Albert Einstein Healthcare Network

Annual Progress Report: 2010 Formula Grant

Reporting Period

July 1, 2011 – June 30, 2012

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 - 6/30/2013

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

During the past 12 months, we have completed the following research activities:

Participant Screening and Recruitment: At this time last year, we had completed start-up work which included developing the intervention; recruitment and enrollment had just begun (we had screened 22 potential participants, enrolled 4, and collected baseline data on those 4). Recruitment, intervention, and data collection have proceeded continuously during the last 12 months. Halfway through this period, we secured an IRB modification to expand the recruitment to include persons nearing discharge from outpatient brain injury treatment at either of the Moss campuses involved in the study, regardless of whether they had been receiving counseling to address goal areas addressed in the study. While this was intended to help catch up on recruitment, it also raised the possibility that participants who were otherwise eligible would not have relevant goals to address in the experimental treatment (which did happen, as explained below).

At this point, we have screened 90 potential participants. Of these, 30 have been eligible. Sixteen have not been approached because they are still involved in outpatient treatment (an impending discharge from treatment remains an inclusion criterion for the study). Of the 14 who have been approached, 2 declined and 12 provided informed consent. Two of these decided to withdraw from the study, and another two were seen for the first part of the intervention but were withdrawn because they did not have goals relevant to the study, i.e., goals to increase social activity or manage their moods. This latter circumstance is one we are working to avoid in future by making our screening more precise, i.e., by asking potential participants more about the goals they might have at the time of consent.

Altogether, we now have 8 participants who have now attended the initial goal setting session and the intervention session to which they were randomized (4 in the Goal Intention Reminding condition and 4 in the Goal Review condition), and we have collected baseline and 4-week/8-week outcome data on 7; one participant remains in progress. For 6 of these participants, a significant other (SO) has also furnished data at all 3 time points.

In recognition of the fact that our enrollment continues to lag significantly behind our volume projections at the outset of the project, we continue to document carefully the reasons that patients who are nearing discharge from our outpatient programs are being screened out as ineligible. Of the 60 not eligible, 18 have been excluded for a history of serious mental illness (e.g., schizophrenia, bipolar disorder), 18 because their TBI was too mild and/or insufficiently documented, 4 because they do not speak English, 3 because treating clinicians could not identify goals related to the study intervention, 6 because the participant was being discharged to another intensive treatment program, and 11 due to probable psychiatric instability/ no means of contact post discharge. Unfortunately, aside from expanding the recruitment pool as we have already done by dropping the requirement of having received counseling, we do not foresee that we could eliminate any of these exclusions and still adhere to the scientific goals of the project.

Other Protocol Changes: In the same modification in which we expanded the participant pool, we made another enhancement to the treatment protocol for the Goal Intention Reminding (GIR)
condition. Instead of asking participants simply to “read each SMS message 3 times,” a procedure which offers no way to verify whether or not it has been done, we are now asking them to paraphrase each message and send it back as a reply. The treatment session now includes a brief training and practice on “paraphrasing” the messages. This procedure has worked well from participants’ point of view and we are permanently storing the replies so as to be able to verify their accuracy.

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.

Web Application Development: This project entails sending SMS messages to participants randomized to the GIR condition daily for 8 weeks. We have been unable to find a free or low-cost web application that allows SMS messages to be sent at a pre-set schedule and allows replies to be received. The website used for the first participant, www.joopz.com, offered both of these features but proved to be unreliable. We then started using Google Chat, which allows web-based sending and receiving of SMS, but only in real time. That is, every message had to be sent to participants anew on each day for all 8 weeks, at the actual time agreed on in the intervention session. To alleviate the extreme labor intensity of this process not only for this study but also for future work, we contracted with a software engineer who also has a doctoral degree in cognitive psychology (George Collier, PhD) to produce a simple but secure web application, called MossGoal, that allows a registered user to enter implementation intentions, schedule their delivery at pre-set times to each participant, and store date-stamped replies in full text. MossGoal is complete as of May, 2012 (mossgoal.herokuapp.com) and is ready to use with the next participant randomized to the GIR condition.

Findings to Date: Since the study is in progress and the participant numbers are small, we do not have quantitative findings to report. However, we are encouraged by qualitative results gained in the “debriefings” conducted with each participant after their final data collection. All 4 participants in the GIR condition have persisted with reading and replaying the messages and have reported positive aspects of doing so. Three of the 4 said that they thought being reminded of their intentions had contributed to changes in their behavior over the 8 weeks. For example, one participant reported that she was going to the gym and socializing with neighbors much more often than before (both activities targeted in her implementation intentions). Another, whose implementation intentions had revolved around management of her irritability, said that she had gone from fighting with her sister numerous times per week to having one fight in a month’s time. A third said he had better remembered to follow through with his intention to “hold his tongue” rather than say things that might make new acquaintances feel uncomfortable. The only 1 of the 4 who reported no direct behavior change said that she “thought about” her intentions to interact more with people as the result of receiving the messages and that she considered that to be positive, but was unsure as to whether she had followed through behaviorally or not. None of the 4 reported serious negative reactions to receiving the messages, although 2 mentioned that it got repetitive to see the same messages multiple times and 1 reported having a hard time keeping up with the needed replies. Although these results are qualitative as well as preliminary, we interpret them to indicate at least that this type of intervention is feasible for people with significant cognitive, affective and behavioral limitations following TBI.
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 – 6/30/2013

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 is in progress and actively enrolling. Since the last progress report, we have acquired the following equipment for performance of the study:

1. Philips Sonos 5500 echocardiograph and S4 transthoracic transducer probe
2. HP Pavilion dv6-6150 laptop computer
3. Omega Engineering PX409 USB electronic pressure transducer
4. MD100B handheld ECG monitor (Beijing Chinese Electronic Technology)

A reliable and competent research team has been assembled consisting of an attending cardiologist, 2 cardiology fellows, 2 medical residents, and a biomedical engineer. “Dry run” testing was carried out on 5 subjects and the study was formally begun. Recruitment was initially spotty. To increase numbers we received IRB approval to reimburse subjects $25 (from study funds) to cover their time and trouble. Since that time we have been able to recruit more easily and are studying one subject/week with the exception of holiday weeks. To date we have enrolled 31 subjects. The study protocol has been “fine tuned” to obtain maximal high quality information. Currently, each study requires 90 minutes of subject time. Given the nature of the study, acquiring study quality echocardiographic images is challenging. Of the subjects enrolled,
all have at least some usable data and approximately 15 have complete or near complete data. We have IRB approval to study up to 50 subjects and will continue to enroll until we have at least 25 subjects with complete data.

Specific variables being looked at:

1. Changes in diameter and cross sectional area of the ascending aorta during a sustained Mueller maneuver (forced inspiration against an occluded airway). Measurements are made in systole and diastole for each cardiac cycle in which echocardiographic images are of suitable quality. These measurements are then compared to similar measurements made under resting conditions.

2. Changes in right and left atrial area (in the apical 4 chamber view) at end systole and end diastole during a series of gasping efforts against an occluded airway (more closely simulating a true obstructive apnea). These are also being compared with measurements made under resting conditions.

3. Changes in right ventricular area (apical 4 chamber view) at end systole and end diastole during a series of gasping efforts (as above); in addition we are looking at fractional area change of the right ventricle as the difference between the diastolic and systolic areas.

4. Changes in TAPSE (tricuspid annular plane systolic excursion - a measure of right ventricular contractility) during a series of gasping efforts, again comparing with baseline.

5. Changes in E wave and A wave velocity across the tricuspid valve during a series of gasping efforts, comparing with baseline. E and A velocity are related to the pressure gradient across the valve, flow across the valve, and compliance of the receiving ventricle.

6. Changes in E wave and A wave velocity across the mitral valve during a series of gasping efforts, comparing with baseline.

7. All parameters above will also be evaluated in the immediate period following the series of gasping efforts.

To date, we don’t have enough measurements made to start drawing any conclusions. However, observation suggests that there is a reciprocal relationship between right and left atrial size during performance of the series of gasping efforts. In addition there may be increased variation (and oscillation) in the E and A wave velocities during the series of gasping efforts and perhaps afterwards.

Echocardiographic measurements are time consuming (approximately 3 hours per subject). These are being made by 2 blinded experienced echocardiographers.