Dysphagia

Project Title:

Outcomes of Rehabilitation Programming for Neurogenic Dysphagia: A Controlled Trial

Primary Investigators:

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Co-Investigators:

Country	Country Coordinator	Co-Investigator	Data Collection Sites
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Germany	S. Stanschus, M.A.		Karlsruhe
Netherlands	HCA Bogaardt	Dr. PP Devriese	Amsterdam
Australasia	ML Huckabee, Ph.D	ML Huckabee, Ph.D	New Zealand, Australia, Singapore
United States	P. Johnson, Ph.D	A. Guilford, Ph.D.	AR, CA, FL (3), GA, IL, MN, NY (2),

Project Summary:

The proposed research project is a multi-national effort, designed to evaluate the efficacy of therapy for chronic dysphagia secondary to stroke. Specifically, the benefits of accelerated treatment and of biofeedback will be explored. Previous case-series studies of accelerated treatment using biofeedback have documented encouraging results. This project is a phase 3 randomized clinical trial study.

Previous Research:

Treatment efficacy data supporting the effectiveness of swallowing rehabilitation programs are limited to only a few published manuscripts. Two prior published reports have documented considerable success in the rehabilitation of chronic and severe dysphagia using a combined approach of intensively provided rehabilitation exercises and surface electromyography biofeedback (Crary, 1995, Huckabee & Cannito, 1999). However, the data reported in these papers were limited to a clinical description of therapeutic programs and do not represent controlled treatment efficacy research. Thus outcome measures were limited and many factors that could potentially influence recovery were poorly controlled. There exists a continued need for well-controlled treatment efficacy research to document the effects of swallowing intervention and to identify factors that influence recovery.

Primary Investigators and Co-investigators:	The primary investigator worldwide is Dr. Maggie Lee Huckabee, at the University of Canterbury in Christchurch, New Zealand. She is supported by a network of co-investigators and clinician researchers who will supervise and carry out data collection in up to 20 sites worldwide. Other participating countries include Canada, Germany, The Netherlands, Australia and Singapore. Co-investigators are responsible for securing national funding in each country and for data analysis and preparation for publication of the results of the national data.. Country coordinators are responsible for identifying appropriate data collection sites and supervising data collection to assure adherence to the research protocol. Dr. Maggie Lee Huckabee will supervise data collection in New Zealand and Australia and will be primarily responsible for data analysis and preparation for publication worldwide.
Data Collection Sites:	Data for this project will be collected in locations in each country. A speech language pathologist at each data collection site a will be trained in the research protocol. Initial training will consist of attendance at a two-day workshop focusing on swallowing rehabilitation techniques and incorporation of SEMG biofeedback in the therapeutic program that is instructed by the lead investigator.
Subjects:	Each data collection site will be asked to find a number of subjects for the research over a 2-3 year period. All subjects will be diagnosed with cerebrovascular accident and will present chronic dysphagia, being at least one-year post onset and three months post discontinuation of swallowing rehabilitation. All will present at least moderate pharyngeal phase dysphagia based on videofluoroscopic and clinical diagnosis.
Procedures:	Subjects who are identified as eligible for (and who consent to) the research will need to undergo a thorough swallowing assessment, including a videofluoroscopy and serum albumin blood screen, 3-weeks prior to beginning their course of treatment. A quality of life tool will also be used to monitor their attitudes regarding dysphagia and their treatment outcomes. Subjects will be randomly assigned to one of four treatment protocols (A-D) for 30 sessions of therapy. In the accelerated treatment protocols, the first 10 sessions for therapy will be provided as two sessions daily for 5 days; sessions 11-30 will be provided on a more traditional schedule of two hours weekly. In the non-accelerated track, all sessions will be delivered on a two session per week schedule. Biofeedback will be used for half of the subjects in each treatment schedule. Subjects will undergo repeated evaluation (including videofluoroscopy and serum albumin screening) following sessions 10, 20 and 30. Although specific treatment plans for the patients in this study will be individualized to reflect the physiologic needs of each patient, the treatment provided to all groups will focus heavily on methods for muscle strengthening and retraining, paired with early and aggressive initiation of oral feeding trials. For those research participants receiving biofeedback-assisted treatment, the MyoTrac3 will be utilized exclusively to minimize variability due to instrumentation.

Outcome Measures:

Treatment outcomes will be based on several physiologic, clinical and psychosocial measures. Videofluoroscopic swallowing studies will be completed on all research participants at the onset of treatment, after ten treatment sessions, after twenty treatment sessions and again at discharge from treatment as appropriate. Severity ratings of many features of swallowing will be made using Scale 1 of the Memphis Index for the Multidisciplinary Evaluation of Swallowing (MIMES; Huckabee & Cannito, 1999). Clinical assessment of nutrition, pulmonary status and cognitive status will be completed at these same intervals using Subscale 2 of the MIMES. Finally, patient satisfaction with treatment and quality of life issues will be assessed using the standardized quality of life index for dysphagia, the SwalQOL (McHorney, Robbins, Rosenbek, 1999).

Budget:

The BFE project manager is responsible for preparing the budget with the co-investigator and country co-ordinator for each country. The application will request funding to reimburse participating facilities (data collection sites) for the following items:

1. Videofluoroscopies
2. Blood screenings
3. Therapist costs
4. Videotapes, audiotapes and electrodes
5. Photocopying and incidental expenses including telephone calls
6. A single SEMG biofeedback device with accompanying software.

The Biofeedback Foundation of Europe is supporting the project through an equipment subsidy/rebate on the deployment of SEMG biofeedback devices with accompanying software and training at approved and qualified data collection sites.

Equipment:

The MyoTrac3 SEMG biofeedback equipment selected for use in this project is manufactured and distributed by a Canadian Company, Thought Technology Ltd., based in Montreal. The company applies and maintains a quality system program that conforms to ISO 9001-1994, EN46001-1996, MDD93/42/EEC, USFDA QSR-1996 and Health Canada Medical Device Regulations at all levels of the company. The MyoTrac3 with customized software will be utilized exclusively to minimize variability due to instrumentation. The MyoTrac3 SEMG biofeedback equipment selected for use in this project is manufactured and distributed by a Canadian Company, Thought Technology Ltd., based in Montreal. The company applies and maintains a quality system program that conforms to ISO 9001-1994, EN46001-1996, MDD93/42/EEC, USFDA QSR-1996 and Health Canada Medical Device Regulations at all levels of the company. The MyoTrac3 with customized software will be utilized exclusively to minimize variability due to instrumentation.

Ethics:

The project has successfully undergone ethics board reviews in New Zealand, Canada and Singapore. Other country coordinators/co-investigators will submit ethics applications at appropriate sites prior to initiating the research.