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Effects of personalized swallowing rehabilitation in patients with oral cancer after free flap transplantation: A cluster randomized controlled trial

Jing Zhang [a], Hong-Yun Wu [a], Qian Lu [b], Xiao-Feng Shan [a], Zhi-Gang Cai [a], Lei Zhang [a], Li Wei [a], Yue Yang [a,*]

[a] Department of Oral and Maxillofacial Surgery, Peking University School and Hospital of Stomatology & National Center of Stomatology, Beijing 100081, China
[b] Peking University School of Nursing, Beijing 100191, China

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ABSTRACT

Objectives: Dysphagia is a common and serious complication in patients with oral cancer after free flap transplantation (OC-FFT), which seriously affects their quality of life. Studies have found swallowing rehabilitation can improve the swallowing ability of these patients, but the studies have design deficiencies. This study's purpose was to test the effectiveness of personalized swallowing rehabilitation for this patient population.
Materials and methods: This is a cluster randomized, non-blind, controlled clinical trial. Participants were 68 OC-FFT patients randomly assigned to intervention (n = 34) or control (n = 34) groups. The control group received routine nursing and health education, while the intervention group received personalized swallowing rehabilitation twice a day for 10 days, based on the results of the Mann Assessment of Swallowing Ability-Oral Cancer (MASA-OC). On the 6th and 15th days and 1 month after the operation, MASA-OC scores and percentage weight loss were measured, and the removal time to nasogastric tube was also recorded. The quality of life was evaluated 1 month after the operation.
Results: On day 15 and 1 month after the operation, MASA-OC scores were higher and the percentage weight loss was lower in the intervention group than the control group ($P < 0.05$). The removal time of the nasogastric tube was shorter ($P < 0.05$), and the quality of life at 1 month was better in the intervention group ($P < 0.05$).
Conclusion: Personalized swallowing rehabilitation can improve patients' swallowing after OC-FFT, promote the early removal of the nasogastric tube, and improve nutritional status and quality of life.

Introduction

Oral cancer is the most common malignant tumor of the head and neck, with 377,713 new cases and 177,757 deaths in 2020 [1]. Radical resection and free flap transplantation are the first options for this kind of cancer [2,3]. Although the free flap has the function of sealing the defect and structural reconstruction, large-scale surgical resection can seriously damage the internal organs, muscles, and nerve tissue of the oral cavity. The incidence of dysphagia in postoperative patients is 41.3–88.0 % [4,5], and can be as high as 98.0 % 7 days after the operation [6]. Dysphagia can increase the risk of leakage, aspiration, and malnutrition, leading to anxiety and depression, and seriously affecting postoperative quality of life [7–10]. There are differences in the clinical manifestations of dysphagia in patients with different surgical sites, such as salivation and food residue in the mouth after lip and cheek injury, limitation of mouth opening and decreased masticatory strength after a jaw operation, and cough and prolonged eating time after tongue injury [11].

Previous studies have shown that swallowing rehabilitation can improve the swallowing function of patients with oral cancer after free flap transplantation (OC-FFT) [12,13], because oral sensory stimulation and oral exercise training can promote the recovery of swallowing through muscle and nerve stimulation. However, most studies have focused on patients with tongue cancer, and there are differences in their training start time, duration, and training methods [12,13]. Moreover, the specific training used in some studies is not clear, and all patients received the same training program, which may not be relevant for patients with different characteristics of impaired swallowing.

Therefore, patients in this study were given personalized training, based on the characteristics of their impaired swallowing after free flap

* Corresponding author.
E-mail addresses: jingzhang0012@163.com (J. Zhang), whyhblf@163.com (H.-Y. Wu), luqian@bjmu.edu.cn (Q. Lu), kqsxf@263.net (X.-F. Shan), czg4209@126.com (Z.-G. Cai), zhlei_doctor@sina.com (L. Zhang), byweili@sina.com (L. Wei), yangyuekq@163.com (Y. Yang).

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transplantation for oral cancer, emphasizing the key parts and key goals of training. We hypothesized that personalized swallowing rehabilitation could promote early recovery of swallowing and improve the quality of life of patients with OC-FFT. We compared and analyzed the effects of personalized swallowing rehabilitation on swallowing function, nutritional status, and the quality of life of postoperative patients using a randomized controlled trial. The purpose of this study was to evaluate the effect of personalized swallowing rehabilitation on OC-FFT patients, in order to provide a reference for clinical medical staff to choose a swallowing rehabilitation program.

Patients and methods

Design

This study is a cluster randomized clinical trial, which was approved by the Ethics Committee of Peking University School of Stomatology (No. PKUSSIRB-202058132) and was registered in the Chinese Clinical Trial Registry (ChiCTR2100050398).

Patients

Patients were recruited in the Department of Oral and Maxillofacial Surgery, Peking University School and Hospital of Stomatology from August 2021 to January 2022. The inclusion criteria were: (1) age $\geq$ 18 years; (2) primary oral cancer confirmed by a histopathological report; (3) extended resection and free flap transplantation; (4) clear thinking and ability to cooperate with the completion of training; (5) daily use of smartphones by patients or their families; and (6) informed consent and voluntary participation in this study. The exclusion criteria were: (1) previous or concurrent diseases affecting swallowing, such as stroke; (2) received preoperative radiotherapy; or (3) language communication obstacles, such as being deaf or mute or not understanding Chinese. The removal criteria were: (1) severe complications, such as flap necrosis and infection after the operation; (2) reoperation during the study; (3) death during the study; or (4) withdrawal or loss of follow-up during the study. All patients signed an informed consent form before participating in the study.

Randomization

Using the ward room as the grouping unit, the rooms were numbered 1–18, and 18 random numbers were generated by SPSS version 24.0 software, to randomly divide rooms into intervention and control groups. The grouping results were jointly saved by the head nurse and one researcher. Nurses who did not know the grouping results were responsible for assigning rooms to the patients. When the patients were included, the researcher gave them information about the grouping.

Methods

Training content

The control group received routine nursing and health education related to swallowing, including closely observing changes in the disease, keeping oral hygiene, guiding eating, carrying out effective coughing, and conducting supraglottic swallowing training for patients with coughing after eating and drinking.

The intervention group received the same nursing and swallowing related health education as the control group. In addition, the Mann Assessment of Swallowing Ability-Oral Cancer (MASA-OC) was used to evaluate the swallowing function of the patients in the intervention group before the start of the intervention on the 6th day after the operation (hereinafter referred to as baseline). If the score of the corresponding item was not complete, it was assumed that the function assessed by the item was impaired, and targeted training was needed. Table 1 shows the training content, the applicable patient populations, and the relevant MASA-OC items. The training began on the 6th day after the operation, 30 min before a meal or 2 h after a meal. The patients took a sitting position or a semi-supine position, once every morning and afternoon. The content of each training session was the same, and the training lasted for 10 days. See the Appendix for the detailed plan.

Table 1
Personalized swallowing rehabilitation program for patients after oral cancer free flap transplantation.

Training methods	Training content	Applicable population	MASA-OC items
Oral sensory stimulation	Cold-acid stimulation	All patients	–
	Vibration training with a vibration rod	All patients	–
	Air pulse stimulation	All patients	–
Oral exercise training	Lip and cheek exercise training	Patients with impaired lip and cheek function	Salivation, lip closure
	Mandibular movement training	Patients with impaired mandibular movement	Mouth opening, oral preparation period
	Tongue exercise training	Patients with impaired tongue function	Tongue muscle movement, tongue muscle strength

Implementation

Both groups were given the same transitional care smartphone App on the 6th day after the operation. During hospitalization, routine nursing was performed by nurses, and swallowing rehabilitation was performed by a swallowing specialist nurse who is a senior professional in the field of swallowing disorder training by the Swallowing Disorder Rehabilitation Committee of Chinese Association of Rehabilitation Medicine. After discharge, the patients in both groups received continuous nursing. For patients in the intervention group, the swallowing specialist nurse presented knowledge and videos of swallowing rehabilitation, and continued to guide and supervise the training of patients. Patients encountering problems in the training process could also ask questions through the platform.

Sample size calculation

A pre-test was conducted with 22 patients, with 11 patients in each group. The outcome measure was the difference in the MASA-OC score at the end of the intervention on the 15th day after the operation minus the baseline score. The sample size was estimated by the formula for estimating the mean of two independent samples, with $\alpha = 0.05$ and $\beta = 0.2$, using a two-sided test and a look-up table to get $t_{\alpha/2} = 1.96$ and $t_{\beta} = 0.84$. According to the pre-test calculation, σ was 9.85 and δ was 6.94.

$N_1 = N_2 = 2 * [(t_{\alpha/2} + t_{\beta})\sigma/\delta]^2 \approx 32$. Taking into account a 10 % drop-out rate, this study selected 36 patients for each group, for a total of 72 patients.

Outcome measures

General information

We collected the patients' demographic characteristics as well as disease and treatment information, including age, sex, smoking history, drinking habits, complications (hypertension, diabetes, and other), tumor site, tumor stage, flap donor site, the presence or absence of mandible osteotomy, neck dissection, and tracheotomy.

Primary outcome

The MASA-OC was used to assess the location and severity of impaired swallowing in patients at baseline, and day 15 and 1 month after the operation. The Mann Assessment of Swallowing Ability-Cancer (MASA-C), was proposed by Carnaby and Carry [14] in 2014 as an evaluation tool for patients with head and neck cancer to assess the physiological mechanism of dysphagia. It has been used in many studies for patients with head and neck cancer [15,16], and the European Society for Swallowing Disorders recommends the MASA-C for clinical assessments of swallowing for patients with head and neck cancer [17]. We translated and revised the MASA-C in a previous study to create the MASA-OC, which contains 15 items, for patients who have had oral cancer surgery [18]. The lowest score is 24 points, the highest score is 120 points, and a total score $\leq$ 105 points can be judged as dysphagia. Cronbach's alpha of the MASA-OC was 0.868, its sensitivity was 95.0 %, and its specificity was 92.5 %.

Secondary outcomes

There were three secondary outcomes. The first was removal time of the nasogastric tube, which was measured from the first day after the operation to the time it was removed.

Percentage weight loss was another secondary outcome, which was used to evaluate the nutritional status of patients. The formula was [baseline weight (kg)-current weight (kg)]/baseline weight (kg) $\times$ 100 %. It was measured at baseline, the 15th day after the operation and 1 month after the operation.

The final secondary outcome was quality of life on one month after the operation, which was measured using the University of Washington Quality of Life Questionnaire version 4 (UW-QOLv4). The tool is a self-report questionnaire specifically developed for patients with head and neck tumors by Hassan et al. in 1993 [19]; the fourth version of it was created in 2002 [20]. Version 4 contains 12 specific items and 3 comprehensive items that have 3 to 5 response options, with each item scored from 0 to 100 points. Higher scores indicate better quality of life. In 2009, Yan et al. [21] developed a Chinese version of it, which had a Cronbach's alpha of 0.725 and a split-half reliability of 0.701.

Statistical analyses

Statistical analyses were conducted using SPSS version 24.0. The normality of distribution was assessed using the Shapiro-Wilk test. Continuous variables that are normally distributed are described by their mean and standard deviation and analyzed by the two independent samples *t*-test; whereas those that are not normally distributed are described by their median and interquartile range (IQR) and analyzed by the Mann-Whitney *U* test. Categorical variables are reported as frequencies and percentages and analyzed by the Chi-square test or Fisher's exact test. Generalized estimating equations (GEE) were used to evaluate the changes in swallowing ability and percentage weight loss over time in the two groups. All tests were two-sided and *P*-values less than 0.05 were considered statistically significant.

Results

Patient characteristics

A total of 123 patients were enrolled during the study period, and 68 patients (34 in the intervention group and 34 in the control group) completed the entire study (see Fig. 1).

There were no statistically significant differences between the baseline characteristics of the two groups ($P > 0.05$; see Table 2), which indicates they were comparable.

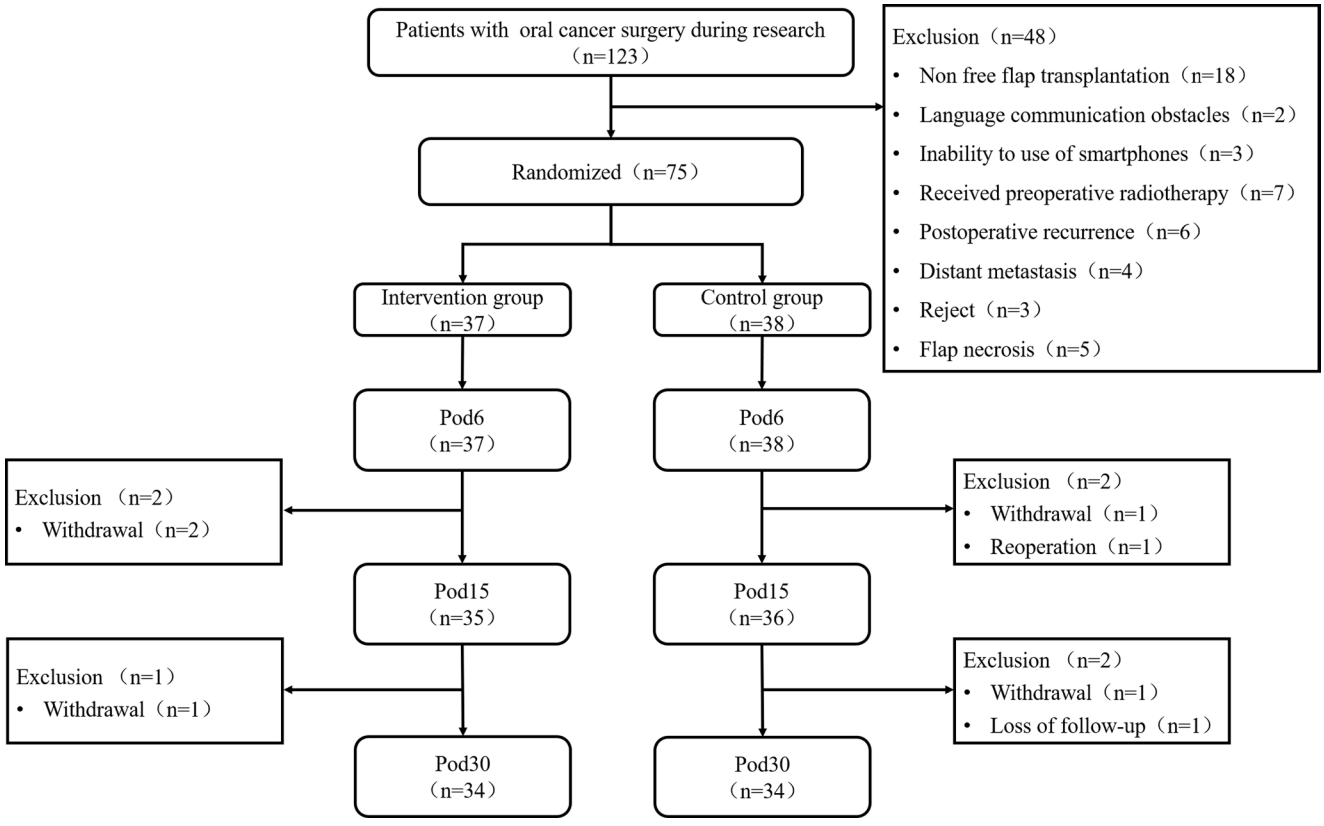

Fig. 1. Flow diagram. Pod6, the start of the intervention on the 6th day after the operation; Pod15, the end of the intervention on the 15th day after the operation; Pod30, 1 month after the operation.

Table 2
Demographic and disease and treatment characteristics.

Variable	Category	Mean score ± standard deviation or *n* (%)			*t*/χ2/*Z*	*P* value
		Total patients(n = 68)	Interventional group(n = 34)	Control group(n = 34)		
Age (years)[a]		52.66 ± 12.61	51.00 ± 13.12	54.32 ± 12.04	−1.088	0.281
Sex[b]					0.066	0.798
	Male	45(66.2)	23(67.6)	22(64.7)		
	Female	23(33.8)	11(32.4)	12(35.3)		
Smoking history[b])					0.530	0.467
	No	35(51.5)	16(47.1)	19(55.9)		
	Yes	33(48.5)	18(52.9)	15(44.1)		
Drinking[b])					0.078	0.779
	No	51(75.0)	25(73.5)	26(76.5)		
	Yes	17(25.0)	9(26.5)	8(23.5)		
Complications[b]					0.239	0.625
	No	38(55.9)	18(52.9)	20(58.8)		
	Yes	30(44.1)	16(47.1)	14(41.2)		
	Hypertension[2])	24(35.3)	12(35.3)	12(35.3)	<0.001	1.000
	Diabetes[2])	11(16.2)	7(20.6)	4(11.8)	0.976	0.323
	Others[3])	5(7.4)	3(8.8)	2(5.9)	<0.001	1.000
Tumor site[c]					–	0.795
	Buccal mucosa	11(16.2)	7(20.6)	4(11.8)		
	Oral floor	5(7.3)	3(8.8)	2(5.9)		
	Tongue	15(22.0)	8(23.5)	7(20.6)		
	Palate	11(16.2)	6(17.7)	5(14.7)		
	Maxillary gingiva	8(11.8)	3(8.8)	5(14.7)		
	Mandibular gingiva	18(26.5)	7(20.6)	11(32.3)		
Tumor stage[c]					–	0.965
	I	3(4.4)	1(2.9)	2(5.9)		
	II	21(30.9)	10(29.4)	11(32.4)		
	III	18(26.5)	10(29.4)	8(23.5)		
	Ⅳ	19(27.9)	9(26.5)	10(29.4)		
	Unclear	7(10.3)	4(11.8)	3(8.8)		
Flap donor site[b]					1.213	0.750
	Forearm	14(20.6)	8(23.5)	6(17.6)		
	Fibula	22(32.4)	9(26.5)	13(38.2)		
	Iliac bone	12(17.6)	6(17.6)	6(17.6)		
	Femoral anterolateral	20(29.4)	11(32.4)	9(26.6)		
Mandible osteotomy[b]					2.125	0.145
	No	32(47.1)	19(55.9)	13(38.2)		
	Yes	36(52.9)	15(44.1)	21(61.8)		
Neck dissection[c]					–	0.329
	Unilateral	46(67.7)	20(58.8)	26(76.5)		
	Bilateral	13(19.1)	8(23.5)	5(14.7)		
	No	9(13.2)	6(17.7)	3(8.8)		
Tracheotomy[b]					2.946	0.086
	No	39(57.4)	16(47.1)	23(67.6)		
	Yes	29(42.6)	18(52.9)	11(32.4)		

[a] Two independent sample t-test.
[b] Pearson's Chi-square test.
[c] Fisher's exact test.

Swallowing function

Table 3 shows the inter-group and intra-group comparisons of the MASA-OC scores in the two groups at different time points.

Table 3
Comparison of MASA-OC scores between the two groups at each time point.

Time point	Median (P_{25}-P_{75})		*Z*	*P* value
	Interventional group (n = 34)	Control group (n = 34)		
Pod6	93.00 (78.00 ~ 99.25)[b, c]	87.00(77.75 ~ 96.00)[b, c]	−0.706	−0.480
Pod15	104.00(98.25 ~ 109.00)[a, c]	94.50(87.75 ~ 104.25)[a, c]	−2.345	0.019*
Pod30	113.00(108.75 ~ 116.00)[a, b]	102.00(94.75 ~ 108.25)[a, b]	−5.128	<0.001*

Pod6, the start of the intervention on the 6th day after the operation; Pod15, the end of the intervention on the 15th day after the operation; Pod30, 1 month after the operation. [a] Compared with Pod6, $P < 0.05$; [b] Compared with Pod15, $P < 0.05$; [c] Compared with Pod30, $P < 0.05$; *$P < 0.05$.

At baseline, the incidence of dysphagia between the two groups was 98.5 % (67/68), and there was no significant difference in MASA-OC scores between the two groups ($P > 0.05$). On day 15 and 1 month after the operation, the MASA-OC scores of the intervention group were always significantly higher than those of the control group ($P < 0.05$).

The GEE analysis showed statistically significant differences in MASA-OC scores by group and time, and that there were interaction effects of group and time ($P < 0.05$). Fig. 2 shows the MASA-OC scores of the two groups at different points in time.

Combined with the comparison results between groups in Table 3, it can be seen that the MASA-OC scores in both groups increased with time.

Table 4 shows the changes of MASA-OC scores in the two groups over time.

The β value of the intervention group × 15th day after the operation and that of intervention group × 1 month after the operation were positive, and the differences were statistically significant ($P < 0.05$). This indicated that the MASA-OC scores of the intervention group at these two time points were higher than the control group.

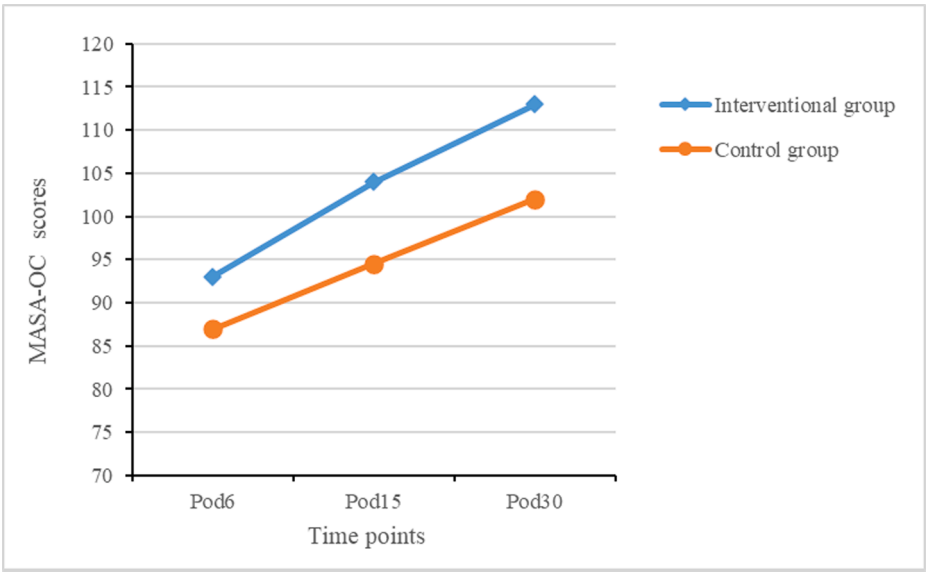

Fig. 2. Changes of MASA-OC scores in two groups. Pod6, the start of the intervention on the 6th day after the operation; Pod15, the end of the intervention on the 15th day after the operation; Pod30, 1 month after the operation.

Table 4
GEE analysis of MASA-OC scores in the two groups.

Parameter	Values	*β*	*SE*	*Wald*$_{\chi 2}$	*P* value
(Intercept)		86.500	1.757	2423.842	<0.001*
Group	Interventional group	1.265	2.923	0.187	0.665
	Control group	0$^{\Delta}$	–	–	–
Time point	Pod30	14.500	1.119	167.794	<0.001*
	Pod15	9.265	1.024	81.827	<0.001*
	Pod6	0$^{\Delta}$	–	–	–
Group × time point	Interventional group × Pod30	9.353	2.007	21.716	<0.001*
	Interventional group × Pod15	4.324	1.769	5.975	0.015*
	Interventional group × Pod6	0$^{\Delta}$	–	–	–

Pod6, the start of the intervention on the 6th day after the operation; Pod15, the end of the intervention on the 15th day after the operation; Pod30, 1 month after the operation; $^{\Delta}$ and – indicate the reference group; *$P < 0.05$.

Removal time of the nasogastric tube

The removal time of the nasogastric tube in the intervention group was 8.38 (7.0–10.0) days after the operation, which was significantly shorter than that in the control group, which was 17.76 (10.0–22.0) days after the operation. This difference was statistically significant (Z = -5.143, $P < 0.05$).

Percentage weight loss

Table 5 shows the inter-group and intra-group comparisons of the percentage weight loss in the two groups at different time points. Compared with their baseline body weight, there were significant differences in the percentage weight loss between the two groups on day 15 and 1 month after the operation ($P < 0.05$).

GEE analysis showed that there were significant differences for group, time, and the interaction of group and time between the two groups ($P < 0.05$). Fig. 3 shows the percentage weight loss at different time points in the two groups.

Combined with the comparison results between the groups in Table 5, we found that the percentage weight loss of the intervention group was always negative on the 15th day and 1 month after the operation, which showed negative and slow growth ($P > 0.05$), and then a negative and rapid growth trend ($P < 0.05$). In the same period, the control group was always positive ($P < 0.05$), and showed positive and slow rapid ($P > 0.05$), and then a positive and slow growth trend ($P < 0.05$). There were significant differences in the percentage weight loss between the two groups from baseline to 1 month after the operation ($P < 0.05$).

Table 5
Comparison of percentage weight loss between the two groups at each time point.

Time point	*Median* (P_{25}-P_{75})		*Z*	*P* value
	Interventional group (n = 34)	Control group (n = 34)		
Pod6	0^{c}	0$^{b, c}$	–	–
Pod15	−0.20(-1.10 ~ 1.09)^{c}	2.45(0.91 ~ 5.43)^{a}	−4.017	<0.001*
Pod30	−1.54(-3.40 ~ 1.12)$^{a, b}$	3.33(-0.54 ~ 4.88)^{a}	−3.858	<0.001*

Pod6, the start of the intervention on the 6th day after the operation; Pod15, the end of the intervention on the 15th day after the operation; Pod30, 1 month after the operation; ^{a} Compared with Pod6, $P < 0.05$; ^{b} Compared with Pod15, $P < 0.05$; ^{c} Compared with Pod30, $P < 0.05$; *$P < 0.05$.

Table 6 presents the changes in the percentage weight loss in the two groups over time. The β values of intervention group × 15 days after the operation and that of intervention group × 1 month after operation were negative, and the differences were statistically significant ($P < 0.05$). This showed that the percentage weight loss of the intervention group at these two time points were always lower than that of the control group.

Quality of life

Table 7 shows the UW-QOLv4 scores of the two groups on 1 month after the operation. There was a significant difference in the total UW-QOLv4 score between the two groups ($P < 0.05$), and the analyses of the scores of each domain found there were significant group differences in activity, recreation, swallowing, chewing, taste, saliva, and overall quality of life during the past 7 days ($P < 0.05$).

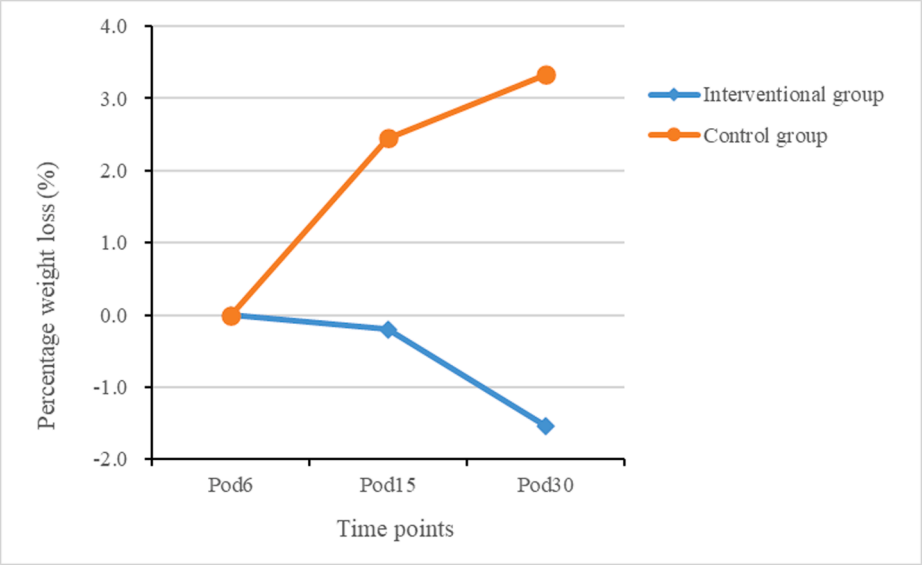

Fig. 3. Changes of percentage weight loss in two groups. Pod6, the start of the intervention on the 6th day after the operation; Pod15, the end of the intervention on the 15th day after the operation; Pod30, 1 month after the operation.

Table 6
GEE analysis of percentage weight loss in the two groups.

Parameter	Values	β	*SE*	*Wald*χ*2*	*P* value
(Intercept)		2.474E-18	9.307E-11	<0.001	1.000
Group	Interventional group	−8.787E-18	1.140E-10	<0.001	1.000
	Control group	0[Δ]	–	–	–
Time point	Pod30	0.024	0.006	15.024	<0.001*
	Pod15	0.032	0.005	39.373	<0.001*
	Pod6	0[Δ]	–	–	–
Group × time point	Interventional group × Pod30	−0.036	0.008	19.000	<0.001*
	Interventional group × Pod15	−0.028	0.007	18.532	<0.001*
	Interventional group × Pod6	0[Δ]	–	–	–

Pod6, the start of the intervention on the 6th day after the operation; Pod15, the end of the intervention on the 15th day after the operation; Pod30, 1 month after the operation; [Δ] and – indicate the reference group; *$P < 0.05$.

Table 7
Comparison of quality of life scores between the two groups.

Domains	Mean score ± standard deviation		*t*	*P* value
	Interventional group ($n = 34$)	Control group ($n = 34$)		
UW-QOLv4 total score	996.39 ± 75.67	809.62 ± 152.12	4.802	<0.001*
Pain	88.89 ± 12.78	82.69 ± 11.77	1.658	0.105
Appearance	76.39 ± 13.48	72.12 ± 14.71	0.980	0.333
Activity	75.00 ± 21.00	58.65 ± 24.44	2.307	0.026*
Recreation	91.67 ± 12.13	66.35 ± 27.33	3.677	0.001*
Swallowing	83.33 ± 15.34	57.69 ± 26.28	3.717	0.001*
Chewing	58.33 ± 19.17	32.69 ± 24.26	3.743	0.001*
Speech	74.44 ± 16.88	65.38 ± 22.50	1.448	0.155
Shoulder	93.33 ± 12.83	78.85 ± 28.47	2.016	0.050
Taste	86.67 ± 15.34	61.54 ± 35.85	2.794	0.008*
Saliva	93.33 ± 12.83	78.85 ± 25.35	2.229	0.031*
Mood	86.11 ± 15.39	77.88 ± 20.41	1.447	0.155
Anxiety	88.89 ± 16.76	76.92 ± 25.89	1.724	0.092
HRQOL, compared with mouth before cancer	51.39 ± 32.62	50.00 ± 28.28	0.150	0.881
In general, HRQOL during the past 7 days	69.44 ± 16.17	65.38 ± 12.40	0.942	0.351
Overall QOL during past 7 days	73.61 ± 13.48	63.46 ± 12.71	2.541	0.015*

UW-QOLv4, the University of Washington Quality of Life Questionnaire, version 4; HRQOL, health-related quality of life; QOL, quality of life; *$P < 0.05$.

Discussion

Swallowing function

On the 6th day after the operation, the incidence of dysphagia in the two groups was 98.5 %, indicating that dysphagia was common in OC-FFT patients. The result is similar to Klingelhoffer et al. [6], who used fiberoptic endoscopic to evaluate dysphagia in 400 patients with oral squamous cell carcinoma on the 7th day after an operation, and found that the incidence rate was 98.0 %. Extended resection for oral cancer has a great impact on the swallowing ability of patients, changing the normal physiological and anatomical structure in the process of swallowing, resulting in swallowing movements and sensory dysfunction of postoperative patients [4]. Although free flap transplantation can repair intraoral defects, maintain the integrity of the oral structure, and maintain swallowing and speech functions, the ability to improve swallowing is still limited [22–24]. In addition, mandible osteotomy, neck dissection, and tracheotomy can also affect the swallowing ability of patients [25,26].

Our study showed that the MASA-OC scores of both groups increased continuously over time, which is consistent with the results of Mao [27], and may be related to the gradual healing of the wound and the gradual reduction of the swelling. A number of meta-analyses have shown that rehabilitation for OC-FFT patients is helpful for the early recovery of

swallowing ability [13,28]. For such patients, the focus of swallowing rehabilitation is to promote the recovery of motor and sensory functions of injured muscles and nerves, and to promote functional compensation of muscles and sensory nerves on the healthy side, and then to increase muscle strength, exercise range, and movement flexibility [29]. Cold-acid stimulation, vibration training, and air pulse stimulation are commonly used sensory training methods, which can improve the sensitivity of patients to food mass perception, provide oral deep sensory stimulation, increase the times of swallowing and swallowing desire, and are highly safe [11]. They have been used in postoperative patients with oral cancer [30–33]. Oral exercise training is done through active or passive exercise of the lips, cheeks, tongue, and upper and lower jaw to enhance movement strength, stability, and coordination. The training method is clear, and the training effect is remarkable, and it has been widely used in postoperative patients with oral cancer [11,34,35]. However, to date, there has been no report on targeted training. Jiang et al. [31] and Hsiang et al. [34] found that swallowing rehabilitation could significantly improve the strength and range of movement of swallowing-related muscles in patients after oral cancer surgery, and reduce the incidence of aspiration and food residue.

Therefore, our study is based on the analysis of damage to swallowing function in different parts of the mouth of postoperative patients, combined with oral sensory training and targeted exercise training. There was no significant difference in MASA-OC scores between the two groups at baseline, but the scores and rising trend of MASA-OC scores in the intervention group were always higher than the scores in the control group at the 15th day and 1 month after the operation, which indicates personalized swallowing rehabilitation can improve swallowing and accelerate the rehabilitation process of swallowing ability.

Removal time of the nasogastric tube

Our study showed that the nasogastric tube removal time in the intervention group was significantly shorter than that in the control group, indicating that personalized swallowing rehabilitation can improve the swallowing ability of postoperative patients, and then promote the early removal of the nasogastric tube, which is consistent with the results of many studies [36–38]. The Enhanced Recovery After Surgery Society recommended, in 2017, that postoperative patients should eat orally early during the perioperative management of patients who have undergone free flap reconstruction for head and neck cancer [39]. Guidera et al. [40] compared the timing of oral feeding in OC-FFT patients and found that early oral feeding did not increase the incidence of postoperative complications or affect body weight, but it can shorten the length of hospital stay. Although there is no unified standard for nasogastric tube removal, many studies have used swallowing function as an indication for nasogastric tube removal [41,42].

Percentage weight loss

The percentage weight loss of the intervention group in our study always showed a negative increasing trend, while that of the control group always showed a positive trend. This shows that personalized swallowing rehabilitation can reduce the percentage weight loss and improve the nutritional status of postoperative patients. Wakabayashi et al. [43] conducted swallowing muscle resistance training in elderly patients with dysphagia, and found that the improvement of nutritional status was significantly related to the improvement in swallowing, which is consistent with our result.

Quality of life

The total score of the UW-QOLv4 in the intervention group in our study was significantly higher than that in the control group, indicating that personalized swallowing rehabilitation is beneficial for improving the quality of life of OC-FFT patients. Dysphagia is one of the most serious symptoms that affect the quality of life of postoperative patients [9]. Many studies have also shown that early rehabilitation intervention of swallowing can effectively improve the quality of life of patients [44,45]. In addition, multiple UW-QOLv4 items in the intervention group were better than those in the control group. There may be several reasons for this. First, activity and recreation may be related to an improvement in the nutritional status of the intervention group. Weight loss and malnutrition can affect the quality of life, whereas fatigue and weakness further restrict activity [46,47]. Second, personalized swallowing rehabilitation can improve patients' swallowing, and mandibular movement training can improve mouth opening, which in turn, has a certain impact on patients' chewing ability. Third, cold-acid stimulation may have some effect on patients' taste, although the specific effect needs to be verified by further research. Fourth, both cold-acid stimulation and vibrator training with a vibration rod can promote saliva secretion [48,49]. The intervention group may have had a beneficial effect on saliva secretion when using these two methods.

Limitations

First, due to the particularity of the training program and the outcome measures, we did not implement a blind method for the research objectives or the outcome evaluators. Second, due to the small sample size, the study did not analyze the specific effects of each training method or analyze the effect of personalized swallowing rehabilitation by surgical site, which may have had some impact on the results. Third, due to the limitations of conditions, we did not use objective assessment tools to analyze the changes in swallowing more deeply. Fourth, because patients with advanced oral cancer often receive concurrent postoperative radiotherapy, which could have an effect on dysphagia, we only did a 1-month followed-up after the operation, and the potential long-term effects of rehabilitation could not be evaluated.

Conclusion

This cluster randomized controlled trial shows that personalized swallowing rehabilitation can improve the swallowing ability of OC-FFT patients, promote early removal of nasogastric tubes and early recovery of oral feeding, and improve nutritional status and quality of life.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.oraloncology.2022.106097.

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