Albert Einstein Healthcare Network

Annual Progress Report: 2010 Formula Grant

Reporting Period

July 1, 2012 – June 30, 2013

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.

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

Tessa Hart, PhD
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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 8 participants who had 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). The 8th participant had been consented on 6/15/12 and that person’s intervention/ data collection was in progress. During the past year, we completed the protocol for this 8th participant (on 8/10/12). All 8 participants supplied complete data in baseline, 4-week, and 8-week evaluations and all complied with assigned treatment protocols. In consideration of the major difficulties encountered in recruitment that have been documented in previous reports, and the dwindling resources available to continue the project, we decided to devote remaining resources to examining the data for these participants. The primary purpose was to determine any trends that would motivate further study and to compile preliminary data to support an extramural grant application (described below). Considering the small sample, only 8-week data, and only self-report (P) data, were examined in comparison to baseline data to explore treatment effects.

Results of Data Analyses:

Participant characteristics. Data were analyzed for 8 participants, 4 female and 4 male. Five were white, 2 African-American, and 1 Hispanic. Participants ranged from 19 to 42 years of age and all but 1 (who lived alone) resided with his/ her parents. Six participants had relatives contribute data about them (“significant other” or SO ratings), for comparison to participant (P) self-ratings, at baseline, 4 weeks, and 8 weeks. Participants’ years of education ranged from 8 to 15; 6 of the 8 were high school graduates. Their self-reported occupational status was: 2 competitive workers, 2 volunteer workers, 2 retired due to disability, 1 homemaker, and 1 part-time student. All participants had sustained severe TBI as reflected in duration of PTA >10 days; PTA was longer than 30 days for 5 participants. Six had been injured in a motor vehicle incident, 1 by assault, and 1 in a fall. They were enrolled between 9 months and 7 years post injury (mean, 3 yr).

GAS scores. By definition, all Ps rated themselves at -1 on the baseline GAS. Change scores (GAS at week 8 – baseline GAS) were used to examine group differences. Change scores for each treatment condition are summarized in Table 1; positive scores reflect positive change across the 8 weeks of treatment. It may be seen that all participants rated themselves as having stayed the same (change score of 0) or improved on their personalized goals. There was no significant difference between treatment groups for the GAS change scores using non-parametric t-test (Mann-Whitney U).

Societal participation. On the PART-O, which measures extent of societal participation, 2 subscales showed a significantly larger positive change in the GIR group compared to the GR group: Social Interaction and Community Activity. The 3rd subscale, Productivity, showed no significant group differences (all values shown in Table 1). Notably, the GI intervention was targeted mainly to social and community activity, and not to activities related to productivity (e.g., paid or volunteer work). Thus, it is possible that differential activity levels prompted by the GI treatment accounted for these differences, even though they were not detected by the GAS.
Emotional function. Neither the GSI (general severity index of the BSI) nor the Anger Expression Index of the STAXI-2 showed differential improvement by treatment group (Table 1).

Dissemination of Findings: The PI organized a Symposium on the use of the GAS method to measure individualized goals in rehabilitation research, in which the design and findings of the funded study were presented to a sizable audience at the Annual Meeting of the American Congress of Rehabilitation Medicine. Two other researchers who are using the GAS, including one from New Zealand, were invited to participate as symposium speakers. Full reference: Hart T, Sander A, McPherson K. Goal Attainment Scaling as assessment and treatment: Concepts and applications for brain injury rehabilitation. Symposium presented at Joint Conference of the American Congress of Physical Medicine and Rehabilitation and the American Society of Neurorehabilitation, Vancouver, October, 2012.

Application for Extramural Funding: The PI submitted an extramural grant application in 8/12 which relied heavily on the preliminary data from the funded project, including qualitative and quantitative findings from participants, and the “MossGoal” web application. This application was approved for funding, which began 10/1/12. Full reference: National Institute on Disability and Rehabilitation Research, #H133A120037, Hart (PI), 2012-2017, “Moss Traumatic Brain Injury Model System.” The specific sub-project that was funded to continue the work started under the current grant, is entitled Use of SMS Messaging to Promote Emotional Health for People With Traumatic Brain Injury: A Randomized Controlled Trial. This project will run for the full 5 years of the grant cycle and will extend the methodology developed in the current grant to examine the effects of a novel SMS-based treatment for depression and anxiety following TBI.

Table 1. Change scores (mean, range) for P and SO ratings from baseline to 8-week evaluation, by treatment group. Positive scores indicate improvement in a given domain. NS = not significant. *denotes measure that was statistically significant between groups.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Goal Intention Reminding (n = 4)</th>
<th>Goal Review (n = 4)</th>
<th>Group Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal Attainment Scaling</td>
<td>1.25 (0-2)</td>
<td>1.5 (0-3)</td>
<td>p = .76 (NS)</td>
</tr>
<tr>
<td>Social Interaction*</td>
<td>0.21 (-.14 - .57)</td>
<td>-.57 (-.86 - -.15)</td>
<td>p = .02</td>
</tr>
<tr>
<td>Community Activity*</td>
<td>0.19 (-.39 - .57)</td>
<td>-.70 (-1.0 - -.50)</td>
<td>p = .02</td>
</tr>
<tr>
<td>Productivity</td>
<td>-.17 (-1.0 – 1.0)</td>
<td>-.16 (-1.33 - .34)</td>
<td>p = .88 (NS)</td>
</tr>
<tr>
<td>BSI (Emotional Status)</td>
<td>-1.0 (-9 – 11.0)</td>
<td>1.5 (-1.0 – 7.0)</td>
<td>p = .77 (NS)</td>
</tr>
<tr>
<td>AX Index (Anger Expression)</td>
<td>7.0 (2.0 – 12.0)</td>
<td>1.0 (-6.0 – 8.0)</td>
<td>p = .24 (NS)</td>
</tr>
</tbody>
</table>
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.

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 OSA size during sustained MMs. This project may also yield unexpected, thought-provoking results.

Summary of Research Completed

During this reporting period 11 additional subjects have been enrolled for a total of 42 subjects. All were healthy volunteers aged < 30 years. Data collection was completed as of June 30, 2013.

Aortic Area Measurement Subgroup
Since the last progress report, 3D aortic images during performance of the Mueller Maneuver (MM) were collected on a subset of 22 subjects; 10 had images suitable for measurement and 6 of these reached a negative intrathoracic pressure of at least -30 cm H₂O. Blinded measurements of aortic cross-sectional area in diastole confirmed our hypothesis that this increases with performance of the MM. These results were presented as an abstract at the American Society of Echocardiography convention in Minneapolis June, 2013.

Doppler Echocardiographic Measurements
Doppler echocardiographic measurements are available for all 42 subjects. Analysis is ongoing looking at:

1. Changes in peak velocity of blood flow across the mitral and tricuspid valves before, during and after a series of gasping efforts against a closed airway (modified MM).
2. Changes in atrial dimensions and function (right- and left-sided) before, during, and after the modified MM.
3. Changes in ventricular dimensions and function (right- and left-sided) before, during, and after the modified MM.