

**Design and Implementation of a Nutritional Intervention in
Patients With Oropharyngeal Dysphagia**

NCT02959450

October 10th, 2021

Patients of 18 years and older, both genders, who had a primary caregiver and a confirmed diagnosis of OD were included. Eating Assessment Tool (EAT-10) and Volume- Viscosity Swallow Test (V-VST) were performed by a clinical nutritionist in order to evaluate the safety and efficacy of swallowing and confirm the diagnosis of OD; select the type of viscosity and volume appropriate for the prescription of the texture-modified diet. Patients with cancer, kidney or hepatic failure, terminally ill patients, as well as high risk of aspiration, reporting a decrease in oxygen saturation $>5\%$ in the V-VST, or with enteral nutrition (EN) through a nasoenteral tube or gastrostomy were excluded. We estimated a sample size of 50 patients per group by the formula of survival of Argimon et al , with an alpha level of 0.05 and more than 90% power to detect a difference of 15% of mortality between groups.

Anthropometry

Anthropometric measurements were performed according to the reference manual for anthropometric standardization. The same scale was used for all patients at each visit. Forearm circumference was measured at the midpoint of the right arm and calf circumference was measured in a supine position with the tape along the calf to measure the greatest circumference without compressing the subcutaneous tissue.

Mini Nutritional Assessment

The nutritional risk was assessed using the Mini Nutritional Assessment (MNA) questionnaire, a valid and reliable tool to identify malnutrition in elderly people. The original version of this tool was used for this study contained 18 questions with a maximum of 30 points. It is considered that a score lower than 17 points represents malnutrition, between 17 and 23.5 points of risk of malnutrition and more than 24 points that the patient is well nourished.

Dietary intake

For the evaluation of the quality and quantity of dietary intake, a 24-hour multiple-step recall was applied and the Food Processor Nutrition Analysis® software was used for the detailed nutritional analysis.

Body composition

The body composition was performed using a single-frequency BIA (50-kHz, Quantum X, RJL Systems, Inc) with the standard technique: all participants were supine with limbs slightly spread apart from the body, refrained from eating, drinking, and exercising for six hours, no alcohol within 24 h before testing and portable electric heaters. The area was cleaned with alcohol and the electrodes (recommended by manufacturers RJL Systems, Inc) were placed on an imaginary line bisecting the ulnar head of the right hand and on an imaginary line bisecting the medial malleolus of the right finger and on the base of the second toe of the right foot. Finally, the R and Xc values were recorded. All measurements were performed under strictly standardized conditions by the observer, using the same device in order to avoid interobserver and interdevice variability. The Quantum X was calibrated periodically by a test resistor with a known value of 495 – 505 ohms of R to ensure accuracy of measurements. The coefficient of variation was reported in a range from 1.8 to 2.9%.

Muscle strength

The muscular functionality was evaluated by a handgrip dynamometer (Takei®). The operator, using the same device in order to avoid interobserver and interdevice variability, performed all measurements under strictly standardized conditions. For the measurement, subjects were placed standing with arms outstretched parallel to the trunk taking the dynamometer and applying maximum strength with each hand without support. The measurement was repeated three times with separation of 1 min to avoid fatigue and the maximum value was recorded. The instrument was routinely checked resistors and capacitors of known values.

Nutritional intervention

Nutritional requirements for both groups were calculated based on the American Society for Parenteral and Enteral Nutrition and Society of Critical Care Medicine (A.S.P.E.N./S.C.C.M.) and recommendations of PROT-AGE Study Group as follows: 25- 30 kcal/kg Body Weight (BW)/day in patients with body mass index (BMI) <30 kg/m² and 20-25 kcal/kg ideal BW/day with BMI > 30 kg/m²; protein were

calculated 1.2-1.5 g/kg

BW/day for patients with BMI <30 kg/m² and in case that BMI was >30 kg/m² protein were calculated 2 g/kg ideal BW/day in both groups. Both groups received swallowing rehabilitation (postural maneuvers, increase oral sensitivity, neuromuscular practices).

Subjects were randomly allocated to intervention group (modified consistency diet, with a nectar or pudding viscosity) or control group (standard treatment) using a blocked allocation strategy. The *control group* received a traditional modified texture diet, with pureed foods and one viscosity of thickened drinks. The viscosity beverages were not systematically controlled. For the *intervention group* a chef and a clinical nutritionist developed the texture- modified foods and thickened drinks diet, with nectar or pudding viscosity and controlled bolus volume. The foods were thickened using Enterex Food Thickener, Victus® and the viscosity of menus was standardized and measured with a Brookfield Viscometer (model RV). The menus with nectar consistency had a viscosity of 51-350 centipoises (cP) and the pudding consistency foods with a higher viscosity at 1,750 cP. The viscosity of the diet was prescribed according to the viscosity and volume tolerated in the V-VST. A recipe book for caregivers and patients was made to facilitate the preparation of the diet with the exact amount of thickener to use in each menu to achieve the desired viscosity. Training was also provided to patients and caregivers by a video on the use of food thickener (modified ediblestarch) on each menu.

The primary outcome was the amount of energy (kcal/kg) and protein (g/kg) consumed, the secondary outcome was body composition and muscular functionality. The follow-up was carried out in 5 visits during 12 weeks. Adherence to the prescribed meal plan was evaluated at each visit. To evaluate the adherence, it was necessary to have an intake of more than 80% of the nutritional requirements with 24-hour recall. If the intake was lower than indicated, oral nutritional supplements were prescribed to meet the nutritional requirements established in both groups.