



PREVENTION AND REHABILITATION: RANDOMIZED CLINICAL TRIAL

The effect of traditional dysphagia therapy on the swallowing function in patients with Multiple Sclerosis: A pilot double-blinded randomized controlled trial

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ABSTRACT

Background: Dysphagia is common following Multiple Sclerosis (MS) and is associated with significant morbidity and mortality. The current rehabilitation program to swallowing therapy is Traditional Dysphagia Therapy (TDT), but there is a dearth of evidence about its effectiveness in MS patients.

Objectives: This study was aimed to determine the effects of the TDT on the swallowing function in MS patients with dysphagia.

Methods: A pilot double blind randomized clinical trial was carried out on 20 patients with MS. Patients were randomly divided into experimental group (TDT) comprising sensorimotor exercises and swallowing maneuvers, and Usual Care (UC) comprising diet prescription and postural changes. Patients in both groups received treatments for 6 weeks, 18 treatment sessions, 3 times per week, every other day. The Mann Assessment of Swallowing Ability (MASA) was the main outcome measure. The swallowing ability was assessed before treatment (T_0), after the end of 9th session (T_1), after the end of 18th session (T_2), and after 6 weeks follow-up (T_3). Penetration–Aspiration Scale (PAS) and Pharyngeal Residue Rating Scale (PRRS) as secondary outcome measures were applied at T_0 and T_2 .

Results: Both groups had improved regarding MASA, PAS and PRRS scores over the time ($P < 0.001$). The improvements achieved in all outcomes were significantly greater in the TDT group than those of the UC group. The Main effect of the Time \times Group interaction was significant for MASA score ($P < 0.001$). The large effect sizes were found for MASA score in both the TDT ($d = 3.91$) and the UC ($d = 1.11$) groups.

Conclusions: This pilot randomized controlled trial showed that the TDT significantly improved the swallowing function of the MS patients with dysphagia.

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1. Introduction

Multiple Sclerosis (MS) is one of the most common neurological diseases globally that usually affects young adults (Compston and

Coles, 2008; Etemadifar et al., 2014). It can cause clinical and neurological symptoms such as dysphagia or swallowing disorders (Milo and Kahana, 2010). Dysphagia is a prevalent symptom in MS (Hartelius and Svensson, 1994; Merson and Rolnick, 1998; Thomas and Wiles, 1999; Calcagno et al., 2002) and more than one-third of the MS patients are affected (Guan et al., 2015).

Dysphagia is a dangerous condition in MS patients because of its potential complications such as dehydration, malnutrition, and aspiration pneumonia. Dysphagia and its complications reduce the quality of life and can lead to morbidity and mortality in the final stages of MS disease (Poorjavad et al., 2010; Guan et al., 2015).

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Therefore, dysphagia should be diagnosed at an early stage, and appropriate therapeutic techniques should be provided, based on a detailed clinical assessment in MS patients (Giusti and Giambuzzi, 2008).

The goal of dysphagia therapy is to achieve a normal diet, as far as possible, in the safest and most efficient way (Logemann, 1998). Treatment of MS related dysphagia includes Traditional Dysphagia Therapy (TDT) (Prosiegel et al., 2004; Logemann, 2006a,b; Restivo et al., 2006; Giusti and Giambuzzi, 2008), pharyngeal electrical stimulation (Restivo et al., 2013), neuromuscular electrical stimulation (Boggardt et al., 2009), and vagal nerve stimulation (Marrosu et al., 2007).

The current standard swallowing therapy is TDT that includes behavioral and rehabilitative techniques (Carnaby-Mann et al., 2006, 2007). The rehabilitative techniques are applied to improve physiology of the swallowing function and involve sensorimotor exercises and swallowing maneuvers (Logemann, 1998; Restivo et al., 2006).

The TDT has been stated as a potential beneficial treatment in MS patients with dysphagia (Prosiegel et al., 2004; Logemann, 2006a,b; Restivo et al., 2006; Giusti and Giambuzzi, 2008). While the MS patients with dysphagia undergoing TDT may improve their swallowing function, there is no sufficient data on the effect of TDT on swallowing function in MS population.

The literature on the effects of TDT on swallowing dysfunction in MS patients is scarce. Thus, the aim of this pilot randomized controlled trial was to investigate the effects of TDT on the swallowing function in patients with MS.

2. Methods

2.1. Study design

This was a pilot randomized, double-blind, clinical trial to evaluate the effects of the TDT in MS patients with swallowing dysfunction. The study protocol was approved by the Research Council, School of Rehabilitation and the Ethical committee of Tehran University of Medical Sciences (TUMS). The trial was registered with the Iranian Registry of Clinical Trials (IRCT2016022426721N2).

2.2. Patients

The patients were recruited from the MS Clinic of the Sina University Hospital and MS Research Center of the TUMS in Tehran, Iran, between February 2015 and November 2016. The inclusion criteria were: 1) established diagnosis of MS according to the McDonald's criteria (McDonalds et al., 2001), 2) age between 20 and 60 years, 3) having dysphagia based on DYMUS questionnaire (Bergamaschi et al., 2009), 4) lack of an acute relapse in the past two months, 5) no other conditions such as stroke. The exclusion criteria were: 1) having severe reflux, 2) having dysphagia due to the drug toxicity, 3) being pregnant. All patients signed a consent form before taking part in the study.

2.3. Randomization

The opaque sealed envelopes were applied for randomization using a computer-generated randomized list of numbers. Before data collection, the patients were randomly assigned to one of two groups of TDT ($n = 10$) or UC ($n = 10$) by secretary of the Dysphagia Clinic who had no other role in the study. Both patients and assessor were blinded to treatment allocation. Patients were told that they will receive one of established treatment protocols. Additionally, the treatment sessions of the groups were planned in such

a way that the patients of both groups were not aware of the treatment protocol of each other's. The dysphagia therapist who was the principal researcher was blinded to the outcomes of assessments, as well.

2.4. Interventions

All patients in both groups received 18 sessions of treatment, three times a week (every other day). The sessions of treatment were provided at the Dysphagia Clinic. However, treatment was provided at home for the patients with motor limitation and transportation difficulties. Before treatment, the patients were requested not to participate in any other dysphagia treatment program. During follow up, patients were phone called by the Speech and Language Pathologist (SLP) once a week to remind them to perform the exercises according to the instructions given by the therapist.

2.5. Traditional dysphagia therapy

The TDT strategies are generally designed to change the physiology of swallowing by improving range of motion of the oral and pharyngeal structures, improving sensory input, and coordinating the oropharyngeal movements during swallowing (Logemann, 1998, 2006; Carnaby-Mann et al., 2006; Restivo et al., 2006). TDT includes oral motor control and range of motion exercises, swallowing maneuvers, and strategies to heighten sensory input (Logemann, 1998; Carnaby-Mann et al., 2006; Restivo et al., 2006). The details of the TDT strategies are provided in Table 1.

2.6. Usual care

The UC consisted of supervision for feeding and precautions for safe swallowing. The UC strategies lead to control the food flow and eliminate the clinical symptoms such as aspiration. However, these strategies do not change the physiology of the swallowing. The UC program includes 1) postural changes (chin up, chin down, head tilt, and head rotation), 2) modifying volume and speed of food presentation, 3) changing food consistency and viscosity, and 4) improving sensory oral awareness (presenting a cold bolus and/or a sour bolus, downward pressure of the spoon against the tongue (Carnaby-Mann et al., 2006, 2007).

3. Outcome measures

3.1. Primary outcome measure

In this study, the Mann Assessment of Swallowing Ability (MASA) (Carnaby-Mann, 2002) was used as the main outcome measure. It was measured before treatment (T_0), after the end of 9th session (T_1), after the end of 18th session (T_2), and 6 weeks after the end of treatment (T_3).

The MASA is a comprehensive clinical tool for examination of neurogenic oropharyngeal dysphagia (Carnaby-Mann, 2002; Ghelichi et al., 2016). The MASA includes 24 items with the maximum possible score of 200 for assessing dysphagia [nil ≤ 178 –200; mild ≤ 168 –177; moderate ≤ 139 –167; and severe ≤ 138] and aspiration [nil ≤ 170 –200; mild ≤ 149 –169; moderate ≤ 148 ; and severe ≤ 140]. The MASA is valid and reliable with a sensitivity of 73% and a specificity of 89% (Carnaby-Mann, 2002).

In this study, thirty MS patients were recruited in advance to investigate the interrater and intrarater reliability of the MASA. The reliability analyses demonstrated good interrater ($k = 0.76$, $SE = 0.082$, $p < 0.001$) and intrarater ($k = 0.71$, $SE = 0.09$, $p < 0.001$) reliability.

Table 1
Traditional dysphagia therapy (TDT).

Type of traditional treatment	Examples/Description
Exercise programs	Oral motor control Exercises Range of motion tongue Exercises Resistance Exercises Bolus control Exercises Bolus propulsion Exercises Laryngeal elevation
Pharyngeal swallowing maneuvers	Mendelsohn maneuver Supraglottic swallow Super supraglottic swallow Effortful swallow Masako maneuver
Compensatory swallowing strategies	Viscosity changes to food and liquids Positional changes Clear throat or cough after each bite/sip No straws Place food on right or left side of mouth Alternate bite/sip
Sensory stimuli	Changing the taste, volume, temperature, or carbonation of the bolus Thermal tactile stimulation Additional pressure on the tongue with a spoon

3.2. Secondary outcome measures

Penetration–Aspiration Scale (PAS) (Rosenbek et al., 1996) and Pharyngeal Residue Rating Scale (PRRS) were used to quantify the functional recovery of the swallowing based on the Fiberoptic Endoscopic Evaluation of Swallowing (FEES). The FEES was performed following the standard protocol (Langmore, 2001). No topical anesthetic or vasoconstrictor was performed to the patients' nasal mucosa during FEES. The FEES was applied before treatment (T₀) and after the end of 18th session (T₁).

The PAS is a standard scale to assess the laryngeal penetration and aspiration. Laryngeal penetration is defined as entry of material into the larynx, but not below the true vocal folds, and the aspiration refers to the entry of material into the airway below the true vocal folds. The PAS is an eight-point scale based on the depth of material invasion into the airway and the patient's reaction to these events. Higher score indicate higher aspiration severity (Rosenbek et al., 1996).

We applied the PRRS based on commonly used descriptors of residue severity. It is a five-point ordinal rating scale to assess the residue severity (Kelly et al., 2006) (Table 2).

3.3. Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 17. Kolmogorov-Smirnov test was used for normality analysis of the data. Repeated measure ANOVA was used to analyze the main effects of Time, Group and Time*Group interaction on the MASA score. Bonferroni test was used for paired multiple comparisons. Independent *t*-test and Mann-Whitney test were used to analyze the between groups comparison of the PAS and PRRS scores. Paired *t*-test and Wilcoxon signed-rank test were applied to within group comparison of the PAS and PRRS scores.

Table 2
Pharyngeal residue severity scale (PRRS).

None	No pharyngeal coating or residue
Coating	Coating of the pharyngeal mucosa; no pooling
Mild	Mild pooling/residue
Moderate	Moderate pooling/residue
Severe	Severe pooling/residue

Furthermore, the effect sizes (Cohen's *d*) of the changed scores were calculated to determine the treatment effects. *P*-values $\leq .05$ were considered as statistically significant.

4. Results

The flow chart of participants is shown in Fig. 1. From the initial 130 patients referred by a neurologist, a total of 20 patients [Mean (SD) age, 43.7 (11.82) years; mean disease duration, 6.6 (2.92) years] were included in this study and randomly allocated into 2 groups: experimental, TDT group ($n = 10$) and control, UC group ($n = 10$). All the patients completed the study protocol. The mean EDSS was 3.4 (SD = 2.3). Eleven (55%) patients had Relapse-Remitting (RR), three patients (15%) had Primary Progressive (PP) MS, and six patients (30%) had Secondary Progressive (SP) MS. The baseline characteristics of patients in both groups did not differ significantly (Table 3). There were no significant differences in all outcome measures at baseline between the 2 groups ($p > 0.05$) (Table 4).

4.1. Primary outcome measure

There was a significant effect of Time ($p < 0.001$) on MASA score. Bonferroni test revealed that the MASA score had improved significantly across the time in the TDT group ($p < 0.001$). The improvements of MASA score was maintained 6 weeks after the end of the treatment ($p = 0.1$) in the TDT group. There was a significant improvement of the MASA score at the end of 9th session ($p = 0.006$) in the UC group, however The MASA score was significantly worsened after 6 weeks follow-up ($p = 0.04$). The main effect of Group for MASA score was significant ($p < 0.001$). The Time \times Group interaction was significant for the MASA score; $F(1.15, 21.93) = 43.69, p \leq 0.001$ (Fig. 2). The large effect sizes were found for MASA score in both the TDT group ($d = 3.91$) and the UC group ($d = 1.11$).

The frequency of the dysphagia severity in terms of the MASA test in both groups is demonstrated in Table 5. There was only one patient with mild dysphagia in the TDT group after treatment. The dysphagia severity was significantly different between groups after treatment (Mann–Whitney *U* test, $p < 0.001$).

The frequency of the aspiration severity in terms of the MASA test in both groups is demonstrated in Table 6. There was no patient with aspiration in the TDT group after treatment. The aspiration

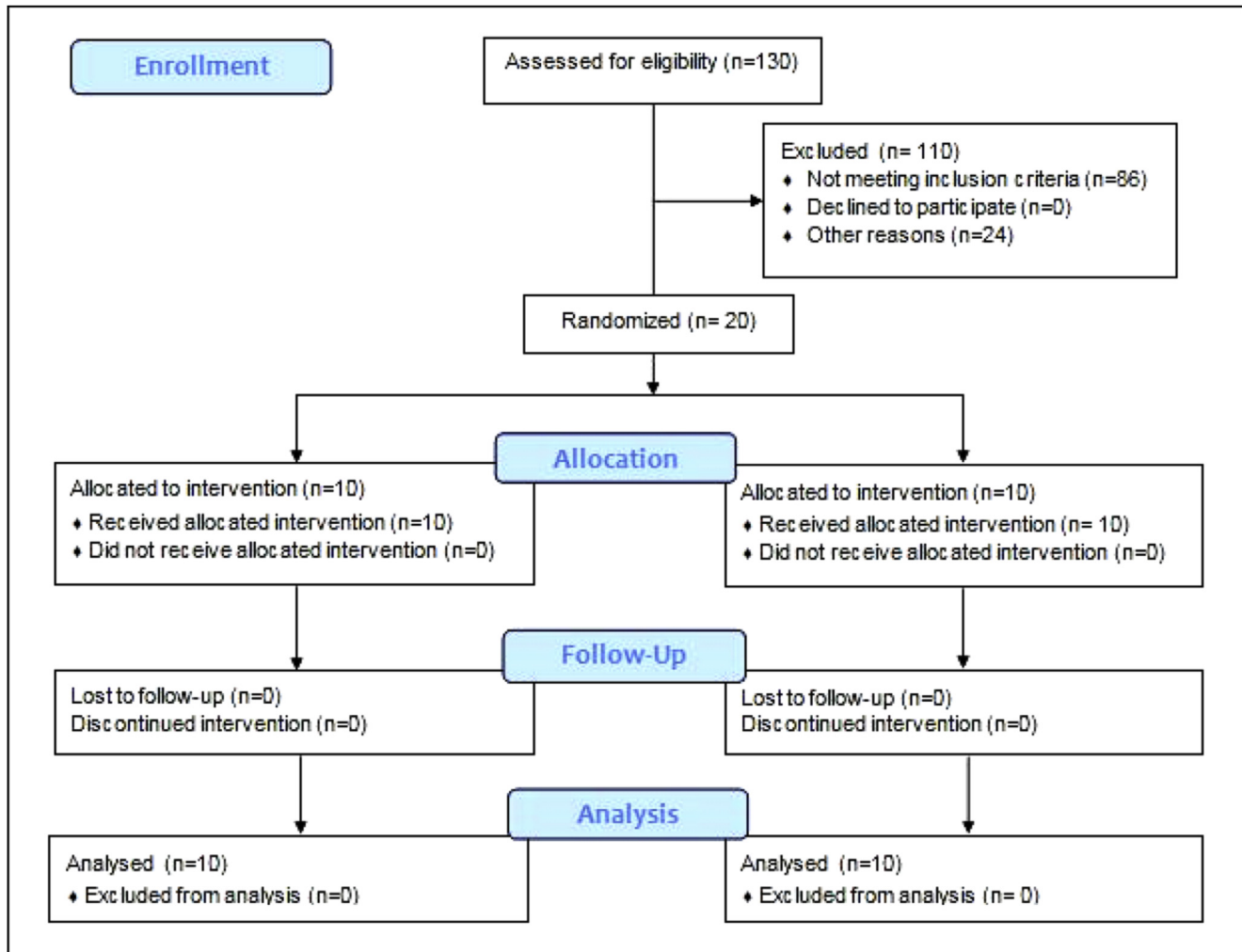


Fig. 1. Flow diagram of patients.

Table 3

Characteristics of the patients at baseline in Traditional Dysphagia Therapy (TDT) and Usual Care (UC) groups.

	TDT (N = 10)	UC (N = 10)	Test (P-value)
Age (mean ± SD)	47.5 (±12.9)	39.9 (±9.7)	Independent T-test (0.15)
Gender (Male/Female)	(2/8)	(5/5)	Chi-square test (0.35)
Age at onset (mean ± SD)	40.7(±12.1)	33.4(±7.9)	Independent T-test (0.13)
Disease Duration (years) (mean ± SD)	6.8 (±2.9)	6.1 (±2.7)	Independent T-test (0.76)
EDSS ^c (mean ± SD)	3.6 (±2.1)	3.2 (±2.5)	Independent T-test (.07)
MS Type (%)			Mann-Whitney U test, (0.4)
RR ^b	4 (40%)	7(70%)	
PP ^c	4 (40%)	1(10%)	
SP ^d	2 (20%)	2 (20%)	

a: Expanded Disability Status Scale; b: Relapse-Remitting; c: Primary Progressive; d: Secondary Progressive.

severity was significantly different between groups after treatment (Mann–Whitney *U* test, $p = 0.005$).

4.2. Secondary outcome measures

The PAS and PRSS scores were significantly improved across the

time in both groups ($P < 0.05$) (Table 2). The PAS and PRSS scores were significantly different between groups after treatment in favor of the TDT group ($P < 0.001$). The large effect sizes were found for both groups; TDT group: PAS ($d = 3.18$) and PRSS ($d = 2.26$), UC group: PAS ($d = 2.75$) and PRSS ($d = 2.06$).

Table 4
Mean (SD) of MASA score and Median (Interquartile Range) of PAS and PRRS for Traditional Dysphagia Therapy (TDT) and Usual Care (UC) groups.

	TDT				UC				P-value ^d
	T ₀	T ₁	T ₂	T ₃	T ₀	T ₁	T ₂	T ₃	
MASA ^a	148.3 (10.7)	170.5 (6.10)	181.7 (3.47)	183.4 (4.60)	147.9 (15.7)	158.1 (11.82)	163.3 (11.48)	159.3 (13.01)	0.94
PAS ^b	5.5 (4–6)	–	1 (1–1)	–	6 (4.75–6.25)	–	2.5 (2–3)	–	0.18
PRRS ^c	2 (1–2.25)	–	0	–	3 m (2.75–3)	–	1.5 (1–2)	–	0.10

T₀: before treatment; T₁: 9th session of treatment; T₂: 18th session of treatment; T₃: after 6 weeks follow up.
a: Mann Assessment of Swallowing Ability; b: Penetration-Aspiration Scale; c: Pharyngeal Residue Severity Scale; d: between group comparisons at T₀.

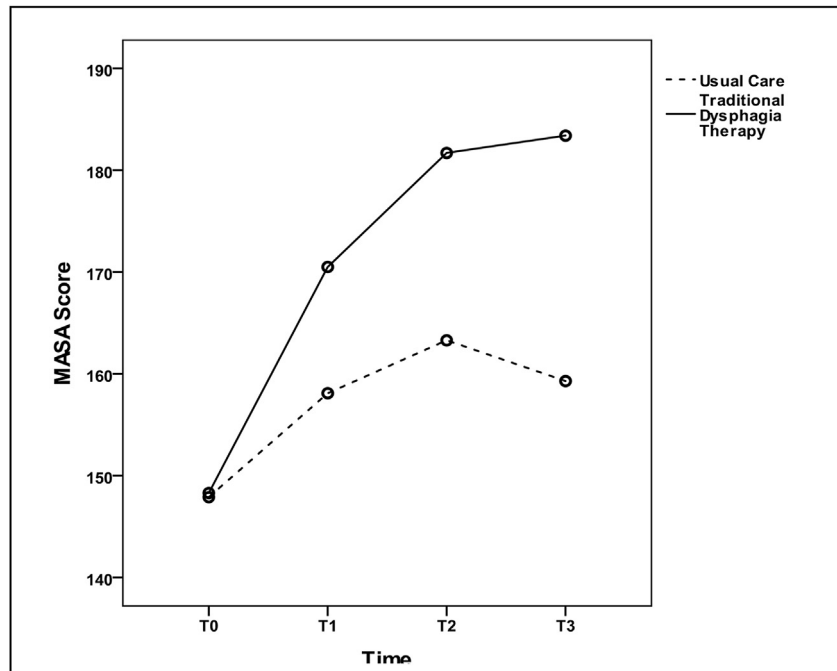


Fig. 2. Interaction of time and group for MASA scores.

Table 5
Severity of dysphagia in terms of MASA test over the time in the Traditional Dysphagia Therapy (TDT) and Usual Care (UC) groups.

	TDT				UC			
	T ₀	T ₁	T ₂	T ₃	T ₀	T ₁	T ₂	T ₃
No	0	2	9	9	0	0	1	1
Mild	0	6	1	1	1	4	4	2
Moderate	8	2	0	0	5	5	5	7
Severe	2	0	0	0	4	1	0	0

T₀: before treatment; T₁: 9th session of treatment; T₂: 18th session of treatment; T₃: after 6 weeks follow up.

Table 6
Severity of aspiration in terms of MASA test over the time in the Traditional Dysphagia Therapy (TDT) and Usual Care (UC) groups.

	TDT				UC			
	T ₀	T ₁	T ₂	T ₃	T ₀	T ₁	T ₂	T ₃
No	0	5	10	10	0	1	4	3
Mild	4	5	0	0	5	6	5	5
Moderate	4	0	0	0	1	3	1	2
Severe	2	0	0	0	4	0	0	0

T₀: before treatment; T₁: 9th session of treatment; T₂: 18th session of treatment; T₃: after 6 weeks follow up.

5. Discussion

Dysphagia treatment approaches most frequently involve rehabilitative strategies (Logemann, 1998). To the best of our knowledge, this pilot study was the first randomized clinical trial to date investigating the effects of the traditional dysphagia therapy on the swallowing function in MS patients with dysphagia. The results showed that the MASA, PAS, and PRRS scores have improved across the time in both groups. The improvements of the MASA, PAS, and PRRS scores were significantly greater in the TDT group.

5.1. Primary outcome measure

This study showed that the MASA score was improved across the time in both groups, but the improvements of the MASA score was different between groups. The MASA scores progressively improved in TDT group and the improvements maintained 6 weeks after the end of treatment. The MASA score in the UC group was significantly improved only at T₁ and significantly worsened at T₃. In addition, there was a significant interaction between time and group on the MASA score such that the TDT group showed more improvements across the time than the UC group. There is not a study with which to compare the results of the current study. The

findings of current study imply that the TDT techniques may improve the underlying pathophysiology, mainly weakness and reduced endurance, sensory thresholds, tone, timing, and coordination, but the UC temporarily eliminates the symptoms of dysphagia and do not change the swallowing physiology (Logemann, 1998; Rosenbek and Joes, 2009).

This study demonstrated the large effect sizes of MASA score after the end of treatment in both the TDT and the UC groups. These findings suggest that the both interventions were highly effective in improving the swallowing function in MS patients with dysphagia. However, the effect size obtained for MASA score in the TDT group was remarkably larger than that in the UC group (3.91 VS 1.11) which indicates that more significant improvements have occurred in the TDT group.

The findings indicated that there was only one patient with mild dysphagia and no patient with aspiration in the TDT group after treatment. But, there were 9 patients with dysphagia and 6 patients with aspiration after treatment in the UC group. The significant differences between two groups on the frequency of the dysphagia severity and the aspiration severity indicated that the TDT is more effective than the UC.

5.2. Secondary outcome measures

The results of our study revealed that the PAS and PRRS scores were decreased after 6 weeks treatment in both groups, but the decrease of the PAS and PRRS scores in the TDT group were significantly greater than the UC group. These findings indicate that although oral feeding becomes safer after treatment in both groups, but the TDT techniques have been more effective in reducing penetration, aspiration and pharyngeal residue than the UC techniques.

Generally, both therapeutic strategies resulted in improved swallowing function in MS patients with dysphagia, but the improvement was significantly greater in the TDT group. The findings of the present study are in accordance with the previous studies (Prosiegel et al., 2004; Logemann, 2006a,b; Restivo et al., 2006; Giusti and Giambuzzi, 2008). The improvements in the TDT group may be assumed that achieved through the skilled movements needed for safe, efficient, and satisfying swallowing as well as alerting the pathophysiology underlying the abnormal swallowing. The UC techniques may simply accommodate the impaired movements by practices such as diet modification, postural changes, and some alteration in how or what the patients can eat and drink (Logemann, 1991, 1998; Carnaby-Mann et al., 2006).

The main limitation of this study could be that the sample size was very small. Future studies with larger sample sizes are therefore needed for generalization of the results.

6. Conclusion

This study demonstrated that the traditional dysphagia therapy was effective in improving swallowing function in MS patients with dysphagia. The future clinical trials are needed to compare the traditional dysphagia therapy with other dysphagia treatment techniques.

Conflicts of interest

The authors declare no conflict of interests.

Trial registration

IRCT2016022426721N2.

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