

Feasibility and Effectiveness of the GLB-AIM (Group Lifestyle Balance Adapted for Individuals With Impaired Mobility) Intervention for People Living with Spinal Cord Injury.

Purpose: The prevalence of obesity in the population living with spinal cord injury (SCI) is greater than the general population. Obesity linked coronary heart disease is a leading cause of morbidity and mortality in the population living with SCI. Behavioral interventions to promote weight loss are limited for the SCI population. GLB-AIM looks to address the lack of behavioral interventions by providing a feasible and effective program to promote weight loss for people living with SCI.

Methods: The GLB-AIM was delivered to participants over the course of 12 months. The sample was assessed for feasibility as measured by attendance over 12-month program and compliance with dietary self-monitoring for the first 13 weeks. Effectiveness was evaluated by measuring weight change over 12 months. The data were analyzed using a mixed models analysis controlling for time living with injury, group assignment, and starting weight.

Results: The 12-month retention rate was 62.5% (20/32), Session attendance for the core sessions averaged 74.6% and dropped to 48.9% during the support sessions. Dietary self-monitoring for group 1 averaged 33% over the first 13 sessions and increased to 77% among group 2. Analysis of the combined SCI groups indicated significant weight loss ($p = 0.017$) that averaged 5.03 ± 8.58 kg over the 12-month program.

Discussion: The GLB-AIM was a feasible and effective approach for promoting weight loss over 12 months for a sample with SCI. Additional adaptations may increase attendance during the subsequent support sessions and reduce program attrition by addressing barriers related to health events and transportation issues. The GLB-AIM program promoted weight loss in people living with SCI, which highlights the program's effectiveness. Future adaptations of the GLB-AIM should seek to enhance weight loss through increased weight feedback and the providing individualized calorie targets.

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for Individuals with Impaired Mobility) Intervention for People Living with Spinal
Cord Injury

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CHAPTER I

Introduction

In the U.S. 17,000 new cases of spinal cord injury (SCI) occur each year, with an estimated prevalence of 282,000. Advances in rehabilitative medicine have increased the ages of individuals living with SCI. As a result, individuals living with SCI begin to develop chronic conditions similar to that of the general population. Obesity is a modifiable factor that is correlated to the development of coronary heart disease (CHD), a leading cause of morbidity and mortality for individuals living with SCI. The prevalence of obesity in the population living with SCI is greater than the general population. Contributing to this disparity is a lack of adapted weight loss and exercise programs adapted to the specific needs of someone living with SCI.

Group Life Style Balance Adapted for Impaired Mobility (GLB-AIM) is a program designed to promote behavioral changes in dietary intake and physical activity to promote weight loss in individuals with impaired mobility. Over the previous 2 years GLB-AIM was used as an intervention in a sample of 67 participants with impaired mobility. The collected sample data was analyzed to determine the feasibility and effectiveness of GLB-AIM among a subset of 32 participants with spinal cord injury. The goal of the research project was to analyze previously collected data from the GLB-AIM project and evaluate the feasibility and effectiveness of the GLB-AIM among the SCI sample.

CHAPTER II

Background

In the U.S., 17,000 new cases of spinal cord injury occur each year, with an estimated total of 282,000 cases in the U.S. (1). Advances in rehabilitative medicine have increased the life expectancy of individuals living with chronic SCI (2). As a result of the increased survivability, people with SCI have become susceptible to chronic conditions that affect the population without disabilities (3-5). Evidence shows that SCI increases risk for insulin resistance, glucose intolerance and abnormal lipid profiles when compared to non-disabled counterparts (6, 7). The increased risk associated with these physiologic measurements has been linked to elevated incidence of cardiovascular disease (6). Coronary heart disease (CHD) is a leading cause of morbidity and mortality in the population of people with SCI (5,8) with an established link between obesity and the development of CHD (9).

Previous studies have shown that there is a higher prevalence of obesity among individuals with disabilities when compared to non-disabled individuals (3, 10). The prevalence of obesity in the population of people with SCI ranges from 40-70% (11-13). It is believed that these values underestimate the true prevalence of obesity in the population due to unadjusted body mass index obesity cutoffs used to classify BMI in people with SCI (6, 7). Muscle atrophy that occurs after the acute phase decreases the basal metabolic rate, and overall energy requirements in individuals with SCI (14). In addition to decreased energy requirements, SCI promotes a relatively sedentary lifestyle. As a result, an individual's energy intake often exceeds their daily energy requirements, predisposing people with SCI to weight gain, much of which accumulates in the abdominal area (7, 15, 16). When compared to a population without a disability it is found that individuals with SCI are at a greater risk for developing chronic illness

linked to obesity (3). This highlights the greater impact obesity has in the population of people with SCI when compared to the general population (17). With increased weight, individuals with SCI have increased pressure placed on their joints, exacerbated during movement transfers and are at risk of developing deep tissue injury (18).

There are a lack of weight loss intervention programs that address the unique issues that face those living with mobility impairment (15, 19), and non-adapted exercise is not accessible as most activities rely on leg use (20). Two previous studies observed that planned behavioral interventions can promote weight loss in individuals living with SCI over 12 weeks (21, 22). The two studies provide promising results; however, in order for weight loss and healthy behavior to confer long-term changes, weight loss programs should be observed over a longer time period.

There is a push to adapt evidence-based programs developed for those in the general population to address issues facing people living with a mobility impairment. The Diabetes Prevention Program Group Lifestyle Balance (DPP-GLB) is a direct adaptation of the Diabetes Prevention Program (DPP) (23). This program was designed to be delivered by trained coaches for groups rather than one-on-one as a method to educate participants to make behavioral changes associated with dietary intake and physical activity. The DPP-GLB consisted of 12 weekly sessions, which transition to 4 biweekly sessions, and followed by 6 months of monthly follow up sessions. The DPP-GLB has effectively resulted in lowering weight and increasing physical activity across multiple community settings (24), teaching people to limit caloric intake and increase physical activity. Due to the success of the DPP-GLB program, the GLB-AIM was adapted for individuals with impaired mobility.

In a current study awaiting publication, the Group Lifestyle Balance Adapted for Impaired Mobility (GLB-AIM) was developed with the goal of appropriating the key

components of the DPP-GLB into a program that would serve as a feasible and effective intervention in participants with impaired mobility. The GLB-AIM team worked with the original DPP-GLB developers to ensure that the key components of the existing protocol were included in the GLB-AIM as they worked with a national advisory board to assure the adaptations addressed the needs of people with mobility impairments. Modifications were made to the required weekly physical activity section. The chapter was re-written and incorporated a myriad of feasible activities that were accessible to those unable to walk or unlikely to walk for exercise. Due to transportation issues, sessions were planned to be completed by phone, or teleconference as opposed to in person. Physical activity education sessions were adapted for people living with a mobility impairment, and an additional session was added to the core program to address kitchen accessibility in the GLB-AIM.

As stated previously, obesity in individuals with impaired mobility, specifically SCI, are at an increased risk of developing chronic secondary health outcomes (3, 6, 8, 10). This highlights the importance of addressing weight for individuals with SCI through behavioral interventions that promote weight loss through changes in diet and physical activity. The goal of the study is to evaluate the feasibility and effectiveness of the GLB-AIM program specifically within subjects living with SCI.

Specific Aims

The goal of the project is to determine if the GLB-AIM is a feasible and effective intervention to deliver to people with SCI. The feasibility of the GLB-AIM program for delivery to individuals with SCI to promote behavioral change will be determined by measuring session attendance and dietary self-monitoring. The effectiveness of the GLB-AIM will be measured by examining weight loss over the 12-month program.

Significance

It is important to address ways to achieve weight loss for people living with SCI given the link between obesity and chronic illness that include CHD and type II diabetes (9). There are a lack of adaptive interventions for those living with SCI. This study represents one of the largest SCI samples studied to date and tracks those with SCI for longer periods than other published studies, which typically last 3 months (19, 21). Results from these analyses can inform how effective adaptations specifically made to address the unique needs of those with SCI are in producing behavioral change and can also inform future weight loss program for people living with SCI.

Research Design and Methods

a) GLB-AIM Intervention

GLB-AIM encouraged participants to adopt a moderate calorie, moderate fat diet, and to progressively increase exercise to meet American College of Sports Medicine and American Heart Association recommendations of 150 minutes per week (25). The program teaches skills that include self-monitoring, problem solving, assertiveness, and stress management. Participants were asked to self-monitor their fat and caloric intake over the first 13 weeks. The GLB-AIM consisted of 13 weekly core sessions, followed by 3 biweekly support sessions, and 6 monthly support sessions. Participants were given the opportunity to attend one in person session per month. Due to transportation limitations, remote sessions were delivered by telephone, conference call, or live audio streaming.

b) Data Collection

The study was designed as randomized control trial and divided into an intervention group (Group 1) and a 6 month wait list control group (Group 2). Data were collected at baseline, 3 months, 6 months, and 12 months for Group 1. Group 2 remained in the study 6 months longer, and therefore had measurements collected at Baseline, 3 months, 6 months, 9 months, 12 months, and 18 months. Data from Group 1 collected from baseline to 12 months will be combined with the data collected from Group 2 collected from 6 months to 18 months, which represents the 12-month timeframe during which each group received the intervention.

c) Outcomes

Study outcomes included physiologic variables. The physiologic variables collected included non-invasive measures of weight, and invasive measurements including waist circumference, blood pressure, and blood draws to determine blood cholesterol, and hemoglobin A1c.

Physiologic Variables

Non-invasive measures were recorded at three month intervals from baseline to 12 months. All participants were weighed using a Seca platform scale (model #672) at every assessment period. Weight for wheelchair users was taken by measuring the total weight of the person in their wheelchair using an accessible platform scale. To obtain each person's weight, the person was first weighed in their chair and then the person transferred out of their wheelchair so that their chair could be weighed separately. The person's body weight was derived by subtracting the wheelchair weight from the total weight. Due to measurement variability, the person and chair were weighed twice and the average was recorded. If the two weights differed by more than 1 kg, a third measurement was taken and all three weights were averaged together.

Invasive measures were recorded at six-month intervals beginning at baseline. Study staff measured participant blood pressure using an automatic cuff Omron 7 Series wrist blood pressure monitor. Waist circumference was measured at the umbilicus with the individual in the supine position. 10 ml of the subject's blood was drawn by a phlebotomist. Hemoglobin A1c was used to observe changes in the subjects glycemic status and total cholesterol.

d) Participants

Study participants were recruited from two physical medicine and rehabilitation departments in the DFW metro area, UT Southwestern and Baylor Institute for Rehabilitation (BIR) outpatient clinics. Recruitment included disseminating fliers to several other organizations that regularly have contact with individuals living with mobility impairment. This included independent living centers, durable medical equipment centers, and additional study advertisement through community organizations.

Inclusion Criteria: Criteria for inclusion include being over 18 years of age, having a SCI for at least 1 year, being overweight as evidenced by an adjusted BMI equivalent value recommended for spinal cord injury, having sufficient upper arm mobility to engage in exercise, have access to a telephone, and able to obtain signed clearance to participate in the GLB-AIM intervention.

Exclusion Criteria: Participants were excluded if the individual had a cognitive impairment that limited their autonomy, medical issues where exercise is contraindicated, over the age of 75, pregnant, or not fluent in the English language.

e) Data Analysis

Feasibility and engagement of the GLB-AIM in the SCI sample were assessed by analyzing subject session attendance over the 12 month GLB-AIM program, and self-monitoring over the first 13 core GLB-AIM sessions. Program effectiveness will be determined by analyzing the SCI sample weight loss using mixed modeling for repeated measures to estimate change from baseline to 3, 6, and 12 months. Models controlled for time with disability, age of disability onset, baseline weight, and group designation.

Results

Demographics

The average age of the 32 GLB-AIM participants living with SCI was 47.70 years old (SD = 11.3). The sample was predominantly Non-Hispanic white (80%), had attended at least some college (78.1%), and unemployed (65.6%). There were an equal number of males (n = 16) and females. Randomization yielded similar groups based on demographics with two exceptions. Those randomized into Group 1 (n=14) lived significantly fewer years with disability (9.9 ± 9.2 vs. 20.2 ± 12.8 years, $p < 0.05$), and had significantly fewer Paraplegia diagnosis (28.6% vs. 77.8%, $\chi^2 < 0.01$). Baseline physiologic measurements for the intervention and control were not significantly different (Table 1).

Table 1. GLB AIM SCI demographic data

Variables	Intervention/ Group 1 (n=14)		Wait-List Control/ Group 2 (n=18)		<i>p</i> value	Full sample (n=32)	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		<i>M</i>	<i>SD</i>
Age in years	44.7	12.5	50.0	10.1	0.198	47.7	11.3
Years live with disability	9.9	9.2	20.0	12.8	0.018 *	15.6	12.3
Age at disability onset	34.9	15.1	30.0	13.4	0.340	32.1	14.1
	<i>N</i>	%	<i>N</i>	%	χ^2	<i>N</i>	%
Paraplegia	4	28.6	14	77.8	0.007 **	18	56.3
Tetraplegia	10	71.4	4	22.2		14	43.8
Male Gender	8	57.1	8	44.4	0.722	16	50.0
Race/Ethnicity							
<i>White</i>	11	78.6	14	77.8	0.596	24	80.0
<i>Black</i>	1	7.1	3	16.7		4	13.3
<i>Other</i>	2	14.3	1	5.6		2	7.7
<i>Hispanic</i>	1	9.1	1	6.7		2	7.7
Marital Status							
<i>Single/Separated/Divorced</i>	7	50.0	7	41.2	0.886	14	45.2
<i>Married or living w partner</i>	7	50.0	10	58.8		17	54.8
Education							
<i>>= High school</i>	4	28.6	3	16.7	0.467	7	21.9
<i>Some college or greater</i>	10	71.4	15	83.3		25	78.1
Employment (full/part-time)	5	35.7	6	33.3	0.623	11	34.4
Self-reported Health Issues							
<i>Diagnosed with diabetes</i>	3	23.1	0	0.0	0.064	3	9.7
<i>Blood pressure medication</i>	3	21.4	4	22.2	0.649	7	21.9
<i>Cholesterol medication</i>	2	16.7	4	23.5	0.513	6	20.7
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>p</i> value	<i>M</i>	<i>SD</i>
Secondary conditions in past year (#)	0.60	0.35	0.63	0.42	0.842	0.67	0.38
Body Mass Index (BMI)	32.8	6.8	33.0	7.2	0.919	32.9	6.9
Body weight (kg)	106.3	21.4	95.7	26.6	0.234	100.3	24.7
Average waist circumference (cm)	114.8	15.5	114.3	18.5	0.940	114.6	17

* $p < 0.05$, ** $p < 0.01$

Feasibility

The 12-month retention rate was 62.5% (20/32), 21.9% formally withdrew and health problems prevented 15.6% from returning for the 12 month follow up. Attrition was higher in Group 2 (8/18, 44.4%) than Group 1 (4/14, 28.6%) and reasons for withdraw are displayed in Figure 1. Figure 2 depicts engagement as average weekly attendance over the 12-month program and average self-monitoring for the first 13 weeks. Group 1 and Group 2 attendance data was aggregated for both groups. Group 2 had more than twice the self-monitoring rate of Group 1 and therefore those results are displayed separately. Over the 13 weekly core session, attendance

for the individuals that completed the study averaged 74.6%. Attendance dropped to 48.9% during the support sessions. Dietary self-monitoring for Group 1 averaged 33% over the first 13 sessions and increased to 77% among group 2.

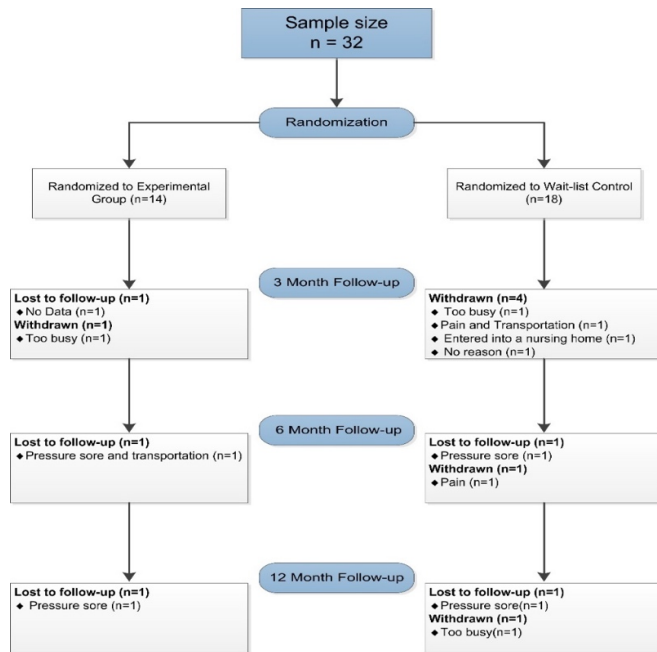


Figure1. Consort Diagram of Sample. This is a consort diagram depicting the original sample size, the stage of the trial where subjects withdrew or were lost to follow-up, and the reasons for leaving the study. A total of six subjects left the study after three months, three left after six months, and five left after 12 months. A final sample size of 20 participants remained through the duration of the trial.

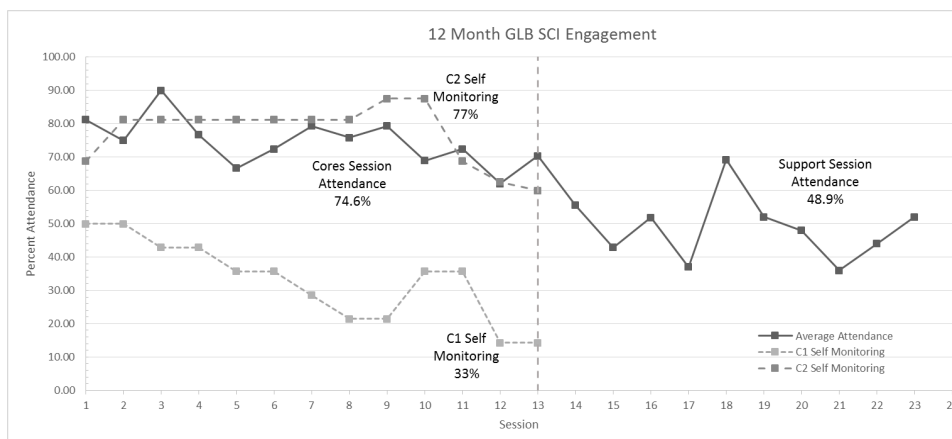


Figure2. GLB-AIM SCI Engagement. Session attendance over the core sessions averaged 74.6% and dropped to 48.9% during the support sessions. Self-monitoring compliance for group 1 averaged 33% over the first 13 weeks. This increased to 77% for group 2 during the same time period.

Effectiveness

Analysis of the combined SCI groups indicated significant weight loss ($p = 0.017$) that averaged 5.03 ± 8.58 kg lost by the 20 participants who returned for 12-month testing (Table 2). Of the 20 participants who returned for 12-month testing, 70% lost weight. Percent weight change from baseline to 3 months ($n = 23$) was $-2.2\% \pm 4.24\%$. Percent change from 3 to 6 months ($n = 21$) was $-1.31\% \pm 3.49$. Percent change from 6 to 12 months averaged $-0.28\% \pm 2.64$. Percent change from baseline to 12 months averaged $-4.14\% \pm 6.53$ ($p = 0.011$). Over the 12 month GLB-AIM program, waist circumference, blood pressure, cholesterol, and hemoglobin A1c did not significantly differ from baseline to 12 months.

Table 2. Physiologic outcomes over 12 months

Physiologic Outcomes #	SCI Sample (n=32)												Mixed modeling results			
	baseline			3 month			6 month			12 month			0 to 12 month change			Time effect <i>p</i>
	n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	
Completer Weight (kg)*	20	106.84	26.61	18	103.80	24.88	19	101.81	24.53	20	101.81	22.96	20	-5.03	8.58	0.017
% weight change**	--	--	--	23	-2.20	4.24	21	-1.31	3.49	19	-0.28	2.64	20	-4.14	6.53	0.011
Full Sample Weight (kg)	31	101.85	24.69	23	99.31	24.19	22	99.94	23.44	20	101.81	22.96	--	--	--	--
Waist circumference (inch)	31	45.53	6.69	--	--	--	23	46.09	6.57	20	46.26	6.71	20	-0.93	2.40	0.195
Systolic BP (mmHg)	28	120.12	18.65	--	--	--	20	119.28	20.32	19	126.45	22.82	19	1.56	15.04	0.468
Diastolic BP (mmHg)	28	72.43	12.64	--	--	--	20	72.73	14.84	19	74.05	15.81	19	0.03	10.98	0.808
Cholesterol	30	179.83	37.45	--	--	--	21	178.62	38.22	20	191.05	37.13	19	3.00	24.16	0.523
Hemoglobin A1c	29	5.41	0.82	--	--	--	21	5.67	1.65	20	5.52	0.73	19	-0.03	0.40	0.916

The models control for time with disability, age of disability onset, baseline weight, and group.

* Completer indicates participants that had recorded data for baseline and 12 month time periods

-- Mixed modeling for repeated measures was not conducted for percent weight change because this variable represents changes over a defined period of time rather than values measured at a particular time point; 0 to 12 month change would be duplicate of "Completer Weight"; Systolic/Diastolic BP, cholesterol, and A1c data was not collected at the 3 month time point

bold numbers = *p* value at < 0.05

** 3 month = % change 0 - 3 months, 6 month = % change 3 - 6 months, 12 month = % change 6 - 12 months

Discussion

The results from the GLB-AIM suggest that the program is both a feasible and effective program to promote weight loss for those living with SCI. Over the 12-month period, program attendance was highest in the core sessions and dropped during the support sessions. Self-monitoring adherence differed by group. Group 1 who predominantly used the paper trackers demonstrated low adherence while Group 2 who predominantly used the app had much higher rates. The GLB AIM program yielded an average 4.7% weight loss over 12 months by those who remained in the program with the largest weight change occurring over the initial 13 cores sessions.

The drop in attendance from core sessions to the subsequent support sessions may be attributed to barriers experienced by people living with SCI. Most support sessions were held as in person sessions, which required study participants to secure transportation to attend. Participants were given the opportunity to call in to these in-person sessions or make them up by phone call the following week, and many did take advantage of these methods to attend. Anecdotal evidence suggests that both transportation barriers and health problems that included pressure sores prevented a number of people from participating in later sessions. The incidence of various health problems and work barriers may have contributed to decreased program commitment over the year.

Further discussion of self-monitoring adherence is warranted, given that it is a core feature of the GLB-AIM program. Instructions given to Group 1 followed the typical DPP GLB approach of providing paper trackers and logs, and adherence data indicated the Group had low adherence. The effort involved in using the calorie guide to track food intake in writing on paper required substantial physical manipulation and time for participants to look up caloric values for

every food they ate and write the values in their notebook. For participants living with SCI with varying levels of impairment, completing this task may increase in difficulty based on participant's finger function. The team discussed these issues and decided to implement a further adaptation in response to low self-monitoring adherence. Thus, providing formal instruction and teaching of Group 2 participants to use a specific app for dietary intake monitor. This change led to more than two times higher adherence for dietary self-monitoring, a finding that suggests self-monitoring using an app may be more feasible for those with SCI. App monitoring takes less time and is more easily performed by those with limited finger function. The app can scan barcodes, populate caloric values of food items, and maintain a running count of calories consumed. Self-monitoring is integral for achieving weight loss²⁹ and future adaptations of the GLB-AIM should implement the use of app tracking to facilitate dietary self-monitoring.

Over the span of the program, 12 people left the study for different reasons. Participants experienced pressure sores, transportation limitations, and time commitment constraints that prevented their ability to complete the program. Previous studies reported lower attrition (19% and 23%), however it should be noted that those studies followed participants for a maximum of 12 weeks (11, 12). The GLB-AIM participants were tracked over a year. The additional complications that people with SCI experience including increased rates of hospitalizations compared to the general population (26), and transportation problems(27) appear to affect people's ability to participate in a health promotion program. People living with SCI for years still encounter secondary health complications that include pressure sores, genitourinary, or respiratory complications (26, 28, 29). While these secondary health complications are preventable, those living with SCI live with a narrow margin of health error (International Perspectives on Spinal Cord Injury, WHO). Physiologic changes as the individual ages (thinning

of the skin due to loss of collagen and elastin and reduced strength) may result in higher risk for developing pressure sores (30). Regular catheter use to urinate can introduce bacteria to the urinary tract resulting in a UTI (31). Caregiver turnover and training may increase risk for health problems (e.g., falls, infections, etc.). While in a given 12-month window, a person may not experience a major health event such as pressure sore, kidney infection, or hospitalization, it is likely that at least some individuals participating in a behavioral program such as the GLB-AIM will encounter health issues due to their increased risk for secondary conditions. Thus, it is important to consider how programs can help individuals remain motivated and progress on their health promotion journey while simultaneously following medical advice to manage their health problem. To improve retention, future GLB-AIM adaptations for an SCI sample should address strategies for promoting program engagement during hospitalizations and recovery periods. Option could include promoting healthy choices when ordering from the hospital menu, and to minimize physical deconditioning by implementing hospital adapted exercises for people with pressure sores or UTIs, and addressing how to safely resume physical activity after hospitalization.

A common self-management strategy taught in weight loss studies for those in the general population is weekly or more frequent weighing (32). Ambulatory individuals can purchase low cost scale for home use. However, those with more severe mobility impairment such as SCI require accessible scales that have a platform, which are prohibitively expensive for home use and not generally available in most primary care offices (33). Accessible scales provide real time feedback on progress or lack of progress when attempting to attain weight loss. The potential reinforcement provided by routine weighing is limited in the population living with SCI, because access to wheelchair accessible scales is limited. Primary care offices often do not

have wheelchair accessible scales (33). Implementing a strategy to promote routine weighing may provide feedback that promotes enhanced weight loss during the GLB-AIM.

Individualized caloric targets could be implemented in future adaptations of the GLB-AIM to further enhance weight loss. Previous research suggests that the resting metabolic rate (RMR) for individuals with SCI is highly variable (34). The variability of the RMR measurement highlights a need to calculate individualized caloric targets for future adaptations of the GLB-AIM. An individualized caloric target may help promote enhanced weight gain by preventing caloric consumption that exceeds their daily metabolic requirements.

Conclusion

The GLB-AIM was a feasible and effective approach for promoting weight loss over 12 months for a sample with SCI. The GLB-AIM had over 70% session attendance and after a responsive adaptation was made promoting the use of an app to track dietary intake, self-monitoring compliance was above 70%. Additional adaptations may increase attendance during the subsequent support sessions and reduce program attrition by addressing barriers related to health events and transportation issues. The GLB-AIM program promoted weight loss in people living with SCI which highlights the program's effectiveness. Future adaptations of the GLB-AIM should seek to enhance weight loss through increased weight feedback and by providing individualized caloric targets.

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CHAPTER III

Internship Experience

I worked at the Baylor Institute for Rehabilitation (BIR) research department from June to November of 2017. While at BIR I was involved in a variety of projects that assisted the staff with work. Each of these projects gave me unique insight into the role of a clinical researcher in a hospital. While at BIR outside of my project for my internship practicum, I worked on the Health Literacy Project, Traumatic Brain Injury (TBI) quality improvement project, Workout on Wheels Internet Intervention (WOWii), and the TBI access to health care project.

The Health Literacy project goal is to assess BIR patient's health literacy, with an aim to highlight the communication deficiencies between health care professionals and their patients. As a student I became familiar with the project through data entry. I later began making phone calls to complete the 2 week and 3-month post follow up questionnaires with the participants enrolled in the study. After fully understanding the protocol and the CRFs I started to receive direct patient interaction at BIR while delivering participant baselines.

I assisted with the TBI quality improvement project. A large scale project with the goal of improving pain points in the hospital. My role involved delivering discharge surveys to patients 2 to 3 days before they left the hospital. The goal of the survey was to evaluate if the patient was knowledgeable about their condition, safety precautions that should be taken, and the medications prescribed to them. The survey also was used to determine if patients used or knew about the various hospital materials provided to them to help them learn about their condition.

WOWii is a study that seeks to address inactivity in a population living with SCI through an internet intervention delivered by health coaches at BIR. My roles included recruitment through phone calls, and recruitment at the outpatient clinic. I also assisted with baseline testing scheduling and delivery. I assisted with data entry from previous cohorts that worked on the project.

The TBI access to health care study aims to evaluate an individual's healthcare utilization over the past year after being diagnosed and discharged from an inpatient rehabilitation facility. The data is collected through a phone interview. For this project, my role has centered around database entry, chart evaluation, and survey delivery.

My time spent at the BIR has been extremely eye opening. It has let me interact with both patients and professional as they seek to improve the quality of care, and assess areas where efforts can be focused to prevent the occurrence of hospitalizations. Through participation across the continuum of research projects from recruitment, deliver, to close out, the experience has given me a greater understanding of a career as a clinical researcher.

APPENDIX A.
IRB Approval

UNT Health Science Center
Office for the Protection of Human Subjects
Institutional Review Board
BOARD ACTION

IRB Project #: 2017-088

Date Submitted: June 29, 2017

Principal Investigator: Stephen Mathew, PhD (with CRM student: Zachary Mazurek)

Project Title: Group Lifestyle Balance Adapted for Impaired Mobility (GLB-AIM): Translating the GLB to Promote Healthy Weight in People Mobility Disability Impairment

Sponsor Protocol #: _____

Department: Clinical Research Management / GSBS

Contact Info: x 5407

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given, is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

- ☒ Project has received approval through: July 3, 2018
- ☐ Informed consent(s*) approved as submitted on: _____

You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

*Including: _____

- ☐ Study Protocol dated _____ approved as submitted.
- ☐ Investigator's Brochure _____ approved as submitted.
- ☐ Protocol Synopsis approved as submitted on: _____
- ☐ Amendment _____ to the protocol approved as submitted.
- ☐ Progress Report/Continuing Review completed, project has received approval through: _____
- ☐ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. **YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.**
- ☐ Project is disapproved for the reason(s) outlined (see attached).
- ☐ Consideration of the project has been **DEFERRED** pending resolution of the issues(s) outlined (see attached).
- ☐ Completion of project is acknowledged and all required paperwork has been received.
- ☒ Special Findings/Other

The UNTHSC IRB acknowledges that the activity is conducted under the oversight of the Baylor Scott and White IRB (Protocol BSWR IRB 015-049). Dr. Mathew serves as his faculty contact for this CRM internship project.


Chairman, Institutional Review Board

7/5/17
Date

IRB Form 2 (revised March 2011)

Board Action-page 2

PI: Stephen Mathew, PhD

IRB Project #: 2017-088

Date: 07/03/2017

SPECIAL FINDINGS:

- ☐ **CHILDREN:** The Board found the participation of children to be approvable under Subpart D of the federal regulations. Specifically, the research satisfies the requirements of:
- ☐ **45 CFR 46.404** ☐ **21 CFR**
- ☐ **COGNITIVELY IMPAIRED:** The Board found the participation of cognitively impaired subjects to be approvable under federal regulations. Specifically, the research satisfies the requirements of:
- ☐ **45 CFR 46.111 (b)** ☐ **21CFR 56.111 (b)**
- ☐ **PREGNANT WOMEN:** The Board found the participation of pregnant female subjects to be approvable under Subpart B of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.204 (a) - (i)**
- ☐ **FETUSES/NEONATES:** The Board found the involvement of fetuses/neonates to be approvable under *Subpart B* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR**
- ☐ **PRISONERS:** The Board found the participation of prisoners to be approvable under *Subpart C* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.305 (a), (b) and (c)**
- ☐ **OTHER:**

OTHER

☒ Expedited Review Procedures (under 45 CFR 46)

Project ☒ Approved ☐ Approved for Continuation ☐ Modifications approved **under the provisions of:**
45 CFR 46.110 (b) (1) category (5) **45 CFR 46.110 (b)(1) category (7)**

D

- ☐ **45 CFR 46.110 (b) (2)** minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
- ☐ **HIPAA Waiver:** The Board finds this study meets all legal requirements for a Waiver of Individual Authorization under HIPAA pursuant to 45 CFR 164.512 (i) (2) (i)-(v) and approves the request under:
- ☐ **Informed Consent Waiver:** The Board finds this project qualifies for a _____
under the provisions of _____
- ☐ **Other IRB Approved Research Documentation Includes:** _____

☐ **Other Comments:**

APPENDIX B.
Daily Journal

Baylor Institute for Rehabilitation (BIR) Daily Internship Journal

Week 1:

05/30/2017

The first part of the day consisted of logistical tasks that included parking/vehicle registration, retrieving of an Identification badge, and gaining access to the Baylor systems. Initial problems were encountered during attempts to log onto the Baylor network. The issues were resolved after contacting the IT department. While waiting to access the system, the BIR Health Literacy protocol was reviewed and evaluated. Questions were addressed to Anne Woolsey (Anne), and Libby Callender (Libby).

05/31/2017

Began evaluating the Group Lifestyle Balance Adapted for impaired mobility (GLB-AIM) protocol. Worked with the IT department to correct the incorrect spelling Mazurek to Mazurek. The issue is still ongoing, and has not been resolved. Initiated a literature review as instructed by Dr. Grobe, and Libby utilizing the Pubmed database. The subject of the literature review was Functional Electrical Stimulation- Cycle Ergometry (FES-CE) in patients with spinal cord injury (SCI). Before conclusion of the day, 25 articles were collected on the topic.

06/01/2017

A literature summary template was acquired, and utilized to summarize the 25 FES-CE articles. In accordance with the summary template title, publishing year, population of interest, sample size, setting, study type, intervention, comparison, outcome measures, results, and conclusions were evaluated for each article collected. This process took the entire day and upon completion it was emailed to Dr. Grobe for evaluation.

06/02/2017

Started an additional literature search evaluating FSE-CE correlation with attenuation of bone mineral density. Reviewed and summarized each article. In addition to the Literature review, data entry for the clinics Esko experiment was entered into the server. This task will be completed on Monday.

Week 2:

06/05/2017

Met with Dr. Driver and Dr. Grobe to discuss potential research questions to focus on for thesis project. Discussed the Group Lifestyle Balance adapted for impaired mobility project. The data for this project has been collected and needs to be analyzed. Patient population includes a large subset of SCI individuals. Needs to be evaluated for feasibility and efficacy. Project protocols were received after the conclusion of the meeting. Received Actigraph link activity monitor. Currently evaluating how to use the newer model. The goal is to present a tutorial to Dr. Driver and Dr. Grobe to determine its use. Collated Libbys notes from SCI pain points study.

06/06/2017

Received a project from Cindy D. Retrieved patient medical records and input patient exposure type into excel table, along with the date each was randomized. Continued evaluating GLB-AIM protocol to form a research question. Continued evaluating the Actigraph software.

06/07/2017

Continued evaluating the GLB-AIM materials provided by Dr. Grobe. This included the GLB-SCI Grant request, and the protocol for the GLB-AIM project. Met with Dr. Grobe to discuss in detail potential research questions to ask for graduate thesis project. The sample size (n=67) collected for the GLB-AIM project included a SCI subset population (n=32). Dr. Grobe previously analyzed SCI subset addressing feasibility of the GLB-AIM program, assessing attendance throughout the 12 month period,

and self-monitoring compliance. The data set used imputed data to account for absent data. Potentially use non imputed data for evaluation. A potential question arose during discussion. When attendance data was collected if an individual was “present” it was not described in what capacity. Individuals were allowed to “make-up” session but still were counted as present in the current data. The plan is to track down raw data and find if the individual was weighed during their in person visit. How does denoting the capacity in which the individual attended. Effectiveness will also be addressed. Worked on a project for Anne W. Data was collected and input for the Stroke Education project.

06/08/2017

Continued preparation for advisor meeting. Attended the SVI Pain point meeting and collated notes from the meeting. Collected additional data from the Esko study after gaining access to eRehab.

06/09/2017

Had a short meeting with Dr. Driver to discuss my first two weeks in the lab, and further address my thesis project. My research question was further refined. The Ekso data was entered into a new data base. Process took the majority of the day. Began working on presentation for advisor meeting. Collected data for the Lightbox randomization study. Recorded cause of injury for study participants. Did not complete, will be continued Monday.

Week 3:

06/12/2017

Completed data collection and entry of the Lightbox randomization study. Attended the Ekso project meeting. Plan on shadowing the machines use in the future. Also received a new project that involves a knowledge assessment survey that will be given to TBI patients 24 to 48 hours before discharge. Helped revise the survey, and drafted a Script that will be followed when addressing the patients. Plan to give first survey Wednesday. Began collecting additional Ekso session data. Will complete tomorrow morning.

06/13/2017

The struggle continues. The difficulty of correcting a last name (Mizurek to Mazurek) is an issue that has perplexed the IT department. At this point it may be easier to contact the state of Texas and legally change my name to Mizurek. However I must persist, for all I know this is a test the BIR gives to all its interns. Aside from the war of attrition I have vaulted against the IT department, I continued collecting and entering data from the Ekso study. The previous entered data was also edited within the database. Additional data was gathered for the lightbox randomization study. Continued working on GLB-SCI background. I drafted a 1 page document summarizing my project and sent it to Dr. Grobe. She returned it with comments and recommended changes. Will make suggested edits tomorrow.

06/14/2017

Prepared edits on my one page project proposal summary submitted by Dr. Grobe. After addressing the edits I continued reviewing the literature on the previously submitted project. I took notes on potential questions that may arise during my meeting tomorrow. Around lunch I received an assignment from Anne. I received additional subject information for the stroke education study. I highlighted issues within the entry data base and fixed them. After completing data entry, IRiS access was granted by the IRB. I was placed as a participants in two studies. Workout on Wheels internet

intervention (WOWii) and GLB-AIM. Typed up a make shift tutorial for the actigraph activity monitor. I began entering subject data into IRiS for the WOWii project. I also started evaluating the information from the WOWii trials. Near the end of the day I began compiling the information needed on my previous course work and placing it into the UNTHSC advisory board committee documents. Then I went home.

06/15/2017

Began the day by delivering a WOWii patient conformation screener to Dr. Hamilton. Met with Dr. Hamilton. After discussing with her I gained an invitation to attend the Grand rounds on Tuesdays starting at 7am. Upon returning to the office I began preparing for my 1 o'clock meeting with Dr. diver Dr. Grobe, Dr. Hodge, Dr. Mathew, Dr. Reeves, and Libby Calendar. During the meeting I described my research project and gained approval to begin composing my research proposal. I also further edited Libys Pain point table. Participated in a screening call with Maria. I will be completing those calls tomorrow. As well as begin writing my formal research proposal. Need to clarify what kind of information can be utilized from stuff Dr. Grobe has previously written. And make a hashed out outline for my actual proposal.

06/16/2017

Began writing my research proposal, found difficult to avoid copying previous protocols. Reevaluated my approach and started a literature search to further understand the problem. After doing that the remainder of the day was spent cleaning up the office. Near the conclusion of the day I was notified on my inclusion by the IRB in the WOWii study and GLB-AIM. Before the day concluded I called people on the WOWii to begin adding more people to the first cohort

Week 4:

06/19/2017

Started the morning by attending the SCI Pain Points meeting. During the meeting we discussed the pain points experienced during patient admission, and patient stay. The root causes of these pain points had been previously identified in earlier meetings and the goal was now to evaluate the relative impact of each individual pain point on the patients, and the percent of patients effected. Notes were taken. Continued to do a literature search on SCI patient population and work on research proposal. Attended the GLB-AIM meeting, and gained information about the data analysis being done on the previous project. Will utilize this information when evaluating SCI GLB-AIM data set. Called the individuals on the WOWii roster and screened 4 individuals for their eligibility for the program. Gained approval to attend the resident's grand rounds tomorrow at 7:00am.

06/20/2017

The day began at 7 am. The time of arrival was novel, and so was the destination. I got out of my car and headed towards the Truett hospital wing and then descended into the basement. After initially being disoriented I gained my heading and located the room where I would be spending the day. "Resident Grand Rounds" is what appeared on a sign outside of the door. I was the second person in the room, and I waited to introduce myself to the residents. After introducing myself I sat and listened to the days presentations. First up the group was presented with Self -Assessment Examination Questions. I followed along, however my ability to answer the subject matter was limited. After, I learned about Myestinia Gravis, Lambert Eaton syndrome, and Botulism. MG and LES were both autoimmune disease that acted at either the postsynaptic or presynaptic sites respectively, where botulism acted to inhibit vesicle fusion to the presynaptic membrane. I learned the importance of cross diagnosis, and making sure to rule out any other possible pathologies. I also learned that while rare catching these things early have the potential to prevent lifelong disability. The day concluded learning about the importance of bowl

management and the different types of catheters needed and how urinary dysfunction can be very troublesome and if not convenient may lead to kidney failure.

06/21/2017

Spent the day completing the SCI background literature review. Found a plethora of articles that chronicled the exercise barriers prevented to individuals with SCI. The lack of range of motion varies and the specific types of activities vary based on the level of their injury. For example tetraplegia and paraplegia have different requirements. In addition SCI individuals have different nutrient requirements catered to their metabolic profile. I will be researching further on this subject tomorrow. Met with Danielle and Dr. Dubiel to assess a plan for the patient Knowledge and quality project. Continued working on research proposal to be submitted to my advisors tomorrow for review.

06/22/2017

Spent the entire day attempting to edit and finalize my research proposal. At certain points throughout the day I helped pilot a new database that was being constructed by Anne that was to be used for data collection for the Health literacy project. Submitted research proposal at the end of the day. Still need recommendations on Limitations and Statistical analysis.

06/23/2017

Received Proposal edits back from Dr. Grobe. Will be spending the day addressing her edits. Submitted proposal to Research advisors. Continued to pilot Health literacy database for Anne and further delved into background as suggested by Libby.

Week 5:

06/26/2017

Crunch time. Received approval to spend the following week flushing out my proposal. Will be attending resident rounds tomorrow at 7am. Emailed proposal for additional edits.

06/27/2017

Attended Rounds in the morning. Continued to work on proposal. Finished filling out documents related to the IRB submission.

06/28/2017

Received edited proposal back from Dr. Reeves. Addressed his edits and made suggested changes. Talked to the biostatistician about the statistical analysis. Added additional information to that section of the paper.

06/29/2017

Thursday, emailed my draft for one additional round of edits before submission on Friday. Formed a working title for the proposal. Begin Entering data for the Health literacy study into the approved database.

06/30/2017

Addressed the last edits though there were not very many and emailed the final version to Dr. Reeves. It will be processed over the span of the upcoming month. Started the process of entering data for the Health Literacy project. There is over 6-months of data that needs to be entered.

Week 6:

07/03/2017

Holiday

07/04/2017

Holiday

07/05/2017

Everyone is back in the office. Continued data entry exclusively for the day. Overall there is a baseline, 2 week follow up, and 3 month follow up for each individual enrolled in the study. Enrollment BL data collection are still ongoing. In total it takes roughly 30- 40 minutes for a complete data set to be entered. With over 100 sets of backlogged data, my time will be devoted to this exclusively over the next few weeks. It will be referred to as Health Literacy Data Entry. Finished the day, and entered a total of 5 case report forms

07/05/2017

Continued Health Literacy Data Entry. Completed 6 case report forms. Was given a 40 person call list by Maria to begin enrollment for the Workout on wheels internet intervention. Have yet to make any calls.

07/06/2017

Continued Health Literacy data entry. Completed 7 Case report forms. Called 40 person list. Able to reach 6, screened 3 for eligibility, only one was eligible. The rest of the 40 person list received voicemails.

Week7:

07/10/2017

Received another call list from Maria to continue enrolling people for the WOWii research project. The list received was 1000 people long. Participated in the WOWii meeting to further hash out questions related to subject autonomy and the inclusion criteria as it relates to the IRB protocol. Reported the success rate of call lists. Overall it was decided that I should continue calling however another way may be needed. Returned to calling participants and entering Data for the Health Literacy Study. So far 2 people were eligible. Entered 4 HL CRF into the database.

07/11/2017

Attended resident rounds, met the new residents and medical students taking part in their PM&R rotations. Observed a presentation discussing the logistics of medicine. Learned about the importance of communication. How to do it properly, and how to ensure that what you say is understood by your target audience. After there was a impromptu discussion about Medical school graduates and their place before residency, how there is a discrepancy between residency position available and medical school spots offered. Short term fix to the problems of physician shortages. After completion of rounds returned to the office and continued entering CRF into the data base. And calling the WOWii list.

07/12/2017

Spent the day entering CRF for the health literacy project. Took up entire day. Was able to enter 10 into the database. A new record. Spent the entire day still haven't made a dent in the overall case file. Will continue data entry until it's complete. At the current rate it will most likely be complete in 2 weeks. Collated the notes and prioritized the Root causes discussed in a previous meeting. Organized by impact on patient and percentage of patience impacted.

07/13/2017

Spent all day entering CRFs into the database online. Attended the SCI process solution brainstorm meeting. Went over solutions to the prioritized problems. Solutions were either designated as “Just Do Its” or ones that needed further assignment. The meeting lasted two hours. Continued calling individuals afterwards, and recruited for WOWii.

07/14/2017

Friday helped prep for the Conference that everyone was attending in Washington D.C. Helped with speech delivery, critiqued presentations. Continued entering CRF into database and finished calling people on from the 400 person list. Overall I recruited 4 additional people to the study. Delivered the patient knowledge and quality survey to 2 individuals in BIR that were 2 days prior to discharge.

Week 8

07/17/2017

The Majority of the staff was attending a conference in D.C. I was the only one in the office. Spent my time entering CRF for health literacy.

07/18/2017

Only individual in the office again. Finished entering the CRF. Now everything is caught up with data entry. It will now be done on an as needed basis. Met with the biostatistician later in the day and talked about my project. Went home.

07/19/2017

Shared the office with Dr. Grobe. Everyone else was absent. People had issues with the flight returning from D.C. because of weather. Helped Dr. Grobe with her grant proposal. Completed literature searches throughout the day. Researched the disassociation between hunger cravings and hunger cues, how there is more things involved in eating cravings.

07/20/2017

Everyone was back in the office today. I started delivering the TBI EDP surveys to patients in their rooms. The goal of the survey is to assess the patients time spent here and learned about things that they found favorable and problem areas that occurred during their care. The goal is to also assess the patient's knowledge of their injury. The Survey was delivered to two individuals. Also called individuals who had discharged previously to assess their discharge and transition experience. Continued to schedule subjects for WOWii fitness assessment. Followed up on MD approvals for WOWii.

07/21/2017

Communicated with Dr. Hamilton about conducting study recruitment at the outpatient clinic located at the Tom Landry center. Next week on Monday, Wednesday and Friday I will be in the clinic conducting study recruitment for WOWii. This will involve screening for eligibility and signing up subjects for fitness assessments. Worked on a literature review surveying research that has been conducted observing the interaction between emergent healthcare use and race plus insurance in individuals with SCI. The goal is to write the background section for a future manuscript.

Week 9

07/24/2017

Today I spent the day at Dr. Hamilton's outpatient clinic located in the Tom Landry center. I was there from 9-5:45. I interviewed and screened 5 of Dr. Hamilton's patients. Each one was eligible. I was only able to sign up one for the fitness assessment. Will be reaching out to the rest of the subjects at a later date. In my down time I continued to complete the literature review/background for LC.

07/25/2017

Followed back up with subjects screened at Dr. Hamilton's clinic. Was able to schedule 3 additional individuals for their fitness assessment. Followed up on MD approvals, scheduled the individual who I received an MD approval form from. Continued to work on literature/background review. Will be back in Dr. Hamilton's clinic tomorrow for additional recruitment.

07/26/2017

Spent the day in Dr. Hamilton's clinic. Screened three individuals. 1 individual was eligible but did not want to sign up. Will schedule appointments tomorrow. Completed lit review.

07/27/2017

Followed up and attempted to schedule subject screened the previous day. Also called to schedule fitness appointments for additional subjects. Followed back up with additional MD approvals. Received a new task that involved writing the methods section for the SCI-ins/race paper. Used LC thesis as a template.

07/28/2017

It is Friday. It is Friday. Gotta get down on Friday. BIR had ice cream Sundays. I partook in the ice creams Sunday festivities. In addition to the Sundays I also continued to follow up on the Wowii MD approvals and subject appointment scheduling. I also input CRF data for newly generated files. Continued working on Methods section

Week 10

07/31/2017

Followed up on MD approvals for WOWii. Finished the methods section. Still needs to be reviewed. Started creating an access database for the AOA.AA injection data that has been collected previously. Also attended the research process meeting and took and collated notes. Created a flow map that chronicled the research steps and the non-research activities that occur in the office.

08/01/2017

Started the morning at 7:25. I rounded with Dr. Sikka and shadowed her. I was able to observe her assessment of each patient. She was very knowledgeable about their condition and current situation as it regards to wounds, medication issues and potential problems that may arise that could hinder their rehabilitation. I received an MD approval that I will now be attempting to schedule the individual for her fitness assessment. Continued to enter data into the access database that was created. Completed the access AO/AA injections data entry. Created an additional access database for the TBI EDP knowledge and quality survey info.

08/02/2017

Met with Dr. Grobe to further hash out the data analysis portion of my project. Received attendance data and self-monitoring data. Started to merge the data from each cohort and then isolate the SCI subjects for separate analysis. Dr. Grobe has a computer with the de-identified patient numbers and

their etiology of injury. Will be including that information in the original table/ data. Computer is broken, so I made an IT appointment.

08/03/2017

Entered the majority of the data for the health literacy project into the data base. Spoke with Dr, Grobe about further analysis for the thesis. Continued to edit the methods section for the race/insurance paper. Confirmed the scheduled shadowing appointment with Dr. Chung.

08/04/2017

Entered HL data into online database. Worked to analyze the PAM scores using a pre-calculated spreadsheet. Issues arose with the spread sheet and spent around two hours troubleshooting. Finally resolved the problem. Spent the morning shadowing Dr. Duan Chung DO during his morning rounds. Further developed an understanding of the PM&R practice. It is starting to appeal to me as a potential career path. The continuum of care is inspiring. Worked on thesis data.

Week 11

08/07/2017

Attended the GLB AIM meeting at 2:00 and learned about how the GLB-AIM team plans to analyze the 12 month data. Talked to Jason after the meeting to discuss the statistical analysis that should be done in regards to the SCI sample data. After the GLB-AIM meeting I attended the monthly Re-Quip meeting where two therapist discussed their finding on the EKso skeleton data that I entered previously.

08/08/2017

Contacted Angela welch and was able to access medilinks after a few hang ups. Now I will be able to independently find subject O-log scores, room number and daily schedule. This will allow me to gain independence while working on the TBI patient knowledge and quality survey for Dr. Dubiels EDP project.

08/09/2017

Updated the survey for the TBI EDP survey and delivered it to one of the patients at BIR. The survey was updated with a question asking about the patient's knowledge and use of the TBI fact Sheets. Met with the GLB-AIM CDC team on the phone in Dr. Grobes office. I learned about the logistics behind the GLB-AIM grant. Helped me better understand what is involved in human research. Printed out subject ID labels for Cindy.

08/10/2017

Attempted to call and schedule the last remaining patients that have either 1. Not returned my phone calls. 2. Have not received MD approval forms. Also created the polar coach account, then invited and accepted the subjects for the first cohort. Continued working on a new project that involved collecting data on geographic data for TBI subjects who lived in certain area codes within North Texas. I utilized an

online database and gathered population data, demographic data, and economic data for those area codes.

Sent the data to Monica B.

08/11/2017

Worked on the introduction for the SCI race/insurance association paper for Libby, emailed the literature search I had completed to Libby and Dr. Sikka. Mailed the early august ironic birthday cards for cindy to follow up on admitted BIR patients in accordance with the TBI model system grant which requires 80% of BIR subjects to remain tracked over the span of the grant. Went out for lunch. Helped Maria with folder organization for the WOWii project, and re numbered subject Ids to identify them by the cohort, and the group they were a part of.

Week 12

08/14/2017

Continued to work on the introduction for the manuscript. Assisted with both the 2 week follow up calls and the three month follow up calls. Completed 1 3 month follow up. Filled in the discharge information for the most recent 3 month follow ups. Worked out a new process to gather insight into the weekly discharges from BIR. Will now be using medilinks to populate the Census data for Dr. Dubiels patients, hopefully this will increase my success rate when interviewing patients. Assisted Maria with WOWii polar subject syncing.

08/15/2017

Travelled to the TWU campus to participate in the fitness assessments for the new WOWii cohort. Assisted with the informed consent process, technology training, and the fitness assessment itself. The fitness assessment included collection of subjects resting blood pressure, and cardiopulmonary variables to determine the maximal VO₂. Technology training included training with the Polar fitness watch, completion of the entrance survey, and Skype orientation, along with the WOWii website orientation.

08/16/2017

Received documents from libby that needed to be reformatted. Composed a new document that collated notes from previous LEAN research meetings and formatted a research process flow map. The Idea is to coordinate the pain points for different research process and try to form solutions to those processes. The solutions brain storming meeting was at 11:00. After the meeting completed I typed up the notes from the meeting and sent them back to the office. At the next meeting scheduled for Friday we will be prioritizing the solutions. I also worked to reschedule the participants that had missed their fitness appointments. I was only able to reschedule one participant. It is likely that the remaining will be shifted to the next cohort.

08/17/2017

Began working on a project for Dr. Grobe. I needed to reorganize the adverse events log for the GLB-AIM study. I utilized the linked log for the study to separate the participants by intervention or waitlist control. The incidence of adverse events that occurred that required hospitalizations were recorded and summated for both groups. Maria also sent me a large file that included participant exercise data that was not de-identified. I was given the task of removing the participant names from the file names anywhere they are present within the file. I was given till the end of the month to complete this task.

08/18/2017

Began the morning assisting Dr. Grobe with a literature search. I was to find out if there is a nationally reported obesity prevalence statistic for populations of individuals with MS, Amputations, and spina bifida. I also tracked down a source and original document for the updated NHANES questionnaire. I typed up the questions that documented the physical functioning assessment. I then trained Marry a 4th year TCOM student on the data entry protocol for the health literacy study. Attended the prioritization meeting for the LEAN research process meeting. Then was tasked with adding the prioritized solutions into the excel file.

Week 13

08/21/2017

The Eclipse was today. Around 1:00 everyone went outside and looked at the event if they had proper eye protection. Across the street people were on the roof using pinhole projections to view the event. I did not view the eclipse because I did not have the proper eyewear. I will have to wait till 2024 until I will view another. Hopefully I will be two years into residency by that time and not bogged down by work to go see the event. Someone threw out their eclipse glasses, so I plan on holding onto those for the next event in seven years. As for actual work I was one of 3 people in the office. I prioritized the solutions from Friday's meeting and sent them to Danielle. I also worked on data analysis for my own thesis project. Finished de-identifying the files that Maria sent me for the WOWii exercise data. Emailed the data files to Jason the statistician.

08/22/2017

Created a quick summary on how to use the MED Gem to measure the resting metabolic rate of a patient. I will be delivering a short presentation on how to use it on Monday. I did notice that it does not calculate VCO₂ which might be problematic. Instead of calculating VCO₂ it uses a Respiratory quotient which is a ratio of VCO₂/VO₂, then it multiplies RQ by VO₂ to cancel out VO₂. This may be problematic because of differential metabolic profiles that exist in the mobility impaired community that is present in the inpatient setting at BIR. I also assisted Lacey with calls for the health literacy study. I completed 2 3-month follow ups and 1 2 week follow up after calling 11 people total.

08/23/2017

Attended the nurses meeting where they were introduced to the research department. Gave them a short introduction to my role at BIR and the different projects that I am involved with. Helped Maria organize the screening forms and folders, and ensured the informed consent documents were in their

proper place. Made additional 3-mo follow up calls, left voicemails. Completed a total of one 3 month follow up call.

08/24/2017

Started to work on the fitness data for the WOWii project. First step involved creating a database. Used SPSS to create a database to record the fitness data for WOWii pre and post assessment. In total, 79 different variables were collected, and entered into spss. After creating the database I went through the given documents to extract the data and entered it into the data fields within spss. This task took me all day. Upon entering the data it was soon realized that post and pre fitness test data was missing. I plan to track down the missing data tomorrow.

08/25/2017

Began the search for the missing data. It turns out that there should be 22 pre fitness assessments for C2 and 16 pre fitness basements for C1. I had only found 12 total. Eventually I was able to track down and locate 18 assessments for C2 and 13 for C1. That leaves three basements missing from C1 and 4 missing from C2. Worked with Maria to locate the missing fitness assessments but not sure what happened. Finished entering the rest of the data for the fitness tests I had. At the end of the day I worked with Dr. Grobe to work through survey gizmo to download the survey data collected after the fitness test and have it formatted for SPSS. The data generated appeared finicky and will work to clean it all up on Monday. Also the office was extremely cold today. The thermostat is broken.

Week 14

08/28/2017

No interview invitations from medical school. About to begin September, and beginning to lose hope. Luckily the maintenance office worked diligently to fulfill our ticket order and repair the thermostat so the temperature would not be unbearable for the week to come. It is still freezing in the office. I placed another maintenance request to have it fixed. I also met with the maintenance individual to discuss our issue. While encased in ice, I worked with Dr. Grobe to analyze the spss. WOWii survey. Together we discussed the variables that needed to be changed and how to address the data discrepancy that appeared after transition survey formats. I worked on data recording and reclassification of the data. At the end of the day everything was completed. Well... everything but the frigid temperature. Received a not from Lacy requesting that I contact a subject for a 3 mo. follow up call tomorrow at 11:30. Agreed to the request.

08/29/2017

Created a power point presentation to teach the office how to use Med Gem. Created a one page word document to describe steps involved with using the medgem. Made a call at 11 and completed a 3 month follow up. Thermostat still on the fritz. Very cold in the office. Used select Medical to capture education data for the stroke education project. Delivered a Baseline discharge survey.

08/30/2017

Edited created PowerPoints, and word document for the MedGem presentation on Thursday. At 2:30 I made a 3-month follow up call to assist with the health literacy project. MedGem software needs a special cable to adapt for use with the software. Could not locate the cable online. Reached out to Microlife to learn about acquiring a cable. Also asked if the number of tests available on the MedGem was limited, which was hinted to in the user manual. Worked with Danielle to finalize figures for a GLB manuscript that will be submitted soon. Drafted a meeting agenda for tomorrows meeting with Dr. Grobe.

08/31/2017

Continued finalizing the figures for Danielle. Completed three 3 month follow ups for the health literacy study. Delivered a TBI EDP baseline survey. Made a call to do a post interview but no answer. Met with Dr. Grobe and made a writing plan for my thesis. Went over guidelines for writing the results section and the discussion session. After the meeting I went back to my research proposal and made edits based on our discussion. I will no longer be including the SRAHP, and IPAQ in the data analysis. Most people were out of the office today, so the MedGem presentation was moved to the following Friday at 2:00.

09/01/2017

Only the 4th year TCOM student Mary, Lacy and myself were in the office. Most people refrained from driving into work because of the “gas shortage.” Attended a Health literacy Baseline with Lacy and learned the flow of everything. Completed one on my own at 11:00. Went home by lunch time and volunteered at a local warehouse that needed assistance organizing donations.

Week 15

09/04/2017

Started finalizing the introduction for the race/insurance SCI project that I had completed a literature search for previously. Updated the WWAD spreadsheet for tomorrow's outreach event. Made calls to recruit for WOWii. Completed a baseline survey for the TBI EDP project. Completed a post discharge survey for the TBI EDP project

09/05/2017

Completed an additional BL survey for the TBI EDP project. Started to further edit the RACE/ins introduction that I will be sending Libby tomorrow. Made 3-mo follow up calls. Contacted a potential participant for WOWii clinical trial Cohort 3. Attended WWAD, I set up the display, and signed in the day's participants.

09/06/2017

Finished tracking down literature sources. Sent the introduction to Libby. Cooperated the Method section that was written with the results section of the paper. Added additional details. Made 4 3 month follow up calls, only completed 1. Completed another BL survey for TBI EDP and began consolidating the subject metrics over the past 3 months.

09/07/2017

Worked with Mary to facilitate her understanding of the Health literacy project. Will be delivering Baseline surveys soon. Also continued to finalize MedGem presentation. IT is going to be delivered tomorrow and I want to ensure that I have covered all the potential questions that may be asked.

09/08/2017

Created my own database to track TBI discharges for the TBI EDP quality project. Re-organized what was sent to Danielle to use as a handout for the meeting today at 12 o'clock. Met with the TBI team to discuss individual data queries. Updated the TBI survey afterwards. Gave my MedGem presentation. Taught the entire office how to use the MedGem to measure their resting RMR and VO2 absolute. Confusion arose about the VO2 units. So I investigated further. The MedGem displays vO2 in ml/min. This is a resting vO2. It is converted to a relative vO2 by dividing by the weight of the subject. This is much lower than the vO2 max.

Week 17

09/18/2017

Out of the office, have a slight fever and was sent home.

09/19/2017

Stayed at home to clear the bug and prevent within office contamination.

09/20/2017

Started planning writing for thesis. Created a rough outline of the flow of the paper. Worked with lacy to develop a purchasing request for the Med Gem mouthpieces, current invitation was out of date. Typed up feasibility data focusing on attendance and Self-monitoring compliance. Did a literature search for SCI and the incidence of ingrown toenails and autonomic dysreflexia.

09/21/2017

Received weight loss results and demographic information for the SCI population. Will begin writing the results. Mostly will be focusing on demographic statistics that were determined to be

significant. Overall the sample lost weight, however there were differences between groups. Plan to do mixed modeling analysis to further hash out sample.

09/22/2017

I grabbed files for Cindy, for the TBI model systems tracking. Also sent out September birthday cards per Cindys request. Completed a Health Literacy BL. BL was split up into two sessions. First session was completed during the day, with the second session being completed that afternoon. Continued to work on thesis. Need to find sources to back up rudimentary hypothesis that were developed.

Week 18

09/25/2017

Was able to work out issues with eRehab that have been causing log in issues. Continued to help with HL, and completed two baseline surveys. In total they took roughly 3 hours. Continued to write for my thesis. Was able to set a date for defense on October 31st at 10:00am. Will be working towards submitting the intent to defend form with required signatures.

09/26/2017

Spent the entire day making phone calls for the TBI access to healthcare research project. Was recently put on this project. Made 50 phone calls and completed 3 surveys. Will continue to complete phone calls when available. Low priority. A total of 17 surveys have been completed for the HL study.

09/27/2017

Completed a health literacy baseline, took roughly 2.5 hours. Lasted longer than previous baselines. Extended an invitation to have a patient complete a TBI EDP survey but was denied. Started composing figures for thesis. Met with Dr. Grobe to discuss analysis.

09/28/2017

Highlighted sample size discrepancies in the data presented for the 12-month SCI sample. Noticed that predicted sample size was 20 yet only 18 subjects were being analyzed. Determined that when the data set was recoded the first two sessions for the control group were included as there intervention, and three month intervention. Assisted with Dr. Grobe to recode the database. Luckily data trends observed from previous analysis remained similar so no true overhaul of the written results section was needed.

09/29/2017

The office was relatively empty today. Used the quite time to make substantial progress writing for my thesis. Started to make a few figures. Talked with Dr. Grobe about the best way to talk about sample demographics. Set a tentative date to turn in a rough draft. Will be most likely next week. Made a few calls for the Health literacy study, and delivered a discharge survey for the TBI EDP project.

Week 19

10/2/2017

Dr. Grobe wants a copy of my thesis by Friday. I have worked on both the results and discussion sections throughout the week. Plan to finish both by Wednesday and further fledge out my analysis. Attended and helped set up the ReQuip meeting. Made a few calls for the health literacy study but did not make contact with anyone. Downloaded the data from Dr. Grobes two Actigraph watches. One was worn on the wrist with the other being worn on the ankle. Data appeared very different for both. Sadly no HR data was collected. Will be investigating further why no HR data was collected.

10/3/2017

Attended WWAD and lead sign in/signup. Disseminated information about the program when prompted by guests at Landry. Updated the sign-in sheets and filed new waivers. Worked to finalize my presentation for the Actigraph meeting. Prepared a 12 page hand out that described how to initialize the actigraph device, download the data, and analyze the data using the actigraph software. I also included a rough analysis of Dr. Grobes data that was collected over the weekend utilizing the Actilife software. Highlighted important features of the actigraph, including proximity features, and group initializations. After giving the presentation I fielded questions about the device. Spent the remainder of the day working towards completion of my thesis.

10/4/2017

Worked on thesis for most of the day. Met with Dr. Grobe to discuss analysis. I wanted to further determine if there were any behavioral linked variables that could help describe the subject weight change variability. Looked at SRAHP, however it did not prove to be significant. The assumption is that because of low sample sizes and heterogeneity of the sample may explain the overall variability seen within the results.

10/5/2017

Helped with the Health literacy project. Made phone calls for both two week follow ups and 3 month follow ups. Made contact with three people, but only completed 1 three month follow up. Established dates to complete three month follow ups with individuals I was able to contact. Assisted in delivering a baseline for the Health literacy project. Worked on thesis, will be submitting a first draft to Dr. Grobe by the end of the week.

10/6/2017

Completed a Baseline for the health literacy project. Completed a survey for the TBI EDP survey. Worked to finish the first draft of thesis. Attended a meeting for WOWii recruitment. Started to iron out dates and times when I could go over to the Outpatient clinic and recruit. Also highlighted week pints that I experienced when recruiting for cohort 2. Spent the majority of time working on thesis. Submitted first draft to Dr. Grobe at the end of the day.

Week 20

10/09/2017

Scored the survey for TBI EDP from Friday. One person was not interested in completing the survey. Have another individual discharging Friday will ask them to complete survey tomorrow. Anne invited me to go to fair at UNTHSC tomorrow with her and Danielle. The goal is to speak to my internship experience at BIR and try to persuade current MPH students to come do their internships at BIR. Attended the GLB-AIM monthly meeting.

10/10/2017

Spent the day at the UNTHSC Masters of Public health fair representing BIR and attended the unsung heroes in public health presentation. BIR is looking to take on a MPH intern to assist with duties. I spoke to my internship experience while at BIR. I also spilled water on my laptop and brought it to the UNTHSC help desk. I will be retrieving the laptop tomorrow or Friday.

10/11/2017

Began to prep for my upcoming medical school interview. Delivered a health literacy baseline. Left office around 12 o'clock to pick up laptop from UNTHSC tech department.

10/12/2017

Was assigned the task of decorating and creating BIR Halloween pumpkin. Will be brainstorming future ideas. Delivered a TBI EDP baseline to a patient at BIR. Worked to make calls for the TBI access to healthcare study. Made multiple calls but only completed one survey.

10/13/2017

Friday worked to complete a health literacy baseline. Was not able to complete so went back after lunch. Completed baseline. Entered health literacy data into database.

Week 21

10/16/2017

Completed a baseline for the Health literacy study. Completed an in person 3-month follow up for a Health Literacy Participant staying at BIR. Used endnote to manage my references for my thesis and made additional changes. Went through and conducted chart review for the TBI access to health care study.

10/17/2017

Addressed additional thesis edits from Dr. Grobe. Plan on submitting final thesis today or tomorrow to committee. Made 50-60 calls for the TBI access to healthcare study. Spent the last half of the day completing that. Attended Journal club where we were served lunch. Participated in discussion that discussed using cognitive evaluation of burn rehab patients as a way to predict outcomes, and a review article that discussed findings related to ambulation deep vein thrombosis and pulmonary embolisms.

10/18/2017

Spent the majority of the day preparing for my interview at Alabama College of osteopathic medicine. Both Libby and Dr. Sikka took time out of their day to conduct mock interviews with me. I received great pointers from both individuals. Specifically the importance of integrating specifics that tie together larger concepts. Made a few calls for the TBI access to health care study, input data into survey genius for survey that had been completed.

10/19/2017

Out of office traveling to medical school interview

10/20/2017

Out of office. Medical school interview.

Week 22

10/23/2017

A new TCOM student was in the office today starting his research rotation. Helped him get up to speed on the Health Literacy study, and started him on data entry. Helped him understand the nuances of the database. Also trained him on the TBI access to healthcare protocol. Worked on designing a schematic for the pumpkin contest. The majority of the staff is going to be out of the office this week. In order for the staff to not fall behind. Collected data from AIM 3 of WOWii and filed corresponding de-identified data. Worked to validate data that was entered into WOWii fitness database.

10/24/2017

Trained Medical Student on TBI access to health care chart review for patients. Where to access variable data in rehab and Medilinks. Delivered Baseline to patient who experienced CHF. Did not complete before 1:45 meeting. Will be continuing tomorrow at 11:00. Worked on drafting plans for the pumpkin competition.

10/25/2017

Worked with medical student to complete TBI access to healthcare project. Made over 40 calls and completed two surveys. Delivered two baselines but did not complete either. Will be completing baselines for the following day. Worked to develop plan for thesis presentation

10/26/2017

Finished delivering baseline to Health literacy participants from the previous day. Continued to develop thesis presentation for delivery on Oct. 31st. Assisted with the TBI access to health care study when available. Only completed a few surveys. Mostly worked to complete chart review for surveys that were completed previously. Overall 12 surveys were completed with corresponding chart data.

10/27/2017

Continued to work on my thesis presentation. Continually worked towards completing calls for the TBI access to health care study. Completed a baseline at the end of the day. In total it took roughly 2 hours. Mailed out remainder of October birthday cards. Office staff will be back on Monday. Will be completing presentation by that time.

10/30/2017

Worked to complete the thesis presentation for tomorrow's thesis defense. The majority of the day was spent reviewing literature related to spinal cord injury demographics. Met with Dr. Grobe in the afternoon to practice presentation delivery. After practicing it was suggested that I make a few updates to the presentation. Also finished addressing Dr. Reeves edits included in the final version of the thesis. Will be completing the pumpkin tonight and bringing it into the office early tomorrow.

10/31/2017

Dropped off the pumpkin at 8am and printed out additional copies of the thesis. Drove to Ft. Worth and defended. While waiting for my committee to discuss defense I was given the opportunity to observe the creative Halloween costumes everyone was wearing. It was a very interesting experience observing such playful attitudes held by individuals on campus while I waited anxiously for a decision from my committee. After waiting I was told that I had completed my thesis requirements and received an A. Hooray! Drove back to BIR and spent the remainder of the day gathering clinical information for the TBI access to healthcare study

11/01/2017

Spent the day following up on committee suggestions. Adjusted Table 2, and incorporated suggestions from Dr. Hodge. Assisted Maria in preparing for WOWii recruitment for cohort III. Called participants from Cohort I and followed up on exit surveys and equipment return. Met with Dr. Grobe to discuss publication of thesis and was determined that I should be included as a second author, a decision I agreed with. Also help shine light on a few data errors in the GLB-AIM database.