OBJECTIVE: This randomized clinical trial is designed to define the short-term and long-term effects of two commonly used interventions implemented with the purpose to eliminate aspiration of thin liquids. These interventions are (1) chin down posture and (2) liquids modified to nectar viscosity or honey viscosity.

RESEARCH PLAN: This is a randomized multicenter clinical trial conducted in two parts. It was generated by a research consortium of the American Speech-Language-Hearing Association and is funded through the NIDCD. Part I of the study (Intervention Trials) examines the effects of the above interventions in the short-term, that is, when aspiration is observed during the videofluorographic (VFG) study. VFG, also known as the modified barium swallow, is a standard procedure assessing oropharyngeal swallow physiology to detect and manage prandial aspiration. The immediate short-term effects of (1) chin flexed posture and (2) thickened liquids will be assessed during the VFG study in those patients with Parkinson's Disease or some form of dementia. These populations were chosen due to the documented prevalence, in the literature, of dysphagia, aspiration and aspiration-related illness for the two groups. Clinicians commonly practice the interventions above as part of routine clinical care. Yet, clinical trials assessing their effects have not been performed.

METHODOLOGY: Patients with Parkinson's disease with or without dementia and patients with dementia are eligible for enrollment in the study. Patients clinically suspected of aspiration while drinking liquids are typically referred to our VAMC for a VFG procedure. If the patient meets age and diagnosis criteria, has signs of dysphagia and is referred for a swallowing evaluation, the clinician will complete the informed consent process with the appropriate responsible party if it is not performed already at the referring site. The clinician will offer the patient enrollment in the study. If the patient accepts, he or she will then receive three boluses of liquid barium in 3ml amounts and three boluses from a cup. If the patient aspirates on one or more of the trials, the clinician will discontinue that consistency and offer the patient participation in Part I of the study. The clinician will present treatment condition interventions in randomized order for each patient. The clinician will analyze the study on site in the typical clinical manner and will then send all data to the study coordinators for independent statistical research analysis. The outcome measure for Part I will be the occurrence of aspiration on swallows utilizing each of the two interventions.

The patient may then enter Part II of the study if (a) both strategies were effective in eliminating aspiration, or (b) neither strategy was effective in eliminating aspiration, but the patient refuses alternative feeding by his advanced directive preference. Enrolled patients will be randomly assigned to one of the treatment groups (chin down posture or thickened liquids). The patient will return to his residential setting with all caretakers aware of patient's treatment. Caregivers at the facility will document health status and compliance with the assigned treatment. Data regarding the occurrence of pneumonia will be recorded during a three-month treatment period. Statistical analysis of this data will be performed to identify the incidence of pneumonia among the groups tested. This will be the outcome measure for Part II of the study.

FINDINGS: Data collection continues. The Data Safety Monitoring Board in January 2002 made no recommendations for changes and reviews the study again in June 2002.