

Albert Einstein Healthcare Network

Annual Progress Report: 2008 Formula Grant

Reporting Period

July 1, 2010 – June 30, 2011

Formula Grant Overview

The Albert Einstein Healthcare Network received \$135,484 in formula funds for the grant award period January 1, 2009 through June 30, 2011. Accomplishments for the reporting period are described below.

Research Project 1: Project Title and Purpose

E-Coaching to Support the Modification of Risk Factors of Metabolic Syndrome using Mediterranean Diet - The Mediterranean Diet has been found to improve risk factors associated with Metabolic Syndrome. The purpose of this study is to determine if it is feasible and effective to deliver support for the Mediterranean Diet using interactive email support and coaching (e-coaching), and educational materials and links found on the internet. In addition, results of this study will be compared to a similar study that examines the effectiveness of face-to-face support for the Mediterranean Diet. This methodology will allow an examination of the feasibility of both modes of delivering MED diet education and support, as well as an examination the effect of each method on outcome variables.

Duration of Project

1/1/2009 - 6/30/2011

Project Overview

The objective of this study is to test the feasibility and effectiveness of adopting the Mediterranean Diet (MED) among low-income, older African American women who have been diagnosed with the Metabolic Syndrome (MSY) using email delivered MED support. Education regarding the MED will be presented in a 3-hour workshop followed by 6-months of weekly email coaching and support (e-coaching) that will also include use of internet links. The e-coaching support is based on a protocol developed for face-to-face MED support, which is grounded in social cognitive theory.

Specific Aims:

1. To determine interest in and successful adoption of the MED delivered in a 3-hour workshop and support delivered via weekly emails for 6-months.
2. To assess the impact of the 6-month intervention on factors associated with MSY by measuring psychosocial, physical, and process outcomes.

3. To compare the outcomes of MED intervention delivered via email to outcomes of a similar study examining the impact of MED face-to-face support.

Twenty women will be recruited from a diabetes education program and primary care practices at the Albert Einstein Medical Center in Philadelphia, and through newspaper articles in community papers. Participants will be assessed pre-intervention and during the intervention at 3-month and 6-month intervals. Assessment measures will include: body mass index (BMI), abdominal obesity (waist size), waist-to-hip ratio, blood pressure, and fasting blood collection (A1c levels, glucose, lipoproteins, C-reactive protein); quality of life, social support, and symptoms of depression, and food composition (percent carbohydrates, fat, and protein). Assessment at 3-months will include all of these measures with the exception of the fasting blood collection. Physical activity will be recorded weekly and used as a covariate in statistical analyses.

Principal Investigator

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Other Participating Researchers

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Expected Research Outcomes and Benefits

It is expected that this intervention will positively impact risk factors associated with MSY and will also have a public health benefit. Randomized, controlled studies like the Diabetes Prevention Program (DPP) have produced evidence that lifestyle interventions (that include improvements in diet) can reduce risk factors of diabetes. However, there is still a need to develop cost-effective and sustainable interventions to reduce risk factors associated with diabetes, heart disease, and the precursor to these diseases, MSY. Research indicates that the MED has been successful in improving risk factors for diabetes, heart disease, and MSY. Very few studies have been conducted in the U.S., and none of these studies were conducted among low-income African Americans. This intervention will test the feasibility of using email delivery of the MED protocol implemented in a similar 6-month face-to-face MED support intervention developed by this research team. If successful, email delivery could make MED support available to a larger number of participants at less cost to the institution and less time effort for participants than face-to-face MED support. The results of the intervention can be used to improve clinical care and improve risk factors associated with MSY. Specifically, it is expected that overweight participants in the intervention will reduce body mass index, reduce abdominal obesity, reduce or maintain blood pressure, and improve glucose control, lipid profile, well-

being, social support, and quality of life. Findings from this study will be used to improve patient care and will be used to develop a larger, randomized controlled study.

Summary of Research Completed

During this period the study was completed and final questionnaires and physical measures were obtained. A database was developed and data entry began. In addition, in January 2011, Principal Investigator (PI), Nadine Uplinger, left Einstein and study co-PI, Vincent Figueredo, MD was named PI. Original study PI, Tina Harralson, remains a consultant on this study.

Fifteen eligible women were enrolled in the study in February 2010, and 11 completed the study. Of the four women who did not complete: one completed the consent process but did not complete any other part of the study, and three have incomplete data (i.e., baseline only or baseline and partial follow-up). Outcome measures included: fasting blood assay (A1C, glucose, lipid panel, and C-reactive protein), physical measurements (waist and hip measurement, blood pressure, and body mass index), and questionnaires pertaining to demographics, medical history, depression, everyday functioning and social support. During this period, participants continued to receive at least weekly communications containing educational materials regarding the benefits of the Mediterranean Diet, and motivational and diet tips. Participants were encouraged to ask questions and seek advice regarding nutrition and dieting. Several healthcare providers asked to receive the emailings, which they shared with their patients. In addition, many of the participants report that they are adapting the Mediterranean Diet at home, and that they are sharing the educational materials they received with friends and family members. Topics covered during the current reporting period are listed in Table 1. Recipes and diet tips were also sent with the educational modules.

Table 1: Topics
The Ideals of Med Diet/Lifestyle Around the World
Greece
Japan
Costa Rica
Loma Linda, California
Hydration and Nutrition
Role of Inflammation in Health
American Diabetes Association Guidelines for Metabolic Syndrome
Mediterranean Diet and Cognition
Cholesterol: Good & Bad

Adapting recipes to include healthy ingredients
Maintaining Health Lifestyle

The investigators continued to send pertinent links and articles of interest to all participants who were initially enrolled in the study, as well as to several persons and clinicians who were interested in receiving the materials even though no data was collected from them.

A summary of results from this study will be reported in the final progress report.

Research Project 2: Project Title and Purpose

The Use of High Flow Oxygen during ED PSA with Propofol: A Randomized Trial - The drugs used during emergency department procedural sedation and analgesia (PSA) can depress breathing and can cause patients to have dangerously low levels of oxygen (hypoxia) in their bloodstream. In previous research that we have conducted, extra low flow oxygen (3 liters a minute via nasal cannula) during PSA does not improve the rate of hypoxia during PSA with one common drug combination (midazolam and fentanyl). With another drug, propofol, it only has a small benefit. Because of the way propofol works in the body, we believe that high flow oxygen (15 liters a minute via mask) may reduce the rate of hypoxia. The purpose of this project is to evaluate whether high flow oxygen significantly lowers the rate of hypoxia during emergency department procedural sedation with propofol.

Duration of Project

1/1/2009 - 6/30/2011

Project Overview

The primary objective of this project is to show that high flow oxygen can lower the rate of hypoxic events by 20% compared to room air during emergency department procedural sedation and analgesia with propofol. This is a randomized, controlled trial. Any patient able to consent, who meets eligibility criteria, and needs sedation and analgesia for a painful, anxiety provoking procedure will be included. All patients that are eligible for the study will receive either high flow oxygen or room air during their procedural sedation with propofol. Patients and the health care team will be blinded to the gas delivered. Patients, five minutes before their sedation, will have a 100% non-rebreather mask fitted over their face, and it will be attached to one of two blinded tanks, the flow rate will be elevated to 15 liters a minute. The mask will remain on until the procedure has concluded and the patient is awake and ready for discharge. During the sedation, patients will have electronic monitoring of pulse oximetry, heart rate, blood pressure, respiratory rate, and end tidal carbon dioxide (ETCO₂).

The primary outcome is the rate of hypoxic events between the two groups. Data to be recorded includes hypoxia, which is defined as any pulse oximetry saturation below 93%. Respiratory depression is defined as hypoxia, or an ETCO₂ level greater than 50 mmHg, less than 30 mmHg,

a change of 10 mmHg or greater from baseline, or a loss of waveform. Vital signs are recorded every five minutes. Pulse oximetry and ET_{CO}₂ are recorded electronically every 5 seconds. Trained research associates will note the time and vital signs at any point a patient meets our criteria for respiratory depression or hypoxia. Other data to be collected include demographics, drug dosage, time of procedure, time to readiness for discharge, and adverse events. To complete this study, we need approximately 60 patients per group.

Principal Investigator

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Expected Research Outcomes and Benefits

Over the past decade, the need to provide safe and effective procedural sedation has prompted an increasing number of emergency department (ED) clinical trials and the introduction of new agents, techniques, and monitoring devices. Yet, despite the knowledge gained by scientific study and clinical experience, early detection of respiratory depression and prevention of hypoxia remains a challenge. To reduce the incidence of hypoxia, the American Society of Anesthesiology recommends the use of supplemental oxygen for patients undergoing deep sedation, and suggests it be considered during moderate sedation. While these recommendations seem intuitive, there is a paucity of information regarding the risks and benefits of supplemental oxygen during ED procedural sedation.

The goal of supplemental oxygen is to increase oxygen reserves, thereby delaying or preventing the onset of hypoxia. However, increasing oxygen reserves is not without risk. It has been shown that super oxygenated patients desaturate only after prolonged apnea. This negates the use of pulse oximetry as an early warning device for respiratory depression, which is very concerning in light of the fact that emergency physicians rarely recognize respiratory depression in sedated patients who do not become hypoxic. In previous research we have conducted, physicians only recognize patients having respiratory depression once they develop dangerous levels of hypoxia.

Patients who have hypoxia during procedural sedation are at risk of other adverse outcomes such as vomiting and aspiration of stomach contents into the lungs, seizures, intubation and assisted ventilation, seizures, brain damage, and death. This is why such care is given to proper dosage of medications, and close clinical and electronic monitoring of patients undergoing PSA in the ED.

Low flow supplemental oxygen has not been shown to confer much of a benefit. If high flow oxygen can be shown to be safe and is effective in lowering the rate of hypoxia during ED PSA, its use should be part of the standard of care.

Summary of Research Completed

We randomized 91 adults to receive 100% oxygen or compressed air at 15 L/minute by non-rebreather mask for 5 minutes before and during propofol procedural sedation. We administered 1.0 mg/kg of propofol, followed by 0.5 mg/kg boluses until the patient was adequately sedated. Physicians and patients were blinded to the gas used. Hypoxia was defined a priori as oxygen saturation less than 93%; respiratory depression was defined as an end tidal CO₂ greater than 50 mm Hg, a 10% absolute change from baseline, or loss of waveform.

We noted significantly less hypoxia in the patients receiving high-flow oxygen compared with those receiving compressed air (19% versus 41%; P=.007; difference 23%; 95% confidence interval 6% to 38%). Respiratory depression was similar between groups (51% versus 48%; difference 2%; 95% confidence interval =15% to 22%). We observed 2 adverse events in the high-flow group (1 hypotension, 1 bradycardia) and 2 in the compressed air group (1 assisted ventilation, 1 hypotension).

This data was submitted to the Society for Academic Emergency Medicine (SAEM) Annual Meeting, and was accepted for oral presentation. This data was presented at the SAEM New England Regional Meeting (Hartford, CT, April 2011) and national meeting (Boston, MA, June 2011). This data was accepted and published in *Annals of Emergency Medicine*, epub ahead June 2011.

Research Project 3: Project Title and Purpose

Performance Evaluation of Spatial Normalization Protocols for Brains with Focal Lesions - The purpose of the current project is two-fold. First, we will evaluate several different protocols that involve spatially transforming images of focally lesioned brains. The evaluation will be conducted in a quantitative manner. The second purpose of the project is to build a small database of images of brains with focal lesions where anatomical landmarks are planted. These brain images with landmarks can be used for future studies that aim to evaluate more spatial transformation protocols.

Duration of Project

1/1/2009 – 06/30/2011

Project Overview

Despite the importance of performance evaluation of the currently available protocols for normalizing focally lesioned brains, quantitative evaluation studies are very scarce. The current project is an evaluation study of four representative methods of spatial normalization in handling brains with focal lesions. The following protocols will be evaluated: affine-only transformation, SPM5 Unified Segmentation approach with and without cost function masking, FNIRT

(FMRIB's Non-linear Image Registration Tool, with and without cost function masking), and SyN (Symmetric Normalization, with and without lesion masking). The selection of these four protocols was based on the popularity of the method and good performance in previous evaluation studies.

The MRI scans in the current study are to be collected from previous research studies conducted at Moss Rehabilitation Research Institute. In those studies, a high resolution structural scan was obtained on a research-dedicated 3.0 Tesla Siemens Trio scanner using a 3D MPRAGE volumetric sequence with the following parameters: TR = 1620ms, TI = 950ms, TE = 3ms, flip angle = 15°, 160 contiguous slices of 1.0 mm thickness, FOV = 192x256mm², matrix = 192x256, 1NEX, and 1mm³ isotropic voxel size.

The first step of the protocol begins with a neurologist, with extensive experience in neuroanatomy and lesion detection, supervising the principal investigator in planting the landmarks in the correct locations. For each normalization algorithm (and with and without cost function masking except for the affine-only method), a root mean square displacement (RMSD) of the distances between the 24 anatomical landmark locations (16 cortical and 8 subcortical) on the normalized individual brain and the homologous landmarks on the custom template brain will be computed in each individual. Then the individual brains' RMSD values will be subjected to a 4X2x2 repeated measures ANOVA with normalization method (Affine vs. SPM5 vs. FNIRT vs. SyN) and cost function masking (with vs. without) as within-subject factors and group (stroke vs. TBI) as a between-subject factor. Examination of main effects and subsequent post-hoc t-tests will reveal which method combination provides the most robust normalization results in presence of focal lesions. Our working hypotheses are that 1) cost function masking (or constrained cost function masking for SyN) will improve the results of normalization and 2) a large deformation method (SyN) with constrained cost function masking will outperform other protocols, yielding the least RMSD.

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Expected Research Outcomes and Benefits

This project does not directly contribute to improving the quality of health in patients with stroke or traumatic brain injury (TBI). However, it will greatly improve the quality of the research that

is needed for improving the status of their health. Specifically, this project aims to find out what type of spatial transformation/normalization protocol is better suited to provide robust results for brains with focal lesions. In fact, focal brain pathology has been one of the major challenges in neuroimaging studies of stroke and traumatic brain injury. Without a valid protocol of spatial normalization, interpretations on any group-level whole brain map may be questioned. Thus, the project information regarding which protocol yields the most robust results for brains with focal lesions will be useful for future neuroimaging studies in these populations.

Summary of Research Completed

During the reporting period, the following activities have happened.

Re-calculation of performance parameters: Root mean square error (RMSE) around the template landmark (i.e., landmark manually planted on the template) has been recalculated for the purpose of bug-fixes in the computer program.

Poster presentation: We presented our results from this project as a poster in the Research Recognition Day at Albert Einstein Healthcare Network (May 2011). The poster title was “Assessment of nonlinear spatial normalization algorithms in the presence of focal lesions: A preliminary study.” The authors are: J. Pluta, J. Kim, E. Europa, J. Whyte, B. Avants, H. B. Coslett, R. Rajan, and M. Schwartz.

Planning for the next phase: A plan for the next study was laid out, including submission of an NIH grant submission and a manuscript.

Research Project 4: Project Title and Purpose

Development of a Haptic Virtual Environment for Upper Limb Rehabilitation - The overall goal of the project is to develop a low cost virtual reality (VR) system for upper limb rehabilitation that provides both visual and haptic feedback to participants. This goal will be accomplished with three specific development aims. The first aim will be to test several system components before final acquisition. The second aim will be to construct and test the system to ensure proper functioning. The third aim will be to prepare for future use of the system by planning experiments with stroke patients and developing proposals for additional funding.

Duration of Project

1/1/2009 - 12/31/2009

Summary of Research Completed

This project ended during a prior state fiscal year. For additional information, please refer to the Commonwealth Universal Research Enhancement C.U.R.E. Annual Reports on the Department's Tobacco Settlement/Act 77 web page at <http://www.health.state.pa.us/cure>.