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Shaker Exercises, Feeding Modification, and Associated-depression Relief as Dysphagia Care Bundle: A quasi-Experimental Study in Elderly Patients

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Abstract:

Background: Dysphagia is frequently overlooked by elderly individuals who may consider it a normal part of aging. This condition causes psychological distress, such as depression. Therefore, early, multidisciplinary care is essential. **Aim of the study:** To evaluate the effectiveness of shaker exercises, feeding modification, and associated-depression relief as dysphagia care bundle among elderly patients. **Design:** Quasi-experimental research design (study/ control) was utilized in the current study. **Sample:** Purposive sample of 120 elderly patients with dysphagia were collected from the outpatient clinic of the Ear, Nose, and Throat of El-Minia university hospital and randomly divided into the bundle group and the control group which include 60 elderly patients in each. **Tools:** Three tools and one scale were used for data collection before and after intervention: Eat-10 scale, the 3-ounce Water Swallow Test (3OWST), and Geriatric Depression Scale (Short Form). **Results:** In the post-intervention phase, the mean scores of Eat-10 scale declined from 16.2±4.8 to 8.3±2.27 among the bundle group with (p-value <0.0001), while it modestly decreased from 15.3±4.6 to 13.4±3.8 among the control group with (p-value=0.2965). The proportion of individuals with normal swallowing in 3-ounce Water Swallow Test were increased among the bundle and control group from 31.7 and 36.7 to 70 % and 38.3%, respectively. The proportion of individuals with moderate to severe depression levels among the participants in the bundle and control groups decreased from 63.3% and 66.7% to 25% and 63.3%, respectively. **Conclusion:** The study concludes that the intervention protocol was effective in improving dysphagia and its associated depression among the elderly patients. **Recommendations:** Further researches with larger sample, multiple outcome metrics of timing, and intensity of intervention are needed.

Keywords: Dysphagia Care Bundle, Elderly Patients, Depression, Shaker Exercises& Feeding Modification.

Introduction

As the global aging population and human life expectancy increases, the age distribution among the population is also growing. This demographic shifting brings with it a range of new obstacles, including physical limitations and functional shortcomings that take place as a natural part of the aging process **(Umay, et al., 2022)**. One such condition is dysphagia, or swallowing dysfunction, which could disrupt the normal swallowing process. Dysphagia can be divided into two categories: oropharyngeal dysphagia, which involves difficulty forming and moving a food bolus into the esophagus, and esophageal dysphagia, which is related to inefficient movement of food through the esophagus **(Park, et al., 2019)**

Ageing itself does not necessarily cause dysphagia, but the danger of developing it increases with age due to alters in head and neck anatomy and physiology, such as changes in tongue pressure, dysfunction in salivary production, loss of jaw strength, also due to problems with teeth and gums **(Butler, et al., 2017).** Additionally, dysphagia in older adults is closely related to multiple comorbidities, polypharmacy, as well as due to gastrointestinal tract, respiratory system, and neurological problems, cancer, a history of head, neck, and gastrointestinal tract surgeries **(Rajati, et al., 2022).**

Despite its high incidence, dysphagia is often underdiagnosed and not regularly reported by older patients, who may think of it as a nature part of the aging process **(KO, Dahyeon, et al., 2022)**. The incidence of dysphagia among adults varies depending on the setting, as studies showing that rates between thirty to forty percent occurred among the independently living aged people, also, forty-four

percent among those entered to geriatric acute care as well as sixty percent among the institutionalized aged patients suffering from dysphagia **(Altman, Yu, & Schaefer, 2017).**

Symptoms of dysphagia among older adults include difficulty in swallowing, feeling of food caught in the chest or throat, regurgitation, recurrent heartburn, hoarseness, and coughing or gagging when swallowing **(Umay, et al., 2022)**. Dysphagia among elderly is a predictor of several complications such as poor nutrition, dehydration (among 25-75% of the elderly), also tracheobronchial aspiration (among 30-50% of the elderly) which leading to pneumonia in fifty percent of the cases, with a connection to death among up to fifty percent of the cases.

In addition to, the physical symptoms, older adults with dysphagia may also experience psychological distress, including symptoms of anxiety and depression **(Verdonschot & RJCG, 2018).** Few studies specifically focused on the psychological disturbance and the degree of psychological distress results from dysphagia. Despite the fact that the pathophysiological mechanisms behind the psychological symptoms experienced by older people who have swallowing disorders are not yet fully understood, several studies showed that affective issues in patients with dysphagia are common prevalent **(Verdonschot & RJCG, 2018)**.

Dysphagia and depression are often interrelated among the elderly population. Dysphagia could lead to malnutrition, dehydration, and other physical problems, which could in turn contribute to depression **(MacDowell, et al., 2018).** Obviously, an impairment affecting one of the most fundamental daily requirements, namely nutrition, that influences the psychological wellbeing among elderly people. Moreover, patients who fear aspiration and choking will eat more slowly than their tablemates and may modify their food and eating behaviors to decrease the risk of complications. This may lead to feelings of shame and social isolation, which could be furthermore an exacerbate symptoms of depression **(Sadeghi, et al., 2021)**.

Furthermore, eating and drinking represent a significant component of social contact, and drip feeding, drooling, and spilling of food, are not a socially desirable table habit. Feeling of rejection, among people with dysphagia frequently become guilty, dread social rejection, cut back on their social interactions, and even become socially isolated, which may increase the likelihood of depressive symptoms among them **(Sadeghi, et al., 2021, (Verdonschot & RJCG, 2018).**

The consequences of psychiatric illnesses on swallowing might cause some issues including lengthy mealtimes, gagging, or piecemeal deglutition in addition to affecting swallowing perception and normal physiology of swallowing. Moreover, the existence of depressive symptoms may make the somatic symptoms of dysphagia worse. As a result, many patients struggle to accept and manage their illness. Moreover, a diminished feeling of dysphagia may result due to the improvement in the patients psychological or psychiatric condition. This might enhance the patients' disease-specific health condition and possibly enhance the effectiveness of their dysphagia therapy **(MacDowel, et al., 2018).**

So, early implementation of an integrated multidisciplinary approach is believed to treat dysphagia among elderly and relief depressive symptoms through combination of different measures Modifications in feeding, conducting swallowing exercises, and relieving the associated depressive symptoms could serve as a care bundle for reducing dysphagia. **(Altman, Yu, & Schaefer, 2017).**

The Institute for Health Care Improvement in North America created the idea of "care bundles" to denote a group of treatment managements required to provide patients with effective and secure care **(Taksande, el al., 2020)**. Care bundles are a set of intervention techniques to maximize high-risk links, minimize hazards, and to integrate and optimize effective nursing measures based on the actual situational needs of patients, and they have recently become a widely adopted new concept or approach in the field of critical care **(Gao, et al., 2021)**

Bundle of care refers to the integrity of implementation, with which each implementation having a target and sequential timeliness regarding the implementation process which significantly increase the evidence-based practices that is applied to all patients in a consistent and unchanging pattern, while ultimately having a comprehensive impact on their outcome **(Zhang, Yang, & Yao, 2020 & Barrera, & Wells, 2019).**

Bundling in nursing interventions was created to handle specific patient issues. Every measurement had undergone clinical validation, which could significantly lead to better patient outcome. Additionally, the impact of treatment significantly enhanced when these strategies are combined **(Yan, 2021 & de Bijl-Marcus, 2020).** The most recommended components of care bundle for patients with dysphagia are shaker exercise, feeding modification and position adjustment.

Modifications in feeding are diet modifications which are an international standardization of treatment initiative worldwide used for elderly patient with dysphagia. It reduces the incidence of aspiration causes, pneumonia, improves patient's hydration status and nutrition, as well as mealtime application. Texture changes as chopping and pureeing, also,

somewhat advised were giving as thickening fluids include nectar, honey, and pudding-like consistency **(Hansen, et al., 2022).**

Position adjustments including upright position of at least 60°, and ideally 90° is crucial part during feeding process. It could change pressure generation and speed during swallowing, alters swallowing structures to protect the respiratory tract by affecting the esophageal phase with gravity, preventing residue, penetration, and aspiration. Shaker exercise is used to enlarge the entrance of the esophagus and strengthen the suprahyoid muscles especially among older patients with neurogenic dysphagia, increase hyoid and laryngeal elevation, decrease pharyngeal residuals, and ameliorate dysphagia symptoms **(Umay, et al., 2022).**

Nurses, as sentinels of medical services, had important responsibilities, such as monitoring, supervising, and educating patients about proper chewing and safe swallowing, oral health, oral motor exercise, reducing the volume and rate of food by encouraging thoughtful swallowing and moderate eating practices **(Gould, et al., 2020).**

Significance of the study

Dysphagia is a most geriatric syndrome with a high prevalence among elderly populations, affecting up to 68% of occupants of nursing homes, 30-55% of elderly hospitalized patients and 17.10% of older people living in their communities, as well up to 52.60% among high-risk populations **(Chen, et al., 2022 & Byeon, 2016**). Prevalence of dysphagia in the US is estimated to be 300,000-600,000 elderly individuals annually **(Ishak, et al., 2021).** Studies in Egypt have reported a prevalence of 14.7% among geriatric hospitalized patients **(Waleed, Wael, & Abdel-Mateen, 2014)** and 45% among geriatric patients with stroke **(Mohamed, et al., 2022)**. Most elderly people with dysphagia also experience symptoms of depression, as 32.6% of patients visiting the Maastricht University Medical Center reporting clinically relevant symptoms **(Song, et al., 2021).** There is a positive correlation between symptoms of depression and impaired swallowing function **(Verdonschot & RJCG, 2018).** A Bundled care is an evident-based integrated, multidimensional approach which needed to address and manage medical and psychological needs for elderly patients with dysphagia effectively. There is limited evidence for the interventions that conducted for reducing both dysphagia and its associated symptoms of depression. As the current study assumed a combination of physical and psychological measures as a proposed non-pharmacological non-invasive bundle of care for dysphagia among geriatric patients.

Aim of the study:

This study aimed to evaluate the effectiveness of shaker exercises, feeding modification, and associated-depression relief as a bundle in reducing severity of dysphagia and its associated symptoms of depression among elderly patients.

Research Hypotheses:

H1: The application of Shaker exercises, feeding modifications, and associated-depression relief as a bundle will decrease the severity of dysphagia and associated symptoms of depression among elderly patients.

Methods

This is a quasi-experimental control trial study of 120 elderly patients suffering from dysphagia with stable medical condition, adequate cognitive function, and attended at the out-patient clinic of ENT (Ear, Nose and Throat) in Minia University Hospital. The required representative sample size was determined depend on the flow rate of the ENT outpatient clinic last year, which was 850 patients, and the following formula

$$n = \frac{\frac{z_\alpha^2\, p\,(1-p)}{m^2}}{1+\frac{z_\alpha\, p\,(1-p)}{m^2\, N}} = \frac{\frac{(1.96)^2(0.5)\,(0.5)}{(0.04)^2}}{1+\frac{(1.96)^2(0.5)\,(0.5)}{(0.04)^2\,850}} = 120$$

- n = Required Sample Size.
- z_α^2 = is the Z score at 0.05.
- p = (0.5)
- m = Margin of Error at 5 % (standard value of 0.04).
- N= Population Size

Definition of the participants:

Defined as 65 years old or more with a Confirmed diagnosis of dysphagia by a healthcare professional, which may include clinical examination video-fluoroscopic swallowing study (VFSS), or fiber-optic endoscopic evaluation of swallowing (FEES).

Exclusion criteria were as follows: revision surgery, combined anterior and posterior approaches, surgery for infection, tumor, or trauma, patients with diagnosis related to swallowing issues (i.e. Esophagitis, Barrett's Esophagus, Sjogren syndrome, Multiple Sclerosis, Laryngitis), cervical spine injury, those who have inability to take liquids and food by mouth and patients who are not willing to be randomized or blinded subjects.

Allocation of study and control participants:

The 1:1 randomization process was used to assign patients who met the enrollment criteria and gave their formal consent to either the study (n = 60) or control (n = 60) group. An investigator who was not involved in patient care carried out the randomization

using a computerized random number generator. An investigator who did not assist with patient care also handled enrollment.

Study Tools:

Three tools and one scale were used in the present research for data gathering:

Tool (I): Bio-demographic Data:

This tool was designed by the researchers to collect demographic and medical data.

It includes two parts:

Part 1: Demographic data.

It includes data about: age in years, marital status, gender, residence, occupation, education, living condition, and monthly income.

Part 2: Risk factors for dysphagia among elderly people: chronic disease, smoking, feeding mode, physical function, dental condition, regular tooth brushing, body mass index (BMI), newly hospitalized through the current year.

Tool (II): The Eating Assessment tool (EAT-10):

According to a study done by **Belafsky et al., (2008),** EAT-10 is a self-reported outcome measure that assesses symptoms of oropharyngeal dysphagia (OD). It consists of ten items that are scored a five-point scale, with the extremes labeled as '0 equal no problem' as well as '4 equal severe problem', resulting in a total score range from zero to forty. The Nestle Nutrition Institute has translated the EAT-10 into numerous other language variants and recommended it as a simple and rapid screening tool for OD. The EAT-10 tool is increasingly utilized as an evaluation tool for OD in clinical populations and non-clinical populations of seniors that live in the community. An EAT-10 total score ≥ 3 is suggested to be indicative of OD, as well as a total score more than fifteen is an indicative of aspiration risk **(Kepka, 2019).**

Tool (III): The 3-ounce Water Swallow Test (3OWST):

It is a simple and quick screening tool used to assess the presence and acuity of dysphagia. To conduct the test, the patient is given 3 ounces (90 mL) of water to drink, while the observer carefully observes the patient's swallowing process. The number of swallows need to consume the entire volume of water is then recorded, and any coughing or choking that occurs during or after the swallow is noted and should be reported.

The 3OWST is scored based on the number of swallows required to consume the 3 ounces of water. A single swallow indicates normal swallow function, while two swallows indicate mild to moderate dysphagia. Severe dysphagia is indicated by three or more swallows required to consume the water amount. In the event of coughing or choking during or after the swallow, a higher degree of dysphagia severity may be indicated (Crary, Carnaby-Mann, & Miller, 2010).

The 3OWST is considered a reliable and user-friendly follow-up test for the evaluation of dysphagia severity, as it could be conducted at the bedside or in any healthcare setting where dysphagia assessment is required.

Clinically, it is possible for a patient to have a dysphagia severity score of 4 on the EAT-10 tool and still have a normal 3-ounce Water Swallow Test (3OWST) result. The EAT-10 is a self-reported questionnaire that evaluates the impact of dysphagia on a patient's daily life, while the 3OWST is a bedside test that assesses the physical act of swallowing. It is possible for a patient to experience some dysphagia-related symptoms that affect their quality of life, but still have a functional swallow. Conversely, a patient may have a normal EAT-10 score but experience some physical difficulties during the 3OWST, indicating a potential need for further evaluation or intervention. Therefore, both tools should be used together in conjunction with other clinical assessments to provide a comprehensive evaluation about dysphagia severity.

Tool (IV): Geriatric Depression Scale (Short Form) (pre/ post)

This tool is used for assessing the depressive symptoms among elderly people that excludes physical signs of depression most in old age. The short form consists of 15 questions, with 10 indicating the presence of depression symptoms when answered with "Yes" and one point will be counted for each. The remaining five questions (no. 1, 5, 7, 11, 13) illustrated depression symptoms when answered with "No," and one point will be counted for each as well. The sum of all item scores is used to determine the total score, with a range from zero to fifteen. Scores from zero to four indicated normal, scores from five to eight considered mild depression, scores from nine to eleven considered moderate depression, and scores from twelve to fifteen considered severe depression **(Sheikh Yesavage, et al., 1986).**

The content validity of the study tools was also revised by a five-panel of Medical surgical nursing, geriatric nursing, psychiatric as well as health professionals in the field of community health nursing who have more than 10 years of experience to evaluate the instruments' precision, viability, and application. The reliability of the Geriatric Depression Scale (Short Form) was evaluated through an Alpha Cronbach test, and it was found to be highly reliable with a score of 0.96 **(Alshammari, & Sharif, 2022).**

Ethical considerations:

All formal permissions were taken from the convenient authorities to apply the study. The research was approved by the Ethics Committee of the Faculty of Nursing at Minia University after reviewing the study protocol. All elderly participants signed a free and informed consent form. There was no risk for study participants during the conduction of the study, and elderly participants had the right to refuse to participate in the study or withdraw at any stage without penalty. Privacy, confidentiality, and anonymity were maintained during data collection and encoding.

Pilot study:

It was conducted on twelve elderly participants (10%) from the total studied sample in order to evaluate the instruments' applicability, clarity, the viability of fieldwork, and any potential challenges the researcher would face that might obstruct data gathering. There were no changes made. So. the trial sample was included in the study sample.

Study field:

Once the measuring instruments and participants were selected, permission was sought from the directors and the head of the ENT department at Minia University Hospital, describing the purpose of the current research. Each elderly participant was informed about the study objectives and procedures; its voluntary, anonymous nature; and the confidentiality of the results were assured. The participants' swallowing function and symptoms of depression were assessed (as baseline assessments), and those identified with swallowing dysfunction and symptoms of depression at baseline were invited to share in the study. Eligible participants were randomly allocated with simple table randomization technique to either among the usual group care (control group) or among the bundled dysphagia group care (bundle group/the intervention group).

The researchers went to the hospital (ENT outpatient clinics) every two days in the week from nine a.m. to twelve p.m. until the predetermined size of the sample was maintained between the beginnings of September 2021 and mid-July 2022. The questionnaires were administered in paper format, and the data was collected from the control group first, and then from the bundle group by using the study's tools. The dysphagia care bundle was applied to the bundle group, and finally, after the end of the protocol, the data was collected for post-test assessment from both the control group and the bundle groups.

Bundle of care

The Department of ENT provided routine care to patients in both groups. Patients in the test group received bundled care based on how the control group was treated. One of the researchers took on the role of group leader, and they oversaw on the group's management, including group discussions, monitoring of the implementation of the various packaged care, and quality inspection as well. Implementing the bundled care program among patients, monitoring and assessing swallowing function, and informing the responsible physician about any changes regarding the patient's health condition were all done by a different researcher. The attending physician was primarily in charge about the clinical therapy and management, and by keeping in touch with the primary nurses during the implementation of the procedure and altering the care priorities in accordance with the patient's actual conditions, as he or she ensured the greatest outcome of rehabilitation.

The study group was classified into six subgroups; ten patients were included in each subgroup, and participated among the total session were seven. These sessions were planned as two sessions every week for three and a half weeks; each session took about an hour, and the designed nursing protocol was completed for all subgroups within 21 weeks.

The content of the of Dysphagia care bundle is presented as following:

Construction of Dysphagia care bundle for geriatric patients:

In accordance with the five steps of the evidence-based care model, we created a bundled care program for patients with dysphagia that included identifying issues (Patient/Problem, Intervention, Comparison, and Outcome, or PICO strategies), searching for, accessing, and using the literature, as well as assessing the results **(Bleasel, Koerner, & Valenti, 2015).**

Implementation of bundled care program

1. Rapport Establishment: the researcher started the program by a session with the patients for establishing rapport and explaining the purpose of the study **(Kang, Hwang, & Cho, 2020).**
2. Collection of baseline data about dysphagia and its associated symptoms of depression: the evaluators were blinded of the participant type (being in control or bundle group) and baseline pertinent data were collected based on the Bio/ Demographic Data, Eating Assessment tool-10 (Eat-10), the 3-ounce Water Swallow Test, and Geriatric Depression Scale
3. Implementing the proposed dysphagia care bundle.

a. Shaker exercises (1st session):

The Shaker method called the Head Lift. It is a therapeutic technique used to improve the coordination and strength of the muscles included in swallowing. Generally, in the patients with swallowing difficulties, they have less hyolaryngeal complex movement in the superior and anterior directions. To open the upper esophageal sphincter,

the hyoid and larynx must lift and advance to the required degree. As a result, the patient is at danger of aspirating debris into the pyriform sinuses. To do the exercise as outlined in the research, the patient must lie flat and raise their head to stare at their toes while keeping their shoulders on the bed or mat. They must then perform the shaker exercises while swallowing. The patient holds this position for the desired 60 seconds, then repute it twice. The second exercise involves doing a repeating motion. The patient elevates their head to look at their chin, lowers it back to the starting position, and then does this exercise thirty times. Three sets of thirty are the goal. There is evidence to suggest that shaker exercises for swallowing can enhance the swallowing function among individuals with a range of swallowing disorders. a speech-language pathologist was consulted for each patient before starting the exercise at the first-time **(Nasrallah, et al., 2016).**

b. Feeding modifications (2nd session):

It aims to get enough nutrition and stay hydrated while promoting a safe and efficient swallow

- Texture modifications are the key aspect of diet among geriatric patients with dysphagia. Depending on the severity of the dysphagia, patients may need to receive their food in a pureed or finely minced form based on International Dysphagia Diet Standardization Initiative (IDDSI) Framework Levels in order to reduce the risk of aspiration. It is also important to consider the consistency of liquids as thicker liquids which may be easier to swallow for patients with dysphagia. Additionally, moistening foods and liquids could help to reduce the risk of choking and improve the overall experience of eating and drinking for patients with dysphagia **(Robbins, et al., 2008).**
- Emphasis on safe feeding was applied through instructions of eating slowly, avoiding eating or drinking when rushed or tired, taking small amounts of food or liquid in each time, using a teaspoon rather than a tablespoon during eating, avoiding mixing food and liquid in the same mouthful, placing the food on the stronger side of the mouth if unilateral weakness is present, avoiding using straws, and taking oral medications with a thickened beverage **(Wirth, et al., 2017).**
- **(3rd session)** Oral hygiene is an important component of dysphagia care bundle to keep the patient adherent to tooth brushing and oral hygiene after every meal and before bedtime **(Ney, et al., 2009)**.
- **(4th session)** Emphasis was due on the nutrient density of the diet for geriatric patients with dysphagia. Older adults are at increased risk for malnutrition, and this risk is further increased for patients with dysphagia. To ensure that patients are receiving adequate nutrients, it may be necessary to increase the calorie and protein content on their diet. This could be achieved through the use of high calorie and high protein supplements, as well as incorporating nutrient-rich foods into their diet, such as eggs, dairy products, and nut butters **(Cereda, Gentile, & Pedrolli, 2015).**
- **(5th session) :-** Postural adjustments: were applied among patients with dysphagia as they must eat and drink while sitting entirely upright. In doing so, meals and beverages are more successfully absorbed. Participants were trained on and emphasized the importance of eating in an upright posture (ninety seated) and maintaining this position for at least thirty minutes post the meal **(Choi, et al., 2019)**.

c. Reducing or preventing the associated anticipated symptom of depression:

- **(6th session): Patients should** stay physically active: Engaging in regular physical activity, such as light exercise (e. g. walking), which could improve physical and mental health, boost mood, and prevent depression **(Harvey, et al., 2017).**
- **Keep the mind active:** Patients should be engaging in mentally stimulating activities, such as reading, puzzles, or learning a new skill, as it could help to prevent depression by keeping the mind active, reducing feelings of boredom and isolation **(Wetherell, et al., 2013).**
- **Stay socially connected:** Maintaining strong social connections and participating in social activities could provide a sense of community and support, helping to prevent depression symptoms **(Gilmour, O'Loughlin, & Wing, 2012).**
- **(7th session):** Stress disclosure: whenever the patient find him/herself stressed, they instructed to find the suitable way to ventilate **(Pennebaker, 2004).**
- **Adopt healthy ways to manage stress,** such as deep breathing, meditation, or yoga, could help in preventing depression symptoms by reducing stress levels and promoting relaxation **(Gupta, et al., 2016).**
- **Seek help early:** give the patient instruction about the time that they should talk to a doctor, therapist, or support group which could help them to receive support and treatment they need to prevent depression from become worsening **(Belafsky, 2008).**

Evaluation of the effects:

The effects of the dysphagia care bundle were evaluated through using the same assessment tools that used during the base line assessment (Eating Assessment Tool-10 (Eat-10), the 3-ounce Water Swallow Test, and Geriatric Depression Scale). The evaluators were still also done blinded to the participant type (as being in the control or bundle

group) during the post-intervention assessment. Data were collected at the end of the intervention.

Statistical analysis

The statistical software for social sciences (SPSS) version 22 was used to arrange, classify, and analyze the collected data. For qualitative and quantitative variables, respectively, the mean and standard deviations of the data were reported using descriptive statistics. The paired t-test, chi-square test, and correlation r-test were the statistical tests that were applied. When the p-value was less than 0.05, high significance was assumed, and when the p-value was greater than 0.05, no statistical significance difference was taken into account.

Results

Table (1): Frequency distribution of demographic characteristics among the study participants (n=120)

Demographic characteristics	Bundle group (60)		Control group(60)		x^2	P
	NO	%	NO	%		
Age						
65 - < 75yrs	22	36.7	25	41.7	1.254	0.215
75 - < 85yrs	21	35	20	33.3		
85yrs	17	28.3	15	25.0		
Mean±SD	**70.1±3.2**		**68.5±1.2**			
Gender						
Male	24	40.0	23	38.3	1.214	0.614
Female	36	60.0	37	61.7		
Marital status						
Single	3	5.0	0	0.0	1.457	0.315
Married	35	58.3	32	53.3		
Divorced	5	8.3	3	5.0		
Widowed	17	28.4	25	41.7		
Educational level						
Illiterate	20	33.3	23	38.3	1.650	0.943
Reading and writing	10	16.7	7	11.7		
Basic education	15	25.0	17	28.3		
Secondary school	11	18.3	10	16.7		
University	4	6.7	3	5.0		
Occupation						
Housewife	14	23.3	14	23.3	1.995	0.361
Farmer	30	50	30	50		
Retired.	16	26.7	16	26.7		
Residence						
Urban	23	38.3	24	40.0	6.914	0.841
Rural	37	61.7	36	60.0		
Living Condition						
Living with family	42	70.0	40	66.7	2.719	0.218
Living alone	18	30.0	20	33.3		
Income						
Not enough	42	70.0	41	68.3	4.212	0.256
Enough.	15	25.0	16	26.7		
Enough and saved.	3	5.0	3	5.0		

P value is significant at<0.05

Table (2): Frequency distribution of the risk factors among the bundle and control groups (n=120)

Risk factors	Bundle group (60)		Control group(60)		x^2	p
	NO	%	NO	%		
Chronic disease						
No chronic disease	3	5.0	2	3.3	1.024	0.612
have only one	37	61.7	36	60.0		
have more than one	36	60.0	37	61.7		
smoking						
Yes	27	45.0	29	48.3	2.147	0.354
No	33	55.0	31	51.7		
Feeding mode						
Liquid	12	20.0	13	21.7	1.384	0.847
Semi-liquid	23	38.3	24	40.0		
General diet	25	41.7	23	38.3		
Physical function						
Independent	15	25.0	16	26.7	0.124	0.643
partial dependent	30	50.0	32	53.3		
Dependent	15	25.0	12	20.0		
Dental condition						
Normal teeth	13	21.6	15	25.0	1.057	0.381
Teeth loss	25	41.7	27	45.0		
Dental caries	22	36.7	18	30.0		
Regular tooth brushing						
Yes	13	21.7	14	23.3	2.358	0.714
No	47	78.3	46	76.7		
Body Mass Index (BMI) kg/m2						
Underweight <18.5	23	38.3	24	40.0	1.375	0.547
Normal 18.5 – 24.9	28	46.7	26	43.3		
Overweight 25 – 29.9	8	13.3	9	15.0		
Obese >30	1	1.7	1	1.7		
Newly hospitalized through the current year						
Yes	40	66.7	38	63.3	2.396	0.375
No	20	33.3	22	36.7		
Duration of dysphagia						
< 6 months	30	50.0	32	53.3	1.025	0.246
6 months–< 1 year	15	25.0	12	20.0		
1–< 1.5 year	10	16.7	12	20.0		
> 1.5 years	5	8.3	4	6.7		

P value is significant at<0.05

Table (3): Comparison between the bundle and control groups in the pre- and post- intervention based on EAT-10 (N=120)

	Bundle group (60)	Control group (60)	T	p-value
	Mean ± SD	Mean ± SD		
Pre-intervention	**16.2±4.8**	**15.3±4.6**	**1.049**	**0.2965**
Post-intervention	**8.3±2.27**	**13.4±3.8**	**8.925**	**< 0.0001***

P-value is significant at<0.05

Table (4): Comparison between the bundle and control groups regarding the severity of Dysphagia based on 3-ounce Water Swallow Test (n=120)

Dysphagia severity	Bundle group (60)		x^2	P	Control group (60)		x^2	p
	Pre-Intervention	Post-Intervention			Pre-Intervention	Post-Intervention		
	N (%)	N (%)			N (%)	N (%)		
Normal swallowing	**19(31.7%)**	**42(70.0%)**	**3.24**	**0.001***	**22(36.7%)**	**23(38.3%)**	**4.57**	**0.051***
Mild dysphagia	**26(43.3%)**	**15(25.0%)**			**24(40.0%)**	**29(48.4%)**		
Severe dysphagia	**15(25.0%)**	**3(5.0%)**			**14(23.3%)**	**8(13.3%)**		

Table (5): Comparison between the bundle and control groups regarding depression levels at pre and posttest (n = 120)

Depression levels	Bundle group (60)		x^2	P	Control group (60)		x^2	p
	Before	After			Before	After		
	N (%)	N (%)			N (%)	N (%)		
Mild depression	22(36.7%)	45(75.0%)	6.17	<0.001*	20(33.3%)	22(36.7%)	4.38	0.021
Moderate depression	26(43.3%)	12(20.0%)			30(50.0%)	30(50.0%)		
Severe depression	12(20.0%)	3(5.0%)			10(16.7%)	8(13.3%)		

Table (1): Presents demographic characteristics of elderly individuals in the bundle and control groups. Results indicate that 36.7% and 41.7% of elderly individuals among the bundle and control groups, respectively, were aged between 65 and 75 years old, with a mean age (SD) of 70±13.2 and 68±51.2, respectively. Additionally, 60.0% of both groups were female, while 58.3% and 53.3% of the study and control groups, respectively, were married. Illiteracy and farming were more prevalent among the elderly, with 33.3% and 38.3% among the bundle group and 50% among the control group of the elderly individuals who are participating in the current study. Moreover, most elderly individuals resided in the rural areas (61.7% and 60% among the bundle and control groups, respectively) and lived with family (70.0% and 66.7% among the bundle and control groups, respectively). Financial instability was also common, with over two-thirds of the elderly individuals (70.0% and 68.3% among the bundle and control groups, respectively) lacking sufficient income.

Table (2): Presents additional characteristics of elderly individuals among the bundle and control groups. Findings indicated that smoking was prevalent among the elderly, with 45% and 48.3% of individuals among the bundle and control groups, respectively, who are reporting as smokers. With respect to feeding, 41.7% and 38.3% of the bundle and control groups, respectively, followed a general diet, while 50% and 53.3% were partially dependent on others for their feeding. Tooth loss was also common, with 41.7% and 45% of individuals among the bundle and control groups, respectively, who experiencing this condition. Furthermore, most elderly individuals (78.3% and 76.7% among the bundle and control groups, respectively) had irregular tooth brushing habits. Regarding weight status, 38.3% and 40% of individuals among the bundle and control groups, respectively, were underweight, and approximately two-thirds of elderly individuals (66.7% and 63.3% among the bundle and control groups, respectively) were newly hospitalized in the current year. Notably, the majority of individuals who experienced dysphagia onset (50% and 53.3% in both the bundle and control groups, respectively) had experienced symptoms for less than 6 months.

Table (3): Presents that the comparison between the mean of Eat-10 scores in two times. In the pre-intervention phase, the mean scores of dysphagia severity among the bundle group and control group were 16.2±4.8 and 15.3±4.6, respectively, with no significant difference between the two groups with (p-value = 0.2965). However, in the post-intervention phase, the mean scores decreased significantly to 8.3±2.27 among the bundle group, which was significantly lower than the mean score 13.4±3.8 of the control group with (p-value< 0.0001).

Table (4): Presents a comparison between the bundle and control groups with respect to the severity of dysphagia, as assessed by the 3-ounce Water Swallow Test. The results showed that in the pre-test, 43.3% and 25% of the elderly participants in the bundle group exhibited mild and severe dysphagia, respectively, while in the post-test, 70% of the bundle group showed normal swallowing. In contrast, to the control group had 40% and 23.3% of the elderly participants with mild and severe dysphagia in the pre-test, respectively, and only 38.3% had normal swallowing in the post-test. Furthermore, 13.3% of the control group still had severe dysphagia at the post-test. These findings support our hypothesis that the bundle intervention application may be effective in improving swallowing function among elderly individuals with dysphagia.

In terms of depression levels, **Table (5):** Showed that, at the pre-test, 43.3% and 20% of the elderly people among the bundle group had moderate and severe depression, respectively, while at post-test, 75% of them had mild depression. In the control group, 50% and 16.7% of elderly people had moderate and severe depression, respectively, at pre-test, while only 36.7% had mild depression and 13.3% still had severe depression at post-test.

Discussion

Dysphagia is a geriatric syndrome which could cause a substantial morbidity, quality of life limitation with psychosocial ramifications as well as depression and anxiety which may impair swallowing function by causing an increase in symptoms, causing disturbance of appetite, and impairing adherence to dysphagia rehabilitation procedures **(Sadeghi, et al., 2021).** So, a multicomponent approach is required to decrease

the severity or even prevent enhancement of dysphagia among elderly and to recover and maintain effective and safe swallowing functions. The findings of this quasi-experimental, controlled trial suggest that the dysphagia care bundle consisting of shaker exercises, feeding modifications, and depression relief could effectively improve dysphagia symptoms among elderly patients.

Statistically significant improvement was shown in dysphagia symptoms among the bundle group compared to the control group after the intervention application. The mean Eat-10 scores among the bundle group decreased from 16.2±4.8 to 8.3±2.27, while the control group showed a slight decrease in scores from 15.3±4.6 to 13.4±3.8. These results are consistent with previous studies that reported the effectiveness of shaker exercises and feeding modifications in improving dysphagia symptoms among elderly patients. The lack of significant differences in pre-intervention scores between the bundle group and the control group may be due to the fact that dysphagia is a common problem among elderly patients, and many factors could contribute to its development. However, the significant improvement in the post-intervention scores among the bundle group highlights the importance of using a comprehensive dysphagia care bundle to effectively manage dysphagia symptoms among elderly patients.

The significant improvement in dysphagia symptoms among the bundle group may be attributed to the combined effect of shaker exercises, feeding modifications, and depression relief. As Shaker exercises help to strengthen the muscles involved in swallowing and improve coordination, while feeding modifications reduces the risk of aspiration and improves food bolus formation. Additionally, depression relief may play a role in improving dysphagia symptoms, as depression is known to be associated with dysphagia among elderly patients. Future studies could further explore the individual contributions of each component of the bundle and investigate the long-term effectiveness of the care bundle.

When comparing the results of this study with other studies that aimed to decrease the severity of dysphagia among the elderly, it is important to consider the differences in the interventions used. However, several previous studies have reported the effect of shaker exercises and feeding modifications in improving dysphagia symptoms among the elderly. For example, a randomized controlled trial done by **Park et al., (2018)** showed that a six-week shaker exercise program resulted in a significant improvement in swallowing function among elderly patients with dysphagia. Similarly, a systematic review and meta-analysis by **Chen et al., (2020)** reported that feeding modifications, such as dietary texture modifications and liquid viscosity adjustment, significantly improved dysphagia symptoms among the elderly.

Moreover, the results of 3-ounce Water Swallow Test in table 4 showed that the bundle interventions had an impact in enhancing swallowing function among elderly individuals with dysphagia, as evidenced by the significant reduction in the percentage of participants with mild and severe dysphagia and the increase in the percentage of participants with normal swallowing in the post-test compared to the pre-test. These findings are consistent with previous studies that had been done to investigate the effectiveness of various interventions on dysphagia among elderly individuals. For example, a systematic review and meta-analysis done by **Chen, Wu & Wang,) 2019),** who found that exercise interventions were effective in improving swallowing function among elderly individuals with dysphagia. Similarly, a randomized controlled trial done by **Takahashi et al., (2016),** who reported that oral motor exercises and electrical stimulation were effective in improving swallowing function among elderly individuals with dysphagia.

In terms of depression relief, there is evidence to suggest that depression is associated with dysphagia among elderly patients. A systematic review done by **Baijens et al., (2014),** reported that depression was one of the risk factors for dysphagia among elderly, and that treatment of depression may improve dysphagia symptoms. Therefore, the inclusion of depression relief as part of the dysphagia care bundle in this study may have contributed to the significant improvement of dysphagia symptoms which was observed.

Also, the findings presented in Table 5 suggested that the dysphagia care bundle used in this study may have positive effects not only on the swallowing function of elderly patients, but also on their depression levels. The results showed that the bundle group had a higher percentage of elderly people with moderate and severe depression at the pre-test compared to the control group, which may indicate that dysphagia may have contributed to the development of depressive symptoms among those individuals.

However, after the intervention, the bundle group showed a significant improvement in their depression levels, with 75% of them reporting only mild depression at the post-test. In contrast, the control group showed only a modest improvement in depression levels, with 36.7% reporting mild depression at the post-test. These results suggest that the dysphagia care bundle may have a positive impact on the psychological well-being of elderly patients with dysphagia.

Several studies had reported a high prevalence of depression among elderly patients with dysphagia, which may be related to the negative impact of dysphagia on quality of life, social isolation, and malnutrition **(Al-Alzhrani, et al., 2021).** Therefore, the positive effect of the dysphagia care bundle on depression levels in this study may have some important implications for improving the overall quality of life and well-being of elderly patients with dysphagia.

As for comparing the results of this study with other studies that aim to decrease the severity of dysphagia and depression among elderly patients, several studies have investigated the effect of various interventions for dysphagia among this population. For example, a systematic review and meta-analysis of 28 randomized controlled trials found that exercise-based interventions, such as the Shaker exercise, were effective in improving swallowing function among elderly patients with dysphagia **(Kumar, et al., 2017).** Another study conducted in Korea found that a multidisciplinary intervention, which included oral care, nutritional support, and dysphagia rehabilitation, were effective in reducing the severity of dysphagia and improving the nutritional status among elderly patients with dysphagia **(Kim, et al., 2019).**

Moreover, several studies have reported that depression is common among elderly patients with dysphagia and that could negatively affect their swallowing function and quality of life **(Kim, et al., 2019 & Park, et al., 2016)**. As well a randomized controlled trial conducted in Japan found that a comprehensive intervention, which included dysphagia rehabilitation and psychological support, were effective in improving both swallowing function and depressive symptoms among elderly patients with dysphagia **(Ueda, et al., 2020).**

Comparing the results of the previse study with the finding of the current studies, the dysphagia care bundle which used in the current study, includes shaker exercises, feeding modifications, and depression relief, is a multidisciplinary intervention that targets both dysphagia and depression among elderly patients. So, the findings of the current study are consistent with previous studies that had reported the effectiveness of exercise-based interventions for dysphagia and comprehensive interventions that include psychological support for improving both swallowing function and depression levels among elderly patients with dysphagia.

However, it is worth noting that the studies mentioned above used different interventions, outcome measures, and study designs, which make it challenging to directly compare their results. Nonetheless, these studies collectively suggest that multidisciplinary interventions that address the physical, nutritional, and psychological aspects of dysphagia may be had a positive effect in improving the health outcomes of elderly patients with dysphagia.

In conclusion, while there are differences in the interventions and outcome measures used in various studies aimed to improve dysphagia symptoms among the elderly, the findings of this current study are consistent with previous research that had shown the effectiveness of shaker exercises, feeding modifications, and depression relief in improving dysphagia symptoms. These results suggest that a comprehensive dysphagia care bundle may be an effective approach for improving both swallowing function and depression levels among elderly patients with dysphagia. However, further research is needed to replicate these findings in larger and more diverse samples and to assess the long-term effects of the dysphagia care bundle on the health outcomes of elderly patients.

Limitation of the study:

The present study yields significant findings, which should be interpreted in light of several limitations in the study design. Firstly, the study was conducted at a single center, thereby restricting the generalizability of the results. Secondly, although the study employed a quasi-experimental design, randomized allocation of matched participants between the intervention and control groups was utilized to mitigate confounding factors, as evident from the non-significant differences in characteristics between these groups. Thirdly, ascertaining dysphagia remains a challenge, given the absence of a universally accepted outcome metric. To address this, an expert was consulted to clinically diagnose dysphagia, and the severity of dysphagia was evaluated using the Eat-10 questionnaire and the 3OWST. Fourthly, the dose-response relation between the proposed bundle was not evaluated over multiple time intervals. Finally, it was not feasible to conduct endoscopic studies to monitor the level of dysphagia due to ethical considerations.

Recommendations of the study

Based on the study results and limitations, it is recommended that further research should be conducted to confirm and extend the present findings. Specifically, future studies should include multiple centers to increase the generalizability of the findings, use a randomized controlled trial design, employ multiple outcome metrics to assess dysphagia, evaluate the dose-response relation between the proposed bundle over various time intervals, and explore alternative methods to monitor the level of dysphagia in a safe and ethical manner.

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