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# PELVIC FLOOR MUSCLE TRAINING IN WOMEN WITH MULTIPLE SCLEROSIS - A COMPARATIVE STUDY: IMPACT ON LUTS AND QOL

**Pelvic Floor Muscle Training in women with Multiple Sclerosis - a comparative study: impact on LUTS and QoL**

**Hypothesis / aims of study** Multiple Sclerosis (MS) is a chronic neurologic disease involving the white matter pathways in the brain and spinal cord. Lower urinary tract symptoms (LUTS) are highly prevalent and affect around 90% of these patients throughout the course of the disease. Most patients report on a combination of both storage and voiding symptoms. These symptoms are not life threatening, and for this reason they are often overlooked by health professionals, but bladder dysfunction is responsible for a significant negative impact on the Quality of Life (QoL) of affected patients. Recognizing the impact of urinary disorders on QoL in patients with MS by the health care professionals is essential to conduct appropriate investigations and the evaluation of potential interventions. This blind, randomised and prospective trial aimed to compare Pelvic Floor Muscle Training (PFMT) and sham treatment in the treatment of women with MS and LUTS. To evaluate the results of the two methods questionnaires of QoL and LUTS were used. The results of the rehabilitation on disability will be discussed in another study.
**Study design, materials and methods** Twenty seven female patients of a total of 42, with a diagnosis of MS and LUTS complaints randomized, by the envelope method, into two groups: Treatment (G-I) (N=13) and Sham (G-II) (N=14). Evaluation included: OAB-V8, SF-36, ICIQ-SF and Qualiveen questionnaires and all patients were assessed before and after treatment. The intervention was performed by a physiotherapist for a period of 12 weeks in both groups with participants attending twice a week. The G-I intervention consisted of Pelvic Floor Muscle Training (PFMT) in lying supine position with assistance of a Perina (Quark, São Paulo, Brazil) perineometer and was instructed to practice the exercises daily at home, without the assistance of any device, in other positions such as sitting and standing. They were also advised to integrate the exercises into their daily lives activities and the regimen was reviewed weekly according to the initial vaginal assessment using the PERFECT system. The G-II received a sham treatment which consisted of the introduction of a perineometer inside the vagina with no contraction required.
**Results** Data analysis was by intention to compare the two groups at the end of intervention and the Repeated-measures ANOVA was used. A P-value of 0.05 was considered significant. Demographic data were calculated by the Mann-Whitney test and there were no statistically significant differences between groups.
Storage and voiding symptoms before and after intervention are shown in Table I.

| | GI | | GII | |
|---|---|---|---|---|
| **SYMPTOMS** | **Baseline** | **Final** | **Baseline** | **Final** |
| **Frequency** | **13** | **4** | **14** | **14** |
| **Urgency** | **13** | **4** | **14** | **13** |
| **Urge Urinary incontinence** | **12** | **4** | **13** | **13** |
| **Nocturnal enuresis** | **8** | **2** | **9** | **10** |
| **Nocturia** | **12** | **2** | **12** | **11** |
| **Hesitancy** | **10** | **3** | **8** | **9** |
| **Slow stream** | **8** | **5** | **6** | **6** |
| **Incomplete emptying** | **8** | **3** | **7** | **7** |

Table I - Storage and Voiding symptoms before and after intervention in Treatment (G-I) and Sham (G-II) groups

The OAB-V8 assessment showed significant differences after treatment ($p < 0.0001$) (Figure 1).

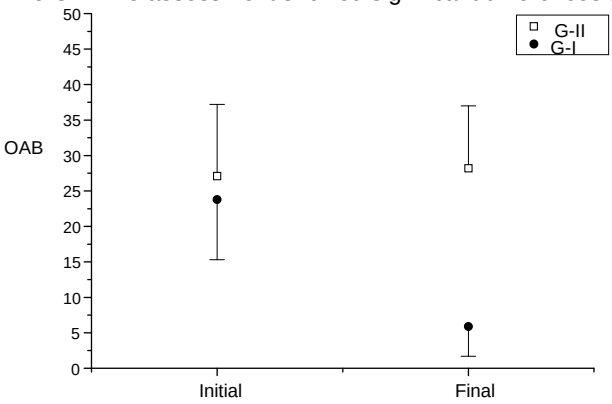


Figure 1 – Mean and standard deviation of OAB-V8 before and after intervention in G-I and G-II.

In the SF-36 assessment no differences were found between GI and GII. In the ICIQ-SF assessment, a significant improvement ($p = 0.0003$) was found between the two groups (Figure 2).

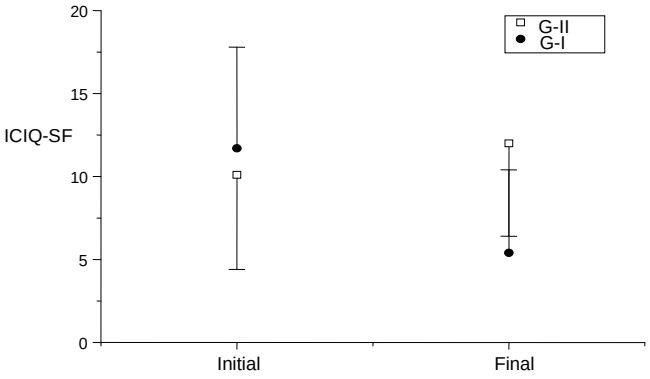


Figure 2 - Mean and standard deviation of ICIQ - SF before and after intervention in G-I and G-II.

In Specific Impact of Urinary Problems on Quality of Life (SIUP) domain of the Qualiveen questionnaire, significant lower scores in G-I (p= 0.0001), were found (Figure 4). In General Quality of Life (GQoL) domain of the same questionnaire, a significant difference was found (p= 0.0443) in G-I (Figure 5). No differences were found in G-II.

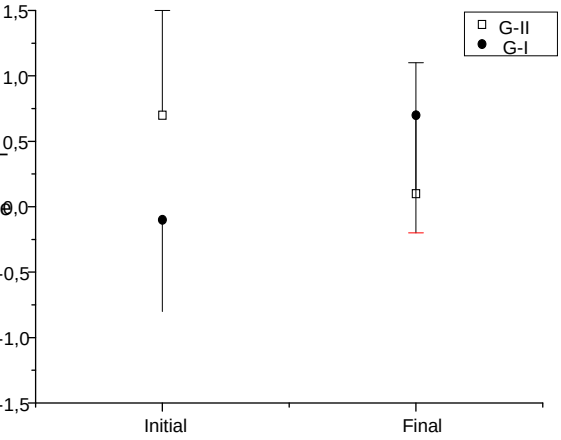


Figure 4 - Mean and standard deviation of Qualiveen – GQoL domain before and after intervention in treatment (G-I) and sham (G-II) groups.

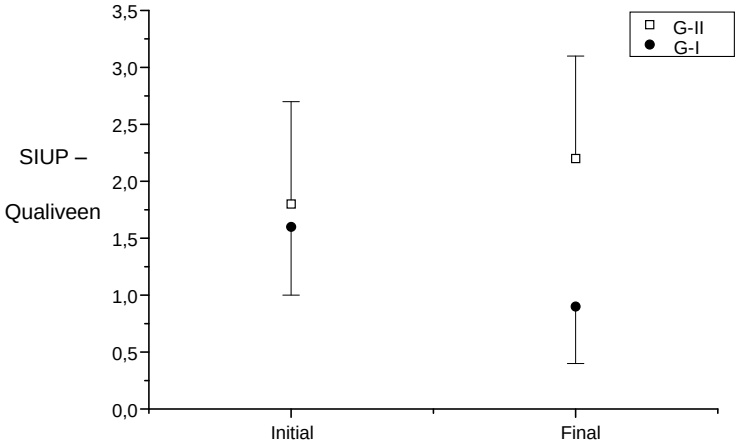


Figure 5 – Mean and standard deviation of Qualiveen-SIUP domain before and after intervention in treatment (G-I) and sham (G-II) groups.

**Interpretation of Results** - Although movement disorders, depressive mood and fatigue affect the QoL of people with MS, urinary problems have a major impact on health-related QoL in these patients(1). Patients underwent to PFMT presented improvement in LUTS and QoL when compare to sham group. It would seem reasonable assume that a decrease in LUTS would increase the QoL but in our study the SF-36 was not sensitive to detect the improvement in the QoL. This result is predictable since this is a general questionnaire and does not measure specifically the impact of urgency, frequency, nocturia and urinary incontinence on QoL. That explains the importance of identifying specific problems that contribute to negative impact in QoL. The QoL was better evaluated using disease specific QoL questionnaires as ICIQ-SF and Qualiveen that demonstrated encouraging results. The findings in this study show that although subjective, the assessment of QoL provides important additional information as the effects of the proposed treatment, measure rehabilitation outcome and patients´ own evaluation of their health. This will help health professionals to choose the best treatment arm that covers major aspects of improvement.

**Concluding message** The improvement of LUTS had a positive effect on QoL in women with MS underwent to PFMT. A disease specific QoL should be use to identify the results of the treatment.

References

1. Lobentanz IS, Asenbaum S, Vass K, et al: Factor influencing quality of life in multiple scleroisis patients: disability, depressive mood, fatigue and sleep quality. Acta Neurol Scand 2004 Jul; 100(1): 6-13


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|---|---|
| ***Specify source of funding or grant*** | **FAPESP** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **No** |
| ***Is this a Randomised Controlled Trial (RCT)?*** | **Yes** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |

| | |
|---|---|
| ***Specify Name of Ethics Committee*** | **Comitê de Ética FCM-UNICAMP** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |