Albert Einstein Healthcare Network

Annual Progress Report: 2010 Formula Grant

Reporting Period

January 1, 2011 – June 30, 2011

Formula Grant Overview

The Albert Einstein Healthcare Network received $74,176 in formula funds for the grant award period January 1, 2011 through June 30, 2013. Accomplishments for the reporting period are described below.

Research Project 1: Project Title and Purpose

Goal Intention Reminding for Treatment of Post-Acute Traumatic Brain Injury - The purpose of this project is to pilot test the efficacy of a brief, innovative treatment designed to address the deficits in goal self-management and emotional regulation that are common after traumatic brain injury (TBI). The innovative treatment involves helping people with TBI to develop "implementation intentions"—if-then statements specifying when, where, and how goal-related behaviors will be carried out. The project will examine whether these implementation intentions, sent as periodic reminders to participants via Short Message Service (SMS) or voice mail messages, will help participants to meet goals related to prevention or amelioration of depression, anxiety, anger/ irritability, and/ or social isolation after discharge from an intensive outpatient therapy program.

Anticipated Duration of Project

1/1/2011 - 06/30/2013

Project Overview

Traumatic brain injury (TBI) leads to difficulties with goal-oriented behavior, including formulating goals and self-regulating behavior, emotion, and cognition in the service of goal attainment. These difficulties contribute to mood disorders, lack of productive activity, and social isolation. We propose a pilot trial of a brief, innovative treatment called Goal Intention Reminding (GI), which is based on a theoretical model of goal attainment with extensive empirical support in healthcare applications. In participants with TBI who are nearing discharge from outpatient treatment, we will examine goals related to domains that are affected by self-regulation deficits and are prone to deterioration after termination of treatment: emotional disorders (depression, anxiety, anger/ irritability) and social isolation. Participants will be randomized to GI or to a control condition, Goal Review (GR). For both groups, goals will be identified using input from participants' counselors, and prioritized in a 1:1 session with participants. For the GI group the session will proceed to development of implementation

intentions: "if-then" statements specifying how, when, and where goal-related behaviors will be initiated. The GI group will also receive periodic reminders of these intentions for 8 weeks. The GR group's 1:1 session will be confined to prioritizing and discussing the importance of their goals, and they will receive reminders about the follow-up assessments only. Outcomes measured 8 weeks after intervention will include scores on standardized scales of emotional status and social participation as well as individualized outcomes measured via Goal Attainment Scaling (GAS), which will also be administered at 4 weeks. Significant others, where available, will provide pre- and post-treatment data using some of the same measures administered to participants.

Specific Aims are: (1) To examine the effects of an intervention designed to promote goal attainment (GI) compared to goal discussion and review alone (GR), on a range of goal-relevant measures including Goal Attainment Scaling and standardized measures of emotional function and social participation; (2) To gather qualitative data on the feasibility and acceptability of the GI treatment so as to improve its content and procedures for future research; and (3) To explore relationships among treatment effects, if any, and process variables such as goal domains selected, number of implementation intentions created, number of messages received, and strength of self-rated motivation.

Principal Investigator

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Other Participating Researchers

Monica Vaccaro, MS - employed by Moss Rehabilitation Research Institute, Albert Einstein Healthcare Network

Expected Research Outcomes and Benefits

The project is expected to increase knowledge regarding the feasibility and effectiveness of a novel method for preventing or ameliorating the negative emotional and social effects of traumatic brain injury (TBI), including depression, anxiety, irritability, and social isolation. Benefits to clinicians involved in TBI care will include knowledge of a new method that may be feasible and effective to prevent or ameliorate mental health problems in people with TBI. Benefits to researchers will include increased knowledge of theoretical models and methods germane to mental health research in the TBI population, which may be refined and used in larger studies. People with TBI and their families may benefit, ultimately, from this project to the extent that it leads to new research and practice that improves mental health status following TBI.

Summary of Research Completed

This project began funding on 1/1/11; thus, this report summarizes the first 6 months of work accomplished by the Principal Investigator (PI; Hart), the Co-Investigator (Co-I; Vaccaro) and the Research Assistant (RA; Hays).

Start-Up: The project entails work on 2 different campuses, is a randomized pilot trial comparing 2 interventions, involves collaboration between research staff and clinicians on both campuses, and includes participants with varying levels of experience in key components of the intervention infrastructure (text or voice messaging). With these complexities, a number of preparatory and organizational activities were required to lay the groundwork before participants were enrolled. Accomplishments in this area included: (1) Secured all tests and instruments required to assess participants pre- and post-intervention; (2) Developed forms for all data collection not captured by standardized instruments such as measures of concurrent treatments, intervention process data; (3) Trained RA on administration and scoring of all instruments as well as informed consent procedures; (4) RA developed an Excel database to store participant data; (5) Co-I led development of a participant tracking system whereby all admissions to relevant outpatient programs are screened for eligibility and reasons for exclusion are logged; (6) PI and Co-I met with clinical staff to develop a method for obtaining detailed clinical data needed for the project using rating forms and a semi-structured interview developed for the project by the PI; (7) PI and RA purchased an inexpensive phone for participants lacking text/ voice messaging capabilities and developed instructions and a training procedure; (8) PI and RA set up and extensively tested accounts for remote text/ voice messaging using joopz.com and SlyDial; (9) PI and Co-I wrote the manuals for the Goal Attainment Scaling (GAS) procedure and both intervention arms, and developed visual aids and other materials to be used in the intervention sessions; (10) PI developed a randomization system whereby participants are randomized within 4 strata by an RA not otherwise connected to the research, so that the RA performing the assessments will remain masked to group assignment; and (11) PI drafted a Manual of Procedures and checklists to guide each step of the study procedure.

Participant Screening and Recruitment: Using the systems described above, to date we have formally screened 22 participants who have both a diagnosis of TBI and a pending discharge from comprehensive rehabilitation at one of the 2 campuses involved in the study. Eight (~30%) have been eligible and of those, 4 have been approached for consent; all 4 have consented, with 3 also having significant others (SOs) who consented to provide pre-, post- and interim data. The other 4 patients have not been approached because we are waiting for their discharge dates to be finalized. We are carefully tracking the reasons potential participants are ineligible. Of the 14 not eligible, 5 have been excluded for a history of serious mental illness (e.g., schizophrenia, bipolar disorder), 4 because their TBI was too mild and/ or insufficiently documented, 2 because they do not speak English, 1 because treating clinicians could not identify goals related to the study intervention, 1 because s/he was being discharged to another intensive treatment program, and 1 due to probable psychiatric instability/ no means of contact post discharge.

Data Collection: Baseline (pre-treatment) data have been collected on all 4 participants who have consented and enrolled in the trial. Data from these participants and the 3 SOs are complete and entered into the database.

Intervention: Intervention sessions have been conducted with 3 of the 4 participants enrolled in the trial, with the 4th participant scheduled. Of the 3 treated thus far, 2 participants have been randomized into the Goal Review (GR) condition and 1 into the Goal Intention (GI) condition. For the one participant in the GI condition, text messages containing implementation intentions have been sent and replies received every other day with no significant problems. The PI and Co-I have conducted all treatment sessions together and the sessions (including development of GAS followed by intervention) have taken the expected 2 hours, with relatively little variation in time required. From a qualitative standpoint, the sessions have gone extremely well and participant engagement/ interest has been high in both treatment conditions.

Research Project 2: Project Title and Purpose

Changes in Cardiac Anatomy and Physiology during the Mueller Maneuver - The purpose of this study is to simulate naturally occurring obstructive apneas by using the Mueller Maneuver (MM) in young healthy individuals. Doppler echocardiography will be utilized to assess right sided flows [superior vena cava (SVC), inferior vena cava (IVC), and tricuspid valve (TV)] and to measure changes in diameter of the ascending aorta at pre-specified anatomic points. This study seeks to define the direction and magnitude of changes in these parameters in normal subjects performing the MM. The knowledge gained will form a baseline data set that can be used in future studies comparing responses in patients with obstructive sleep apnea (OSA) and other cardiopulmonary diseases with the normal response.

Anticipated Duration of Project

1/1/2011 – 06/30/2013

Project Overview

OSA is an accepted cause of hypertension and has been associated with multiple cardiovascular diseases including atrial fibrillation and heart failure. It is thought to possibly contribute to aortic dissection. Little is known of what happens to the heart and aorta during an obstructive apnea. Prior work by our group used the MM to simulate an obstructive apnea. That project evaluated effects of the MM on left heart blood flow patterns and function. The current project will evaluate effects of the MM on right heart blood flow patterns and function. We will also investigate possible effects of the MM on the ascending aorta.

Specific aims:

1) Evaluate, using Doppler Echocardiography, blood flow in the SVC, IVC, and across the TV during a sustained MM. Our hypothesis is that these flows will increase during the early part of the MM, then stabilize, and possibly decrease in the face of continued negative inspiratory pressure.
2) Evaluate, using Doppler Echocardiography, blood flow in the SVC, IVC, and across the TV immediately following a series of five (5) brief MMs (more closely simulating a naturally

occurring apnea). Our hypothesis is that these flows will increase following the series of MMs.
3) Investigate the effects of the MM on the ascending aorta. Our hypothesis is that there will be a measurable increase in aortic diameter during a sustained MM.

Healthy volunteers will be recruited for this project. Standard Doppler Echocardiography examinations will be performed at baseline, during sustained MMs, and after repetitive short MMs. Doppler Echocardiography is well established for measuring the parameters noted above. A simple apparatus, consisting of a mouthpiece, filter and standard respiratory tubing will be used for the MM, with one end of the tubing occluded. An electronic pressure gauge will be attached to the apparatus to record negative inspiratory pressures (graphically). Subjects will be coached to achieve a negative pressure of at least -40 m Hg for each MM.

Principal Investigator

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Other Participating Researchers

None

Expected Research Outcomes and Benefits

Obstructive sleep apnea is a significant public health problem with prevalence rates estimated at 20% for middle-aged adults in the general population. While it has been associated with many significant cardiovascular diseases there is little information available regarding events occurring at the time of an obstructive apnea. The knowledge garnered from this project will help to understand the pathophysiology existing during such events. By better understanding the effects of obstructive apneas on cardiovascular structure and function we will gain insight into the ways in which OSA contributes to such important and common diseases as atrial fibrillation and heart failure. We also hope to observe changes in aortic diameter during the MM which might provide a link between OSA and aortic dissection. In our previous work we found an unexpected sudden decrease in left atrial size during sustained MMs. This project may also yield unexpected, thought-provoking results.

Summary of Research Completed

This project has received approval from the Albert Einstein Medical Center Institutional Review Board. Efforts to date have consisted of assembling a research team and identifying and ordering necessary equipment. A research coordinator with a strong background in clinical research has been hired and a sonographer has been identified. We have also located space in which to conduct the study. Initially, we had intended to have hospital staff perform the research

echocardiograms on hospital-owned equipment. However, we were presented with the opportunity to purchase a used Echocardiograph machine for a very reasonable price. This will allow us more control of the study, and flexibility in scheduling research subjects. Funds for this purchase were reassigned from the budget dedicated to the performance of echocardiograms. We also identified a need for a high fidelity electronic pressure gauge which has been ordered. This equipment should be delivered in a month's time. We do not anticipate any other equipment purchases except for that of a laptop computer to be used in acquisition and storage of data – that will be purchased in the next 2 weeks. Biomedical engineers have been identified who will help us assemble and maintain the equipment. We anticipate having all the equipment operational within two months and will then do "dry run" testing on a few volunteer subjects after which the study will begin in earnest. A cardiology fellow has also been assigned to help run the project.