflexology positively affected muscle strength and tonus and also reduced sensory and urinary symptoms.

Further clinical and laboratory studies are needed to validate these results and to understand the mechanisms by which reflexology improves symptoms secondary to MS.

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