Original Article

Appropriate nutritional management in patients with impaired mastication and those with mild dysphagia: a multicenter study of the usefulness of novel foods processed and softened by enzymes

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Background and Objectives: Our aim was to investigate the safety of iEAT (a food that is softened by heat and enzyme homogeneous permeation) and iEAT-affected nutrition parameters, e.g., nutrition intake (calculated from the consumption rate in patients with impaired mastication and those with mild dysphagia). **Methods and Study Design:** A multicenter, randomized, cross-over study of iEAT was conducted in 50 patients (mean age 77.0±11.0 years) with dysphagia due to Occasional aspiration (4 points on the Dysphagia Severity Scale [DSS]) or Oral problems (5 points) randomly assigned to the study diet (iEAT) or its opposite (the modified traditional [control] diet) for 1 week and then switched for 1 week to the opposing diet. Intake of energy, protein, lipid, carbohydrate, and sodium were evaluated along with questionnaire-assessed levels of satisfaction. **Results:** The mean intake was significantly lower for the study diet, whereas the intakes of energy, protein, carbohydrate on day 1, intake of protein on day 7, and body weight on day 7 were significantly higher for the study diet. We found no between-group differences in hematologic and blood biochemistry parameters, no diet-related adverse events, greater satisfaction with the appearance of the study diet ($p<0.001$), and comparable levels of satisfaction with ease of eating, ease of swallowing, and taste for both diets. **Conclusions:** iEAT was provided to patients with mild dysphagia as safely as a blender diet or other diets usually provided at each study site, and can serve as an efficient nutrition source.

Key Words: dysphagia, intake, modified diet, satisfaction, taste

INTRODUCTION

Consumption of appropriate amounts of meals cooked with appropriate foodstuffs is essential, as one of the important bases of life, for the maintenance or improvement of nutrition status and the joy or satisfaction of eating. Symptoms associated with inability or insufficient ability to take in nutrition from foods include impaired mastication and dysphagia caused by cerebrovascular disorders, dementia, head and neck cancer, Parkinson's disease, and broad categories of diseases.[1-6] Various efforts have been made to enable patients with these disorders to eat food by mouth by altering the physical properties or shapes of foodstuffs (such as the blender diet, minced diet or paste diet).[7-9] However, shortcomings of these diets have been pointed out, and they may impair the joy of eating. Modified texture diets are often associated with decreased oral intake because of changes in appearance, texture, and mouth feel of the food and therefore, are likely to exacerbate the incidence of malnutrition, particularly in a vulnerable population group.[10]

iEAT (EN Otsuka Pharmaceutical Co. Ltd., Japan), a recently developed food product that resembles ordinary meals in appearance but is cooked to soften and then

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mashed by the tongue, may have appropriate physical properties for meals provided to patients with impaired mastication and those with mild dysphagia.[11] We previously conducted a multicenter study (single-arm, before-after design) in patients with impaired mastication but intact swallowing, and reported that iEAT significantly improved patient satisfaction with meals and increased energy intake and protein intake compared with the blender diet prepared at each hospital.[12] However, to our knowledge, there are no previous studies involving this novel food in dysphagia patients with swallowing problems. Considering that the rate of aging of the Japanese population is the highest in the world, it is necessary to establish appropriate nutritional management for dysphagia patients and to enhance their quality of life. Therefore, we performed a multicenter clinical study involving dysphagia patients to verify the usefulness of iEAT using a randomly assigned cross-over design.

The present study used the Clinical Classification of Dysphagia Severity: Oral/Pharyngeal Function to evaluate the achievement of swallowing (a classification mainly used for functional eating disorder/dysphagia; hereinafter referred to as the DSS classification) shown in Table 1,[13] and included patients rated as DSS 4 (Occasional aspiration) or DSS 5 (Oral problem). The objectives of the study were to investigate the safety, consumption rate, nutrition intake, and hematological parameters for nutrition evaluation and to evaluate patient satisfaction with meals by a questionnaire survey using iEAT (study diet) and the diet usually provided to patients with swallowing difficulty (modified traditional diet), as well as to explore the appropriate nutritional management with the study diet for the patients.

The study was designed as a multicenter, randomized, cross-over study with a study diet-first group and a modified traditional diet-first group, and was part of a 2011 project entitled "Investigational project on impaired mastication and dysphagia" of the Ministry of Health, Labour and Welfare for promoting health and welfare services for the elderly.

MATERIALS AND METHODS

The study was conducted in compliance with the Ethical Principles for Medical Research Involving Human Subjects of the Helsinki Declaration (amended by the World Medical Association General Assembly, Seoul, in October 2008) and the Ethical Guideline for Clinical Studies (revised by the Ministry of Health, Labour and Welfare on 31 July 2008). Furthermore, before the conduct of the study, the study was reviewed and approved by the institutional review board of each study site from the viewpoint of ethical and scientific validity.

Participants

The study participants were male or female Japanese inpatients or residents of nursing care facilities rated as DSS 4 (Occasional aspiration) or DSS 5 (Oral problem) on the DSS classification (see Table 1) under nutritional management with the modified traditional diet who did not need to avoid certain foodstuffs because of allergy, and who provided written informed consent. Those who met the following criteria were excluded from the study: (1) patients or residents with gastrointestinal symptoms of Grade 2 or greater of the Common Terminology Criteria for Adverse Events version 4.0 translated in Japanese by Japan Clinical Oncology Group/Japan Society of Clinical Oncology dated 25 April 2011 (CTCAE v4.0-JCOG); (2) among those requiring meal assistance, patients or residents in whom the level of meal assistance may greatly fluctuate during the study period; (3) patients or residents on a therapeutic diet, e.g., with sodium restriction; (4) patients or residents with dementia of Rank II or greater on the Independence Degree of Daily Living for the Demented Elderly; (5) patients or residents who had blood transfusion or hemorrhage of 200 mL or more within 1 month before study initiation; and (6) other patients or residents who were deemed inappropriate for inclusion by the principal investigator.

Study design

This study was conducted at 22 sites, designed as a cross-over design with the following two groups receiving the study diet and modified traditional diet for 1 week each: the study diet-first group and the modified traditional diet-first group. The participants were centrally registered and randomly assigned to one of the two groups. The blender diet or other diet usually provided at each study site was used as the modified traditional diet. In advance of the study, we evaluated each diet's form and recipe, and confirmed that there was little difference between sites (data not shown). To prevent any decrease in food intake through participants' preferences for foods, the

Table 1. Dysphagia Severity Scale (Kagaya et al, 2011)[13]

7:	Within normal limits No condition of dysphagia
6:	Minimum problems Some symptoms of dysphagia without aspiration
5:	Oral problems Significant symptoms of oral preparatory or oral phase without aspiration
4:	Occasional aspiration Possible aspiration or aspiration under chew swallow
3:	Water aspiration Aspiration of thin liquid
2:	Food aspiration Food aspiration with no effect of compensatory techniques or food consistency changes
1:	Saliva aspiration Unstable medical condition because of severe saliva aspiration

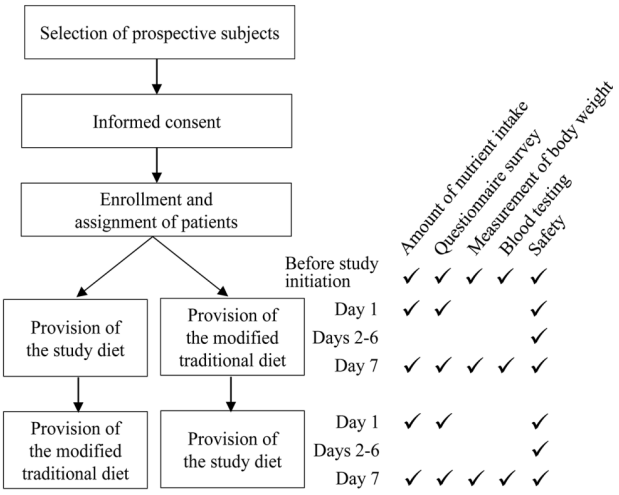

Figure 1. Study schedule, evaluation items, and evaluation time points.

study diet included three types of menu: one with side dishes of meat; one with side dishes of fish; and one with side dishes of both meat and fish. The participants were allowed to freely choose one of the three menus. A soup usually provided at the study site was included in the menus.

Study schedule and evaluation items

The Figure 1 shows the study schedule, evaluation items, and evaluation time points. The safety evaluation included observations of the presence or absence of aspiration and gastrointestinal symptoms including abdominal distension, diarrhea, nausea, vomiting, and abdominal pain. CTCAE v4.0-JCOG was used to grade the symptoms. The evaluation items included intake of energy, protein, lipid, carbohydrate, and sodium calculated from the consumption rate, and a seven-item questionnaire to evaluate patient satisfaction level with the diet by responding Yes (○) or No (×) was administered. The seven items comprised good appearance, good smell, easy to eat, easy to swallow, soft, tasty, and enjoyable. In addition, measurements of body weight and parameters in blood samples for nutrition evaluation were performed.

Statistical analysis

To evaluate the safety, McNemar's test was performed for the proportion of participants who had at least one new-onset aspiration/gastrointestinal symptom during the study period for which a causal relationship with the diet could not be ruled out (level of significance: $p<0.05$; two-sided).

Descriptive statistics of the consumption rate, dietary nutrition intake, and results of the questionnaire survey on the first day and last day of each diet were calculated, and a paired *t*-test was performed (level of significance: $p<0.05$; one-sided).

Descriptive statistics of the body weight and parameters in blood samples for nutrition evaluation on the last day of each diet were calculated, and a paired *t*-test was performed (level of significance: $p<0.05$; one-sided).

RESULTS

Patient characteristics

During the registration period, a total of 50 patients at 22 hospitals participated in the study; 27 men and 23 women. Study sites, investigators, and patient distribution are shown in Table 2. Patients' characteristics are shown in Tables 3-1 and 3-2. In total, 21 patients were rated as DSS 4 (Occasional aspiration: occasional aspiration is observed, or clinical aspiration is suspected with notable pharyngeal residue) and 29 patients as DSS 5 (Oral problem: no aspiration is observed, but there is difficulty eating because of problems during the oral phase of swallowing). The mean age was 77.0±11.0 years.

Table 2. Study sites and investigators

Study site	Study director	Investigator
Department of Surgery & Palliative Medicine, Fujita Health University School of Medicine	Takashi Higashiguchi	
Tokeidai Hospital		Yoshiyuki Kodama
Higashi Sapporo Hospital		Nobuhisa Nakajima
General Rehabilitation Mihono Hospital		Hirofumi Nishiyama
Hokuto City Koyo Hospital		Hajime Nakase
Kanazawa Nishi Hospital		Tsutomu Kikuchi
Kizankai Memorial Hospital		Yasuhiro Shimizu
Hamamatsu City Rehabilitation Hospital		Takashi Shigematsu
Fujita Health University Hospital		Takashi Higashiguchi
Tsujimura Surgery Hospital		Yosuke Wada
Nishichita General Hospital		Atsuko Ishikawa
Fujita Health University Nanakuri Memorial Hospital		Akihiro Ito
Owase General Hospital		Hiroyuki Kato
Hirano General Hospital		Makoto Simazaki
Japanese Red Cross Kyoto Daiichi Hospital		Fumiko Oshima
Minoh City Hospital		Shohei Iijima
Wakakusa Daiichi Hospital		Hideharu Yamanaka
Wakakusa Tatsuma Rehabilitation Hospital		Masataka Itoda
Hyogo College of Medicine Sasayama Medical Center		Yoshihiro Fukuda
Kaneda Hospital		Takuji Mimura
Nishi-Hiroshima Rehabilitation Hospital		Takatsugu Okamaoto
Shinbeppu Hosptial		Nobuyuki Kikuchi
Kumamoto Daiichi Hospital		Tetsushi Nogami

Table 3-1. Patient characteristics

Patient characteristics	Category	Total (n=50)		Modified traditional diet first group (n=23)		Study diet first group (n=27)	
		n	%	n	%	n	%
Sex	Male	27	54.0	16	69.6	11	40.7
	Female	23	46.0	7	30.4	16	59.3
DSS	4	21	42.0	12	52.2	9	33.3
	5	29	58.0	11	47.8	18	66.7
Thickening of fluids	Yes	25	50.0	14	60.9	11	40.7
	No	25	50.0	9	39.1	16	59.3
Meal assistance	No	42	84.0	19	82.6	23	85.2
	Total assistance	3	6.0	2	8.7	1	3.7
	Partial assistance	5	10.0	2	8.7	3	11.1
Use of dentures	Yes	28	56.0	13	56.5	15	55.6
	No	22	44.0	10	43.5	12	44.4
Main dish	Rice	4	8.0	2	8.7	2	7.4
	Porridge	26	52.0	12	52.2	14	51.9
	Paste diet	5	10.0	3	13.0	2	7.4
	Other	16	32.0	7	30.4	9	33.3
Side dish	Blender diet	7	14.0	5	21.7	2	7.4
	Minced diet	11	22.0	4	17.4	7	25.9
	Minced diet in thick sauce	9	18.0	3	13.0	6	22.2
	Other	25	50.0	11	47.8	14	51.9

Table 3-2. Patient characteristics

Patient characteristics (before study initiation)	Total			Modified traditional diet-first group			Study diet-first group		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Age (yr)	50	77.0	11.8	23	75.5	12.6	27	78.3	11.2
Body height (cm)	50	156	13.0	23	160	13.0	27	152	12.0
Body weight (kg)	49	48.8	12.6	22	49.8	13.9	27	48.0	11.6
Body mass index	49	19.9	3.8	22	19.2	3.7	27	20.6	3.9
Consumption rate before study initiation (%)	50	86.1	15.5	23	84.7	19.9	27	87.2	10.6
Amount of food intake before study initiation (g)	50	1417	458	23	1415	529	27	1419	400
Energy intake before study initiation (kcal)	50	1221	315	23	1239	383	27	1206	251
Protein intake before study initiation (g)	50	47.4	14.7	23	45.7	16.7	27	48.9	13.0

Comparison of dietary nutrition intakes

Table 4 shows the mean provided nutrient amounts and the mean dietary nutrition intakes on the first day (day 1) and last day (day 7) of the study diet and modified traditional diet. No difference was observed in the consumption rates. In all patients, the mean food intake was significantly lower for the study diet than for the modified traditional diet, whereas the energy, protein, and carbohydrate intake on day 1 and the protein intake on day 7 were significantly higher for the study diet. Comparing the DSS 4 and 5 groups, a similar trend was observed for the mean food intake (lower for the study diet) and energy and protein intake (higher in the study diet).

Body weight, hematology, and blood biochemistry

Table 5 shows the values measured on the last day of each diet. The mean body weight in the study diet group (48.2±12.4 kg) was significantly higher than that in the modified traditional diet group (47.8±12.5 kg) after consuming each diet for 7 days. No significant differences were observed in the other parameters for hematology or blood biochemistry.

Safety

Abdominal distension of Grade 1 was reported in one patient receiving the modified traditional diet, but no diet-related adverse events were reported in the other patients. The two diets were safely consumed.

Results of the questionnaire

Table 6 shows the results of the questionnaire survey performed on the first day (day 1) and last day (day 7) of the modified traditional diet and study diet. A significantly higher level of satisfaction with appearance was shown for the study diet than for the modified traditional diet on both day 1 and day 7 (satisfaction levels, 80% or higher).

DISCUSSION

In Washoku, the traditional dietary culture of Japanese people, seasonal foods are eaten with a focus on the joy of eating by appreciating the food's delicate appearance. The expression, "tasting foods with one's eyes" is part of this culture.[14] The so-called Yoshoku, a westernized diet introduced into Japan in the modern age, has even spread to home-cooked meals as it has changed over time to become part of the Japanese cuisine. For Japanese people with esthetic sensibility for foods like this, the blender diet used as the modified traditional diet in this study may greatly impair the joy of eating.

In a modified traditional diet for people with impaired mastication or mild dysphagia, the physical properties of foods have been a focus of attention, and the preparation of international criteria for physical properties is ongoing.[15] However, we believe that the joy of eating through appreciation of food appearance is as important as the physical properties for patient satisfaction. Consequently, we focused on iEAT and aimed to establish safe and appropriate nutritional management for dysphagia patients, and to enhance their food satisfaction.

The DSS classification of dysphagia severity consists of seven grades from DSS 1 (saliva aspiration), the most notable impairment of swallowing function, to DSS 7 (normal). DSS 4 (Occasional aspiration) is defined as "occasional aspiration is observed, or clinical aspiration is suspected with notable pharyngeal residue," while DSS 5 (Oral problem) is defined as "no aspiration is observed, but there is difficulty eating because of problems during the oral phase of swallowing."[13] During the study period, mild abdominal distention was reported in one patient receiving the modified traditional diet, but no other abnormalities were reported. Therefore, the study diet was judged to be consumed without aspiration in patients with mild dysphagia as safely as the modified traditional diet.

Dysphagia is a major risk factor for malnutrition in stroke and dementia patients, and older patients in community-living.[16-21] In this study, energy intake and protein intakes were significantly higher during the study diet period, which was similar to our previous findings in a study of patients with impaired mastication.[12] This may be because the blender diet requires the addition of water during its preparation and the nutrients are diluted with the increased volume of water, whereas iEAT, softened enzymatic ally, does not require additional water; therefore, iEAT contains higher nutrient levels per unit weight.[22,23] Although patients in previous studies eating traditional texture-modified diets, such as blender diets, ingested fewer calories or protein than those eating regular-texture meals,[24,25] our results suggest that dysphagia patients may benefit from a reduced risk of malnutrition. Also, because iEAT is ingested in smaller volumes and does not require repeated swallows compared with traditional texture-modified diets with equivalent energy, this novel food may be well suited not only to stroke, dementia, and other dysphagia patients but also to patients with fatigable symptoms such as those seen in Parkinson's disease, myasthenia gravis, myopathy, and chronic obstructive pulmonary disease. However, further studies are needed to assess the appropriateness of iEAT for these patients.

Houston et al investigated muscle mass in 2066 elderly adults categorized by quintiles of daily protein intake for 3 years.[26] They reported that participants in the highest quintile of protein intake lost approximately 40% less muscle mass than those in the lowest quintile of protein intake. They also observed a significant inverse correlation between protein intake and loss of muscle mass. As the protein intake from iEAT increased by approximately 1.3-fold compared with that from the modified traditional diet in the present study, the study diet may have higher potential to prevent or treat sarcopenia than the modified traditional diet. Body weight, an index of the effect of nutrient intake, was significantly higher for the study diet on the last day of the diet, but the difference was too modest to be considered as clinically relevant. However, taking account of the study diet period of only 1 week, long-term consumption may lead to clinically relevant weight gain.

The results of the questionnaire survey showed that the satisfaction level with appearance was significantly higher for the study diet on day 1 and day 7 compared with the modified traditional diet. These are logical conclusions because iEAT retains the appearance of the original foodstuffs.

Thus, iEAT, which resembles ordinary foods cooked

Table 4. Comparison of intake of nutrients

				Modified traditional diet group (1)		Study diet group (2)		Difference of intake (2)-(1)	*p*-value	
				Provided	Intake	Provided	Intake			
			n	Mean±SD		Mean±SD		Mean±SD		
DSS 4+5										
Day 1	Amount of food (g)		48	1687±362	1470±430	1365±292	1184±290	-287±370	<0.001	*
	Consumption rate (%)		48		86.1±11.9		88.1±17.6	2.0±12.0	0.254	
	Nutrient amount:	Energy (kcal)	48	1435±227	1241±292	1582±524	1336±310	95±216	0.004	*
		Protein (g)	48	55.0±12.9	47.8±14.8	70.6±28.6	59.2±13.6	11.4±12.2	<0.001	*
		Lipid (g)	48	34.0±11.9	29.5±11.2	28.8±13.5	23.9±7.0	-5.5±11.1	0.001	*
		Carbohydrate (g)	48	222±44	192±50	250±77	212±57	20±41	0.001	*
		Sodium (mg)	47	2636±873	2282±839	2922±962	2445±554	162±839	0.192	
Day 7	Amount of food (g)		46	1732±542	1528±629	1337±315	1126±353	-403±568	<0.001	*
	Consumption rate (%)		46		86.5±15.8		83.9±18.3	-2.6±11.9	0.151	
	Nutrient amount:	Energy (kcal)	46	1523±622	1257±297	1635±568	1346±399	88±367	0.110	
		Protein (g)	46	61.2±32.5	50.1±14.2	76.3±29.8	62.6±18.8	12.5±18.8	<0.001	*
		Lipid (g)	46	35.6±16.9	29.6±11.6	38.7±16.1	31.9±12.6	2.3±15.5	0.322	
		Carbohydrate (g)	46	239±99	197±53	235±89	193±65	-4±62	0.672	
		Sodium (mg)	46	2874±946	2416±740	3139±990	2605±789	189±905	0.164	
DSS 4										
Day 1	Amount of food (g)		20	1754±375	1628±387	1302±349	1191±279	-437±360	<0.001	*
	Consumption rate (%)		20		92.6±6.3		94.4±15.4	1.9±13.2	0.538	
	Nutrient amount:	Energy (kcal)	20	1469±280	1363±297	1496±388	1394±397	31±256	0.591	
		Protein (g)	20	56.3±15.8	52.2±16.0	64.8±14.9	60.4±14.7	8.1±14.3	0.020	*
		Lipid (g)	20	36.4±12.8	33.6±11.4	25.3±8.1	23.5±7.5	-10.1±11.3	<0.001	*
		Carbohydrate (g)	20	227±53	210±54	243±73	226±75	16±52	0.185	
		Sodium (mg)	20	2475±814	2277±728	2605±695	2374±427	97±717	0.551	
Day 7	Amount of food (g)		18	1895±730	1769±761	1271±382	1165±380	-605±766	0.004	*
	Consumption rate (%)		18		92.7±8.9		90.4±13.3	-2.3±13.0	0.464	
	Nutrient amount:	Energy (kcal)	18	1464±306	1355±319	1560±437	1448±493	923±501	0.443	
		Protein (g)	18	58.9±11.9	54.6±13.0	69.8±18.0	64.8±19.8	10.2±22.9	0.076	
		Lipid (g)	18	34.8±10.4	32.0±9.3	34.5±11.1	32.0±11.5	0.0±15.7	0.996	
		Carbohydrate (g)	18	230±55	212±56	231±77	214±85	2±81.8	0.923	
		Sodium (mg)	18	2675±801	2446±654	2857±934	2628±789	182±902	0.403	
DSS 5										
Day 1	Amount of food (g)		28	1640±351	1358±430	1410±241	1179±302	-179±344	0.010	*
	Consumption rate (%)		28		81.4±12.8		83.5±18.0	2.1±11.4	0.334	
	Nutrient amount:	Energy (kcal)	28	1410±182	1154±259	1642±602	1294±229	140±172	<0.001	*
		Protein (g)	28	54.0±10.5	44.6±13.3	74.7±35.0	58.3±12.9	13.7±10.1	<0.001	*
		Lipid (g)	28	32.3±11.1	26.5±10.3	31.4±15.9	24.3±6.7	-2.3±9.8	0.232	
		Carbohydrate (g)	28	219±37	179±42	254±81	202±39	23±32	<0.001	*
		Sodium (mg)	27	2755±911	2286±927	3157±1072	2497±634	210±930	0.251	

p-value (paired t-test), * $p<0.05$.

Table 4. Comparison of intake of nutrients (cont.)

				Modified traditional diet group (1)		Study diet group (2)		Difference of intake (2)-(1)	*p*-value	
				Provided	Intake	Provided	Intake			
			n	Mean±SD		Mean±SD		Mean±SD		
DSS 5										
Day 7	Amount of food (g)		28	1628±353	1373±480	1380±262	1101±339	-273±351	<0.001	*
	Consumption rate (%)		28		82.5±18.0		79.8±20.1	-2.7±11.3	0.214	
	Nutrient amount:	Energy (kcal)	28	1561±763	1195±269	1684±642	1280±317	86±259	0.092	
		Protein (g)	28	62.8±40.8	47.2±14.5	80.5±35.1	62.1±18.4	13.9±15.8	<0.001	*
		Lipid (g)	28	36.2±20.2	28.1±12.9	41.4±18.4	31.9±13.5	3.8±15.4	0.208	
		Carbohydrate (g)	28	245±119	187±50	238±97	180±45	-8±45	0.385	
		Sodium (mg)	28	3002±1022	2397±802	3320±999	2590±803	193±923	0.278	

p-value (paired t-test), **p*<0.05.

Table 5. Comparison of hematological parameters on day 7

Evaluation items	n	Modified traditional diet group (1)		Study diet group (2)		Difference (2)-(1)		*p*-value	
		Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation		
Body weight (kg)	45	47.8	12.5	48.2	12.4	0.40	0.9	0.007	*
Total protein (g/dL)	46	6.6	0.6	6.5	0.6	-0.1	0.5	0.133	
Albumin (BCG method) (g/dL)	46	3.5	0.5	3.4	0.5	-0.1	0.2	0.101	
Total cholesterol (mg/dL)	46	167	48	164	46	-3	18	0.166	
Triglyceride (mg/dL)	46	97.7	37.8	101	41.2	3.0	31.6	0.520	
C-reactive protein (mg/dL)	46	0.8	1.2	1.1	2.8	0.3	2.1	0.312	
White blood cell count (/μL)	43	5386	1650	5449	1547	63	870	0.639	
Basophil (%)	42	0.5	0.3	0.5	0.3	0.0	0.3	0.694	
Eosinophil (%)	42	4.2	3.9	3.6	2.4	-0.6	3.4	0.293	
Neutrophil (%)	41	57.8	10.6	57.4	9.0	-0.4	7.2	0.735	
Lymphocyte (%)	42	32.1	9.9	31.9	9.1	-0.2	6.9	0.855	
Monocyte (%)	42	5.6	1.9	5.8	2.0	0.2	1.5	0.369	
Prealbumin (mg/dL)	46	17.7	6.5	17.8	6.3	0.1	1.8	0.659	
Retinol-binding protein (mg/dL)	46	3.1	1.3	3.1	1.2	0.0	0.5	0.598	
Transferrin (mg/dL)	46	215	46	211	44	-3.0	16	0.166	

p -value (paired *t*-test). **p*<0.05.

Table 6. Questionnaire results

Day of survey	Evaluation items	Modified traditional diet group		Study diet group		*p*-value	
		n	%	n	%		
Day 1	Good appearance	25	53.2	40	85.1	<0.001	*
	Good smell	17	36.2	23	48.9	0.327	
	Easy to eat	37	78.7	40	85.1	0.581	
	Easy to swallow	35	74.5	33	70.2	0.791	
	Soft	19	40.4	16	34.0	0.690	
	Tasty	31	66.0	36	76.6	0.383	
	Not tasty	7	14.9	8	17.0	1.000	
	Enjoyable	19	40.4	16	34.0	0.607	
Day 7	Good appearance	22	47.8	39	84.8	<0.001	*
	Good smell	15	32.6	17	37.0	0.839	
	Easy to eat	35	76.1	36	78.3	1.000	
	Easy to swallow	30	65.2	29	63.0	1.000	
	Soft	19	41.3	23	50.0	0.481	
	Tasty	27	58.7	32	69.6	0.359	
	Not tasty	8	17.4	10	21.7	0.754	
	Enjoyable	16	34.8	20	43.5	0.523	

p-value (McNemar's test). *$p<0.05$

by typical methods in appearance but is cooked to soften, is a food product that offers patients with mild dysphagia an opportunity to enjoy meals with their eyes and to receive nutrients safely and efficiently. In conclusion, the present results suggest that iEAT can be safely provided to patients with mild dysphagia and is highly useful for nutritional management to achieve appropriate energy intake and protein intake.

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AUTHOR DISCLOSURES

The authors have declared no conflicts of interest.

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