Effects of oral neuromuscular training on swallowing dysfunction among older people in intermediate care—a cluster randomised, controlled trial

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Abstract

Objectives: this prospective, cluster randomised, controlled trial investigated the effect of oral neuromuscular training among older people in intermediate care with impaired swallowing.

Methods: older people (\geq 65 years) with swallowing dysfunction were cluster randomised according to care units for 5 weeks of neuromuscular training of the orofacial and pharyngeal muscles or usual care. The primary endpoint was the change in swallowing rate (assessed with a timed water swallow test) from baseline to the end-of-treatment and 6 months post-treatment. The secondary endpoints were changes in signs of aspiration during the water swallow test, and swallowing-related quality of life (QOL). An intention-to-treat principle was followed, and mixed-effects models were used for data analysis with the clustered study design as a random factor.

Results: in total, 385 participants from 36 intermediate care units were screened, and 116 participants were randomly assigned to oral neuromuscular training (intervention; n = 49) or usual care (controls; n = 67). At the end of treatment, the geometric mean of the swallowing rate in the intervention group had significantly improved 60% more than that of controls (P = 0.007). At 6 months post-treatment, the swallowing rate of the intervention group remained significantly better (P = 0.031). Signs of aspiration also significantly reduced in the intervention group compared with controls (P = 0.01). No significant between-group differences were found for swallowing-related QOL.

Conclusions: oral neuromuscular training is a new promising swallowing rehabilitation method among older people in intermediate care with impaired swallowing.

Trial registration: ClinicalTrials.gov: NCT02825927.

Keywords

swallowing disorders, dysphagia, rehabilitation, quality of life, nursing homes

Key points

• Oral neuromuscular training improves impaired swallowing rate and reduces signs of aspiration in older people.

- 5 weeks of oral neuromuscular training has lasting effects on swallowing function at 6 months post-treatment.
- Oral neuromuscular training is a new promising method for rehabilitation of impaired swallowing.

Introduction

Swallowing dysfunction is a growing health problem among older people [1] and is considered a geriatric syndrome [2] associated with an increased risk of malnutrition, pneumonia, mortality, and reduced quality of life (QOL) [1]. Common signs of swallowing dysfunction are impaired swallowing efficacy, e.g. with residual bolus in the oral cavity or pharynx, and impaired swallowing safety with penetration or aspiration of a bolus into the airway [3]. Although highly prevalent, swallowing dysfunction is both underdiagnosed and poorly treated among older patients [4].

A swallowing dysfunction is commonly managed by compensatory strategies to avoid or reduce it. However, recent research on swallowing rehabilitation aimed to improve the physiology of swallowing dysfunction, e.g. through strengthening muscles [5, 6], with biofeedback [7–9], or neuromodulatory approaches [10–12]. One promising method of swallowing rehabilitation is oral neuromuscular training that aims to strengthen the orofacial and pharyngeal muscles. This has been explored in a small study of patients with swallowing dysfunction after stroke [13]. However, the method has not been evaluated among older people with various diagnoses and swallowing dysfunction. Therefore, we aimed to investigate the effect of oral neuromuscular training on swallowing function in older people in Swedish intermediate care with an impaired swallowing.

Subjects and methods

Study design

This cluster randomised controlled study is part of a multidisciplinary and multicentre project, Swallowing function, Oral health and Food Intake in old Age (SOFIA). Information on the study design, study protocol [14] and sample size can be found at Clinical Trials.gov, identifier: NCT02825927. The study was conducted according to the recommendations for Interventional Trials, SPIRIT and the CONSORT extension for cluster randomised controlled trials guidelines (Appendices 1 and 2 available in Age and Ageing online). Eligible participants with swallowing dysfunction were randomised based on cluster to either usual care (control group) or additional oral neuromuscular training (intervention group). Swallowing function was clinically assessed with a timed water swallow test and diagnosed as dysfunction when the swallowing rate did not exceed 10 mL/s, in accordance with previous studies [15, 16].

Subjects and settings

This study was conducted in five Swedish counties, including 36 intermediate care units that, to facilitate implementation, were cluster randomised for intervention, (n = 18) or as control (n = 18). Intermediate care provides basic nursing care for days to months for people in need, e.g. recovering after being discharged from the hospital, waiting for care-home placement, undergoing rehabilitation, respite care, or end-of-life care [17]. Inclusion criteria for participation were the following: age ≥ 65 years, admittance to intermediate care for \geq 3 days, ability to understand Swedish and swallowing dysfunction assessed with a timed water swallow test. Individuals that received end-of-life care or had moderate or severe cognitive impairment were excluded. Written informed consent was obtained. This study was approved by the Uppsala Regional Ethics Review Board, Sweden (Dnr 2013/100).

Intervention

The oral neuromuscular training procedure has been described in detail [14]. The device IQoro[®] (MYoroface AB, Hudiksvall, Sweden) was used in the present study for oral neuromuscular training. The device is designed to stimulate sensory input and strengthen the facial, oral, and pharyngeal muscles [18]. The training was performed according to Figure 1a. The participants in the control group were given usual care with adjustments in food consistencies and posture instructions.

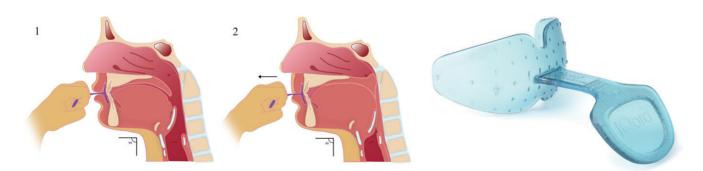


Figure 1 (a) Oral neuromuscular training of orofacial and pharyngeal muscles (left). The training is performed as follows: (1) the device is placed in the mouth, predentally, behind closed lips; (2) the participant pulls the handle of the device straight forward, as if to pull it out of the mouth, for approximately 5 to maximum 10 s. The manoeuvre is performed three times, with a 3 s rest between each manoeuvre [18]. The pulling force should be as high as possible without losing grip of the device. The oral neuro-muscular training device (right).

Outcome

The primary outcome was a change in swallowing rate measured by the timed water swallow test [15] at the end-oftreatment compared with baseline, and 6 months posttreatment, comparing the intervention group and the control group. The participant swallowed 150 mL as fast and safe as possible, and the rate was measured on a continuous scale in mL/s. The clinically relevant increase in swallowing rate is estimated to $\geq 2 \text{ mL/s}$. This presumption is based on results showing no significant difference in swallowing rate between two assessment of the same individual with the timed water swallow test (mean -0.17 mL/s (SD 1.98)) [15, 16]. The secondary outcomes were changes in signs of aspiration such as cough and/or voice change when swallowing, assessed during and after the timed water swallow test. Signs of aspiration were dichotomised as signs of aspiration were present or not. The swallowing assessment procedure is described in the study protocol [14]. Further, the swallowing-related QOL was measured by a self-reporting swallowing-related QOL questionnaire [19]. The questionnaire is rated on a 5-point Likert scale from 1 (least favourable state) to 5 (most favourable state). All scales were linearly transformed from a 5-point Likert scale and ranged from 0 to 100, according to validation [20], and a score below 86 is considered subjective dysphagia [21]. A total score was calculated.

Procedure

The cluster randomisation for oral neuromuscular training or usual care was based on which intermediate care unit the participants resided in at inclusion. For both study groups, the swallowing rate, signs of aspiration and swallowingrelated QOL were assessed at baseline, the end-oftreatment after 5 weeks and 6 months post-treatment. Clinical data, such as age, sex, height, weight, care dependency and medical diagnosis based on social service and nursing documentation, were collected at baseline [14]. Calibrated professionals (eight registered dental hygienists and one speech-language pathologist) collected data in the environment where the participant was staying at the time of the assessment (e.g. in the intermediate care unit, the participant's home or care home) and provided instructions about the training. If the participants had difficulties performing the training, staff or family members were instructed on how to assist [14]. A flow-chart of the included participants is depicted in Figure 1b.

Statistical analysis

We used descriptive statistics to describe the characteristics of the study population.

The primary outcome of swallowing rate and the secondary outcome of swallowing-related QOL were analysed using a linear mixed model with the logarithm of the outcome being the dependent variable due to non-normality. The secondary outcome of signs of aspiration was analysed with a generalised linear mixed model with a logit link function. Both models included the group (control or intervention), time (5 weeks or 6 months), group-by-time interaction and baseline value for each outcome as fixed effect factors, and the cluster and subject as random effect factors. For the primary outcome analysis, the covariate age was also considered a fixed effect. The models provided the mean change of each outcome for both groups, between baseline and the end-of-treatment, and at 6 months post-treatment. Further, differences in the mean change of the outcomes for the intervention group were compared with the control group (treatment effect). Results were expressed as observed geometric means (mean_o) and geometric standard deviation (SD_o). Between-group comparisons were expressed as ratios of the geometric mean (ratio) or odds ratio (OR) with 95% CIs. The intention-totreat principle was applied to between-group comparisons for the primary outcome analysis. Missing data were handled as missing at random and using multiple imputation [22]. Additionally, per-protocol analysis was performed on both primary and secondary outcomes. All statistical analyses were performed in R [23]. The models were fitted using the R-function *lmer* and *glmer*, respectively, from the lme4 package. To control the family-wise type I error-rate when comparing the primary outcome at two different time-points, the P-values underwent Holm-Bonferroni adjustment. The significance level was set at 0.05 in all statistical tests.

Results

Study subjects

Between October 2013 and February 2016, 385 older people were enroled at 36 intermediate care units and screened for swallowing dysfunction. After screening, 172 participants had a normal function and were excluded, while 209 participants showed swallowing dysfunction of which 97 declined to participate. The remaining 116 participants from 34 intermediate care units were randomly assigned to receive oral neuromuscular training (n = 49) or usual care (n = 67) (Figure 1b). The baseline characteristics of the participants are presented in Table 1. After the treatment period, a total of 85 participants (73.3%) were alive and available for per-protocol analysis; at 6 months post-treatment, 62 participants (53.4%) were available (Figure 1b).

Primary outcome

Swallowing rate

At the end-of-treatment, the observed mean_g of swallowing rate in the intervention group and control group were 6.22 mL/s (SD_g 2.16) and 3.64 mL/s (SD_g 2.72), respectively (Table 2). In total, 31% in the intervention group gained normal swallowing rate ($\geq 10 \text{ mL/s}$) at end-oftreatment compared to 12% in the control group. The results from the adjusted linear mixed model for testing changes in swallowing rate between baseline and the end-

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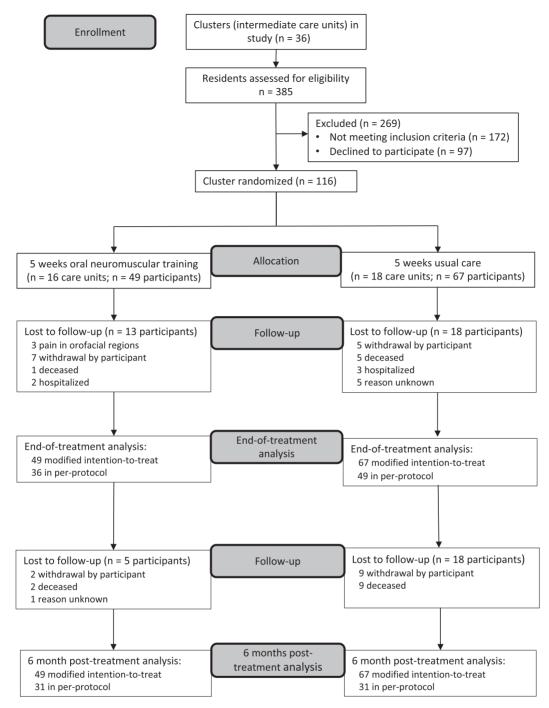


Figure 1 (b) Flow-chart of the subject inclusion and data collection processes. Swallowing dysfunction was assessed for all participants at allocation, after the end-of-treatment and at 6 months post-treatment.

of-treatment showed significant between-group differences (ratio 1.60, 95% CI 1.14–2.23; P = 0.013; Table 2), with the intervention group demonstrating a 60% higher swallowing rate compared with the control group. Furthermore, at 6 months post-treatment, the changes in swallowing rate were significantly higher in the intervention group compared with the control group (ratio 1.50, 95% CI 1.04–2.19; P = 0.031; Table 2). Similar results were obtained for the treatment effect on swallowing rate for both the intervious statement.

to-treat and per-protocol population analyses (Appendix 3 available in *Age and Ageing* online).

Secondary outcomes

Signs of aspiration

At the end-of-treatment, the generalised linear mixed model revealed a significant between-group difference in the change in signs of aspiration (OR 6.11 CI 1.82–28.45; P = 0.01;

Table I. Baseline d	lemographic and	clinical characteristics
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Variable	Control group, $n = 67$	Intervention group, $n = 49$	
Age	85 [80, 89]	83 [77, 87]	
Sex			
Male	29 (43.3)	27 (55.1)	
Female	38 (56.7)	22 (44.9)	
BMI	24.3 [19.7, 27.5]	24.5 [22.1, 28.9]	
Multimorbidity ^a			
Yes	40 (59.7)	24 (49.0)	
No	27 (40.3)	25 (51.0)	
Cognition			
No cognitive impairment	62 (92.5)	47 (95.9)	
Mild cognitive impairment	5 (7.5)	2 (4.1)	
Dysphagia risk condition ^b			
Yes	32 (47.8)	25 (52.1)	
No	35 (52.2)	23 (47.9)	
Education			
Compulsory school	47 (74.6)	31 (63.3)	
Upper secondary school	14 (22.2)	11 (22.4)	
Higher education	2 (3.2)	7 (14.3)	
Care dependency (Katz-ADL)			
Independent	3 (4.5)	5 (10.2)	
Moderate dependent	27 (40.9)	18 (36.7)	
Total dependent	36 (54.5)	26 (53.1)	
Swallowing rate (mL/s)	4.10 [2.14, 6.82]	5.31 [2.33, 7.14]	

Data are presented as n (%) or median [IQR]. BMI = body-mass index; Katz-ADL = activity of daily living.

^aDefined as three or more diagnoses from three different organs/organ systems. The most frequent diagnoses were stroke, musculoskeletal disorders, neurological diseases and cardiovascular diseases.

^bRefers to any condition that may contribute to dysphagia, e.g. neurological disease, stroke, traumatic brain injury or chronic obstructive pulmonary disease.

Outcome	Control Intervention	Between-group differences		Intracluster correlation coefficient	Units analysed	Subjects analysed	
	Mean _g (SD _g)	Mean _g (SD _g)	(95% CI)	P value	(ICC)	Control/ Intervention	Control/ Intervention
Swallowing rate ^a							
Baseline	3.00 (3.20)	3.18 (3.28)				18/16	67/49
End-of-treatment	3.64 (2.72)	6.22 (2.16)	1.60 (1.15–2.29) ^{b,c}	0.007	0.014	16/15	49/36
6 months post-	3.86 (2.66)	6.02 (1.92)	1.51 (1.04–2.19) ^{b,c}	0.031		14/13	31/31
treatment	. ,	. ,	. ,				
Signs of aspiration							
Baseline	25 (39%)	30 (61%)				18/16	64/49
End-of-treatment	26 (54%)	13 (35%)	6.11 (1.82–28.45) ^d	0.01	0.00	16/15	48/36
6 months post-	12 (39%)	17 (55%)	$0.63 (0.14 - 2.36)^{d}$	0.46		13/14	31/31
treatment	. ,		. ,				
Swallowing QOL							
Baseline	91.9 (3.12)	86.5 (3.26)				17/16	62/48
End-of-treatment	91.2 (2.87)	88.4 (2.79)	0.97 (0.60–1.57) ^c	0.90	0.15	16/15	46/35
6 months post-	92.6 (2.98)	91.1 (3.27)	1.01 (0.61–1.66) ^c	0.98		13/14	30/32
treatment							

Table 2. Mixed models repeated measures analysis at the end-of-treatment (5 weeks) and 6 months post-treatment for the changes in primary (swallowing rate) and secondary outcomes (signs of aspiration and swallowing QOL).

Results were obtained from linear mixed models with log-transformed data and generalised linear mixed models with a logit link function. The models included group, time, group-by-time interaction and baseline value as fixed factors and clustered study design and subject as random factors. Mean_g indicates observed geometric means; SD_g indicates geometric standard deviation; CI indicates confidence interval. In addition to swallowing rate, the data of mL swallowed, and the time it took during the timed water swallow test is available in the Supplementary (Appendix 4) (Supplementary data are available in *Age and Ageing* online).

^aNormal swallowing rate is $\geq 10 \text{ mL/s}$, whereas a rate < 10 mL/s indicates swallowing dysfunction. An increased rate indicates improvement of swallowing function.

^bPrimary analysis adjusted for the pre-specified covariate age; thus, included as a fixed effect. Unadjusted data are given in the Supplementary (Appendix 5) (Supplementary data are available in *Age and Ageing* online).

^cRatio of geometric mean with 95% CIs obtained from linear mixed models.

^dOdds ratio with 95% CIs obtained from generalised linear mixed models.

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Table 2); the intervention group showed a significant reduction in aspiration signs compared with the control group. No significant between-group difference in signs of aspiration was found at 6 months post-treatment compared with baseline (OR 0.63 CI 0.14–2.36; P = 0.46; Table 2).

Swallowing-related QOL

At the end-of-treatment, the results from the linear mixed model for testing changes in the swallowing-related QOL score between baseline and end-of-treatment showed no significant between-group difference (ratio 0.97 CI 0.60–1.57; P = 0.90; Table 2). Further, no significant difference was found at 6 months post-treatment (ratio 1.01 CI 0.61–1.66; P = 0.98; Table 2).

Adverse events

Two participants in the intervention group experienced temporary pain in the orofacial region during the treatment period that disappeared after treatment was stopped. One previously had trigeminal neuralgia that was triggered.

Discussion

This cluster randomised, controlled trial showed that oral neuromuscular training had a positive effect on swallowing dysfunction among older people in intermediate care. The participants in the intervention group significantly increased their swallowing rate and reduced clinical signs of aspiration after 5 weeks of oral neuromuscular training compared with controls. Persisting improvements in swallowing rate was also found at 6 months post-treatment. These results show that the non-invasive oral neuromuscular training is a promising new rehabilitation method of swallowing dysfunction. The finding is a first step to gain evidence on the training method among individuals with impaired swallowing.

Exercise-based swallow training was previously demonstrated to improve swallowing function, and reduce the frequency of malnutrition and pneumonia in older people [24]. Earlier studies on the effect of oral neuromuscular training among stroke patients with swallowing dysfunction suggested similar results as the present study, with increased swallowing rate [13, 25]. One study showed that 63% of the stroke patients regained normal swallowing rate after 5–8 weeks of training [13], another found that 71% normalised their swallowing rate after 13 weeks of training [25]. Thus, an increased treatment period with oral neuromuscular training may further improve the swallowing rate.

Although our study showed the effect on swallowing rate was maintained 6 months after the training period, the effect on signs of aspiration was not sustained. Thus, it could have been beneficial for the participants to continue with the training to maintain a safe swallow. Studies on strength training effects on older people have shown that continued training once per week is needed to maintain both strength and muscle size [26]. The need to maintain swallowing training in older people may be due to many factors, including sarcopenia (agerelated reduction in muscle fibres, especially Type II, which are common in the muscles involved in swallowing). Another factor is different age-related diseases that might cause swallowing dysfunction. Older people with degenerative diseases might benefit from consistent training of orofacial and pharyngeal neuromuscular training since there is a decline in their functional capacity over time [27]; while, a shorter training period may have a more lasting effect on people suffering from a stroke due to regained function by swallowing network reorganisation [3, 13]. In this study, the participants with swallowing dysfunction had a variety of diagnoses.

Hägg *et al.* [13] postulated that the mechanism by which oral neuromuscular training may improve swallowing function is afferent stimulation of the brain stem swallowing centre through sensory receptors of the lips and the oral cavity combined with the motor function to create lip closure and increased activity of the buccinator mechanism. This would activate the muscles of the oral floor and cause the tongue to retract and stimulate the anterior pharyngeal pillar, the soft palate, and intraoral mucous membranes, and strengthen the pharyngeal, suprahyoid and infrahyoid muscles involved in swallowing. The training should be performed three times for 5–10 s per session and be repeated three times daily. This results in the optimal force-generating capacity needed to gain neuromuscular adaption, since a longer duration results in fatigue of the orofacial and pharyngeal muscles.

Changes in swallowing-related QOL did not differ between groups at any time-point. Not all participants complained about symptoms of dysphagia and had high baseline scores of swallowing-related QOL, which explain the lack of improvement in swallowing-related QOL at the group level. This result corresponds to previous findings that many people are unaware of their swallowing dysfunction [28] or often believe that their condition is untreatable [4]. Thus, objective assessment of oral and pharyngeal swallowing dysfunction is important in the care of older people to minimise the risk of severe complications, regardless of the subjective perception. As shown in this study, older people might not recognise nor complain about their swallowing difficulties.

This study has several strengths. It is the first randomised, controlled trial evaluating oral neuromuscular training in older people with various diagnoses and swallowing dysfunction. A simple timed water swallow test was used, that could both identify individuals at risk of aspiration and evaluate the treatment effect. In addition, the test has high sensitivity, Wu et al. reported that 47 of 49 individuals with scores <10 mL/s also showed videoradiographic signs of swallowing dysfunction [15, 16]. Intervention with oral neuromuscular training is easy for nursing staff to carry out and can therefore be implemented for improved treatment of swallowing dysfunction in the care of older people. Furthermore, the generalisability of the results to other groups of older people with different aetiologies for their swallowing dysfunction is high since the study was conducted in several intermediate care units and data analysis was adjusted for this.

There are limitations that needs to be acknowledge. The inclusion criteria was based on impaired swallowing rate and not on clinical signs of aspiration. The swallowing assessments were not performed blinded to intervention; and additional instrumental examinations (e.g. videoendo-scopy or videofluoroscopy) for confirmation of swallowing dysfunction were not performed. However, that would not have been feasible in the study context, and the timed water swallow test has shown high inter- and intra-rater reliability [15]. Although the intervention method shows promise, the confidence interval for effect size is wide, the clinical impact of the changes in rate is uncertain and with the further limitations of the study, including attrition and baseline imbalance in groups, the clinical benefit is not clarified.

Conclusion

Our results show that oral neuromuscular training is a new promising method for rehabilitation of swallowing dysfunction in older people in intermediate care. Further studies are however needed before this intervention could be recommended for clinical practice.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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Declaration of Conflict of interest: The oral neuromuscular training device (IQoro[®] patented and CE-marked by MYoroface AB, Hudiksvall, Sweden) was invented by MH. Swedish patent: SE 1350314-9, 2014 July 14. Therefore, M.H. was not involved in data collection or the data analysis. The authors declare no conflict of interest.

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