

# LIFESTYLE BALANCE MANUAL



*A Lifestyle Intervention Targeting Enhanced Health and Function for  
Persons with Chronic SCI in Caregiver/Care-Receiver Relationships: Effects  
of Caregiver Co-Treatment*

# LIFESTYLE BALANCE MANUAL PERSONAL NOTEBOOK



NAME:		
MY LIFESTYLE COACH IS:		
	ADDRESS:	
	PHONE:	

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## PERSONAL DATA AND SCREENING ASSESSMENT

ID:	
D.O.B.	
Height:	
Weight:	

Injury level		AIS A-D C5-L1
Injury duration		≥ 1 year
Age		18-70
Gender		
Racial/Ethnic background		
Waist Circumference		≥ 94 cm
BMI		≥ 21 kg/m <sup>2</sup>
Fasting dyslipidemia		HDL-C ≥ 40 mg/dL OR TG ≤ 150 mg/dL

## OVERVIEW

Body weight gain through addition of fat is commonplace after SCI, and is likely caused by physical deconditioning, loss of metabolically active muscle mass, reduced whole body energy expenditure, restricted choices for exercise conditioning, and a diet that is too high in calories and fat. Health risks posed by obesity are strongly associated with 15 conditions including: cardiometabolic syndrome, hypertension, diabetes, coronary artery disease, congestive heart failure, stroke, osteoarthritis, sleep apnea, depression, cancer, respiratory failure, disorders of coagulation, and degenerative joint disease. Irrespective of cause, weight gain following SCI brings about diminished work capacity, musculoskeletal decline, pain, accelerated cardiovascular disease (CVD), worsening of neurological status, and progressive life dissatisfaction. It is also disturbingly co-morbid with dyslipidemia, glucose intolerance, and insulin resistance, has wide-ranging effects on health and function, and is far more difficult to manage and reverse than obesity occurring in persons without disability.

**TO ADDRESS THIS PROBLEM YOU ARE BEING ASKED TO PARTICIPATE IN A RESEARCH STUDY** because you have a spinal cord injury resulting in paraplegia or tetraplegia, have been injured for more than one year, and are 18-65 years old. The purpose of this study is to determine whether exercise alone, or the combination of exercise and diet with professional support, will reduce body weight and decrease your risk for developing obesity, and related cardiovascular disease and diabetes. This study will use methods from the National Institutes of Health Diabetes Prevention Program (DPP) trial, and modify the exercise programs to fit the needs and abilities of people with spinal cord injuries. The study methods will then examine whether this eighteen-month program (one year and a half) involving supervised and unsupervised treatment can lower your body weight, reduce your body fat, reduce your risk factors for developing heart disease and diabetes, and improve your quality of life. The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) is the sponsor of this study and is providing the funding for this study.

### **A. STUDY PARTICIPANTS:**

You are one of thirty (30) individuals with spinal cord injury (SCI) who are expected to participate in this study. Twenty-four are expected to be men and 6 women.

You have qualified for this study because you have met ALL of the following screening characteristics:

- you have an SCI between C5 and L1 (the neck and the lower spine)
- you have been injured more than one year
- you are 18-70 years old
- you use a wheelchair as your primary means of mobility
- the relationship between your height and weight indicates you are overweight
- One or more of your fasting blood fat levels, and your fasting blood sugar, are outside of acceptable ranges

You are disqualified from participating, or may be disqualified, if ANY of the following are true or become true:

- you had a head injury along with your SCI
- you experience repeated infections that require antibiotics or hospitalization
- you have lost or gained 5% of your body weight within the past 6 months

- you have had surgery with the last 3 months
- you have had a pressure ulcer within the last 3 months
- you have arm, shoulder, or upper back pain that limits your ability to exercise
- you are currently taking antibiotics
- you have diabetes
- you are taking medications for diabetes, high blood pressure, or cholesterol
- You are taking any of the medications that we will discuss with you, including high doses of vitamins and minerals
- You have undergone a structured exercise conditioning program for leisure or competition within the past 3 months

## B. DURATION OF STUDY:

You will be enrolled in this study for approximately 14 months. During the initial 2 months you will be instructed to maintain your typical eating and activity habits. After the 2<sup>nd</sup> month you will begin the study intervention. You will undergo exercise, diet, and an educational program taught by the study investigators. After 5 months of treatment you will work with a study coordinator to identify a type of exercise you would find appealing when continued in the home setting. Choices include resistance exercise (weight lifting) with elastic bands, boxing, or other exercise you can perform at home. You will then perform the selected exercise in the laboratory for your last month of supervised exercise, which will allow the Investigators to monitor your progress and make any suggestions for use of the equipment. At the end of the 6<sup>th</sup> study month you will continue the exercise at home (or other) for another 6 months.

The following table shows what the Investigators will be studying, and when. Each study activity and the time needed to accomplish it will be described. Treatments (Exercise, Diet, and Behavior) will begin at study month 0. Thus, you will be studied for 2 months before treatments begin (-2 months).

	<b>Study Topic (Variable)</b>	<b>How the Variable is Measured</b>	<b>Study Month</b>						<b>Time (Min)</b>
			<b>-2</b>	<b>0</b>	<b>2</b>	<b>4</b>	<b>6</b>	<b>12</b>	
<b>Outcomes Focus 1: Fitness, Cardioendocrine Risk, and Inflammatory Stress</b>									
	Body Weight	Weight Measured on a Scale	X	X	X	X	X	X	<b>5</b>
	Fitness Endurance	Arm exercise test	X	X			X	X	<b>40</b>
	Fitness-Strength**	Strength when lifting weights	X	X			X	X	<b>30</b>
	Heart Disease Risk and Sugar Metabolism	Blood test from your arm	X	X			X	X	<b>10 min</b>
	Dietary Record**	Food Log (4 consecutive days)	X	X			X	X	<b>20</b>
<b>Outcomes Focus 2: Multi-Dimensional Function and Pain</b>									
	SCI Function, Participation and Pain	Five tests using written and computer evaluation of how well you function in performing	X	X			X	X	<b>45</b>

		daily activities, and how much pain you experience in daily life							
	Basic Pain and Classification	An interview with a study Investigator that determines where you have pain, the type and intensity of pain, and how much and how often you are affected by pain.	X	X			X	X	<b>10-15</b>
<b>Outcomes Focus 3: Life Quality - Independence</b>									
	Independence	How independent you are in performing daily activities	X	X			X	X	<b>20</b>
<b>Outcomes Focus 4: Self-Efficacy, Acceptance and Satisfaction</b>									
	Self-Efficacy	Confidence in your ability to exert control over your life	X	X			X	X	<b>5</b>
	Treatment Acceptance	How satisfied you are with the interventions you are doing	X	X			X	X	<b>5</b>
	Life Satisfaction	How satisfied you are your life	X	X			X	X	<b>5</b>

In addition to the described studies, we will quickly test your strength each month during months 1-6 using methods that are described below. We will test your strength in this way so that we can determine the resistance used during the exercise training sessions as you become stronger.

## DESCRIPTION OF STUDY OUTCOME VARIABLE MEASUREMENTS

- A. **Body mass** - To measure your body weight you will wheel your wheelchair on a scale where you and the wheelchair will be weighed. You will then transfer to a therapy mat and the chair will be weighed without you. The difference between the two measurements is your body weight.
- B. **Fitness tests** - You will undergo two types of fitness tests for endurance, and strength.
- **Endurance Testing** - An arm exercise test will examine whether there are reasons that you should not undergo the exercise testing (such as risks of heart damage or abnormal responses to exercise) and determine your level of fitness. You will be prepared with electrode patches placed on your chest and stomach, and have a soft flexible mask placed over your nose and mouth. The mask will collect air that you breath out during exercise and allow the Investigators to determine how hard you are working. After preparation and instructions are completed you will position your wheelchair in front of an arm exercise machine and begin exercising at a low level. Every minute the resistance on the machine will increase making it harder to exercise. You will be instructed to work as hard and long as possible, but can stop the test at any time. The Investigators will be monitoring the rhythm of your heart and breathing responses while you exercise, and may stop the test at any time if they feel you have completed the test or your continued exercise may pose a hazard. After testing the Investigators will monitor your heart rhythm for 10 minutes and provide water and a towel.
  - **Strength testing** - To determine the resistance levels assigned for your exercise session the Investigators will measure your maximum strength on a weight-lifting machine adapted for use by persons in a wheelchair. Testing will be performed using six weight-lifting maneuvers: The initial test for each station will be set at light weight. You will be instructed to perform eight repetitions of each maneuver at this weight, with each repetition lasting six seconds (3 seconds lifting, 3 seconds lowering). If eight repetitions are completed in controlled fashion the weight will be increased and the exercise repeated. You will continue to lift until you cannot complete 8 repetitions in a controlled manner using good lifting form.
- C. **Dietary habits** - After providing instructions on measuring and recording of foods you eat, we will give you an intake form to take home to write down what you eat for four days. After four days you will return the record for review. The information you provide will be entered in a computer and analyzed for how many calories you eat and the nutrients in your food. You will be taught to change your diet.
- D. **Insulin resistance and risk of cardiovascular disease** – We will take fasting blood sample for insulin, glucose (sugar), lipids (fats, like cholesterol) and inflammatory markers. Blood samples will be taken on an empty stomach.
- E. **Health Related Quality of Life** – At four time points during the study you will take four computer assisted tests to see how you are feeling about life and your health. Some of the questions will ask you about your feelings about the relationship between your health and the quality of your life, some will ask you about how much support you need from those with whom you come in contact and how you feel about that, and some will ask you if you have been sad, depressed and nervous.

- F. **Pain Assessment** – Pain will be tested by a specialist; testing will include a pain classification performed by health care provider examination and self-reported information regarding the number of pains, location, intensity, onset, presence and number of days with pain duration, variation in intensity, pain interference with activities, mood, and sleep for each specific pain problem. Additional instruments will assess neuropathic (burning) pain features and factors associated with chronic pain. Before these assessments you will undergo a physical exam (American Spinal Injury Association Neurologic Assessment) to confirm the level of your SCI, if we do not have one available within 2 years. This exam measures your strength and ability to feel touch and includes a rectal examination.

## PROCEDURES

- A. **Initial visit and assessment** - If you are given clearance to participate you will undergo a series of assessments. All of the assessments will be performed 2 months before you begin the intervention.

If it is found during the initial exercise test that the exercise may pose a risk to your heart you may be excused for the study. The same is true if the resistance exercise causes pain, or the test of your sugar shows that you have diabetes. If you have a mild form of diabetes you may still be enrolled in the study, although if it doesn't improve by the time of the 2-month study sampling, you may be released from the study and referred for needed medical treatment of the condition.

During the first 2 study months you will keep your diet and exercise activities unchanged.

### **B. EXERCISE TRAINING SESSIONS:**

**1 hour/session – 3 x weekly – 24 weeks**

Each of your exercise training sessions is to be performed in the clinic (initial 6 months) and will last 45-60 minutes and employ resistance training (weight lifting) and high-speed, low resistance activities (arm cranking). You will perform 10 repetitions of lifting. Every time you complete two resistance exercises you will perform arm exercise for two minutes on a stationary machine. You will rest 10 seconds between each set of repetitions, and will complete three cycles of the exercises. At the end of each month we will retest your strength and change the weight you lift to match your change in strength. Sessions will be on non-consecutive days within a week (Monday-Wednesday-Friday).

### **BEHAVIOR AND DIETARY TRAINING SESSIONS:**

**1 hour/session – Once weekly – 16 weeks**

If you have been assigned to Group 1, you will participate in 16 educational sessions that will focus on behavioral control of your body weight. If you have someone who does your food shopping and cooking they are welcome to attend the sessions. The sessions will include information about ways to eat, changing your diet to one that is healthier, and what to do if you feel like overeating. The diet being used for Group 1 will include lean meats and fish, healthy fruit and vegetables, and products with olives and olive oil. For education sessions 7, 8, and 10 the two groups will receive different types of information.

The topics of the sessions are listed in the following table:

C. <u>CORE INTERVENTION TRAINING CURRICULUM OUTLINE.</u>		
Session	Topic	
Focus is on diet and exercise goals and education	1	Introduction to lifestyle intervention. Explain study goals.
	2	Introduce self-monitoring of weight at home.
	3	Teach 3 ways to eat less fat.
	4	Educate about healthy eating. Recommend alternate foods.
	5	Introduce physical activity modules.
	6	Tailor physical activity regimen to needs of the individual.
	7	-Teach principles of energy balance between calories and exercise. -Teach principles of health maintenance from exercise.
	8	-Introduce principles of stimulus control as a method to prevent unhealthy eating. -Introduce principles of stimulus control as a method to maintain exercise adherence.
Focus is on psychosocial and behavioral strategies	9	Present five-step model of problem solving.
	10	Introduce basic skills for eating and exercising away from home. Introduce basic skills for exercising away from home.
	11	Practice identifying negative thoughts and how to counter them.
	12	Introduce concept that slips are part of lifestyle change and provide tips for behavioral change maintenance.
	13	Introduce principles of aerobic fitness and coping with boredom.
	14	Provide strategies for managing social cues, both stressful and supportive.
	15	Summarize stress management principles presented over the course of the intervention.
	16	Focus on enhancing motivation and maintaining behavioral change post-lifestyle intervention.

\* Red Cells denote sessions with dietician.

#### **D. LIFESTYLE COACH:**

At the beginning of the study you will be teamed with a Lifestyle Coach, who will help you to modify your behaviors and assume a healthier lifestyle. The Lifestyle Coach may attend some of your training sessions, and might contact you if you need assistance. You may also call this individual if you are in need of additional support.

As part of the study you will be contacted by your lifestyle coach every 1-2 weeks to see how you are managing your exercise and diet.

## SESSION OUTLINE FOR CORE INTERVENTION CURRICULUM

### A. Session 1A:

#### Welcome to the Lifestyle Balance Program

##### Objectives:

In this session, you will:

- Meet the lifestyle coach and study team.
- Review the Standard Healthy Lifestyle Guidelines, if not presented at the time you receive your study group assignment.
- Be given the Lifestyle Balance notebook.
- Discuss your initial reaction to being assigned to the Lifestyle Balance group.
- Receive an overview of the Lifestyle Balance Program.
- Learn the two Lifestyle Balance goals and why they are important.  
Discuss key aspects of the coach-participant relationship

Choose to focus either on the weight loss or the physical activity goal first.

### B. Session 1B:

#### Getting Started Losing Weight

##### Objectives:

In this session, as you have chosen to focus on the weight loss goal first, you will:

- Learn the reason for self-monitoring foods eaten and the basic principles of self-monitoring.
- Be assigned self-monitoring of foods eaten and circling of high-fat foods; practice this.

You will receive weighing and measuring tools.

### C. Session 2:

#### Be a Fat Detective

##### Objectives

In this session, you will:

- Begin to graph weight and be assigned self-monitoring of weight.
- Learn the reason for basic principles of self-monitoring fat grams.
- Receive your fat gram goal.
- Practice finding foods in the Fat Counter and figuring out the number of fat grams in foods.

Learn to calculate a running fat gram total for the day.

#### **D. Session 3:**

### **Three Ways to Eat Less Fat**

#### **Objectives:**

In this session, you will:

- Review self-monitoring skills, and learn in more detail how to weigh and measure foods, by guessing the amounts of selected high-fat foods, actually measuring the amounts, and then calculating the fat grams.
- Learn three ways to eat less fat.
- Make a plan to eat less fat.

#### **E. Session**

**4:**

### **Healthy Eating**

#### **Objectives:**

In this session, you will:

- Discuss how eating less fat fits into the overall context of healthy eating.
- Review the Food Guide Pyramid and its recommendations, including to lower fat.
- Compare your eating pattern to the Food Guide Pyramid.
- Review more examples of ways to eat lower-fat foods instead of high-fat foods.

Be introduced to the importance of eating more grains, vegetables, and fruits.

#### **F. Session 5:**

### **Move Those Muscles**

#### **Objectives:**

In this session, you will:

- Receive the Lifestyle Balance activity goal.
- Discuss why the activity goal is important.
- Discuss current level of physical activity.
- Be encouraged to participate in the Lifestyle Balance activity sessions.
- Identify other activities equivalent to brisk walking that you enjoy.

You will develop an activity plan for the coming week that includes the Lifestyle Balance activity sessions and other moderate activities that you enjoy.

### **G. Session 6:**

#### **Being Active: A Way of Life**

##### **Objectives:**

In this session, you will:

- Begin to graph activity.
- Discuss time as a barrier to activity.
- Learn two different ways to find the time to be active.
- Discuss lifestyle activity.
- Discuss ways to prevent injury and receive handouts on how to do some simple stretches and when to stop exercising.
- Develop an activity plan for the coming week (for most participants, this will be a weekly total of 90 minutes).

### **H. Session 7:**

#### **Tip the Calorie Balance**

##### **Objectives:**

In this session, you will:

- Discuss how healthy eating and being active are related in terms of calorie balance.
- Discuss how calorie balance relates to weight loss.
- Review your progress so far in terms of a) changes made in fat/calorie intake and activity, and b) weight change. Discuss how this relates to calorie balance.
- Develop an activity plan for the coming week.

If weight loss is less than what is expected, you will make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

### **I. Session 8:**

#### **Take Charge of What's Around You**

##### **Objectives:**

In this session, you will:

- Learn about food and activity cues and ways to change them.
- Mentally search the participant's home, work place, and where the participant shops for food, looking for problem food cues and discussing ways to change them.
- Learn ways to add positive cues for activity and get rid of cues for inactivity.
- Develop an activity plan for the coming week (150 minutes per week).

**J. Session 9:  
Problem Solving**

**Objectives:**

In this session, you will:

- Learn the five steps to problem solving.
- Practice the steps using a problem you are experiencing now with eating less fat/calories or being more active.

**K. Session 10:  
Four Keys to Healthy Eating Out**

**Objectives:**

In this session, you will:

- Learn four basic principles for healthy eating out: **planning ahead, assertion, stimulus control, and healthy food choices.**
- Identify specific examples of how to apply these principles at the type of restaurant you go too often.
- Practice making a meal selection from an appropriate menu.
- Practice out loud how to ask for a menu substitution.

**L. Session 11:  
Talk Back to Negative Thoughts**

**Objectives:**

In this session, you will:

- Recognize that everyone has negative thoughts and identify examples of them.
- Learn how to stop negative thoughts and talk back to them with positive ones.
- Practice stopping negative thoughts and talking back to them with positive ones.

**M. Session 12:  
The Slippery Slope of Lifestyle Change**

**Objectives:**

In this session, you will:

- Review your progress since Session 7 or 8 ("Tip the Calorie Balance").
- Identify some things that cause you to slip from healthy eating or being active.
- Discuss what to do after a slip to "get back on track again."

**N. Session 13:**  
**Jump Start Your Activity Plan**

**Objectives:**

In this session, you will:

- Discuss ways to add interest and variety to your activity plans.
- Learn the definition of “aerobic fitness.”
- Learn the F.I.T.T. Principles (frequency, intensity, time, and type of activity) as related to heart (aerobic) fitness.

**O. Session 14:**  
**Make Social Cues Work *for* You**

**Objectives:**

In this session, you will:

- Review examples of problem social cues and helpful social cues.
- Discuss ways to change problem social cues and add helpful ones.
- Review strategies for coping with social events such as parties, vacations, visitors, and holidays.
- Make an action plan to change a problem social cue and add a helpful one.

**P. Session 15:**  
**You Can Manage Stress**

**Objectives:**

In this session, you will:

- Discuss how to prevent stress and cope with unavoidable stress.
- Discuss how the intervention curriculum and objectives can be a source of stress and how to manage that stress.

**Q. Session 16:**  
**Ways to Stay Motivated**

**Objectives:**

In this session, you will:

- Receive a certificate of participation.
- Review your progress since Session 1, and if not at goal, develop a plan to attain your goal.
- Discuss the importance of motivation and ways to stay motivated.

## **RISKS AND DISCOMFORTS OF STUDY PARTICIPATION:**

- The risks of blood drawing include: fainting, the occurrence of temporary discomfort and/or bruise at the site of puncture; rarely, infection or the formation of a small clot or swelling to the vein and surrounding area may occur.
- You will be undergoing a series of assessments to test your strength, and endurance. You will also perform multiple weekly sessions of exercise including both strength and endurance exercises. During endurance testing and the exercise session you will wear a flexible mask over your nose and mouth to collect the air you exhale, which will allow the investigators to measure how hard you are working. The mask placed over the mouth and nose may feel confining, although the air flowing through it will not be restricted in any way.
- It is likely that you will feel tired after the exercise sessions. During intense arm cranking exercise you may injure your hands, arms, or shoulders, which may make your daily activities more difficult to perform.
- There is a risk of complications involving the heart. In exercise testing to exhaustion, 1 in 3000 persons sustains symptoms that require them to be seen by a physician or to be transported to a hospital. One in 30,000 persons sustains permanent heart damage or dies.
- In rare cases the tape used to affix the EKG electrodes to your chest can cause an allergic reaction. This normally goes away within several hours after they are removed.
- Completing the questionnaires may make you feel nervous or upset.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the research staff. You have the right to ask any questions about the potential and/or known hazards of this study at any time. You will be asked to tell the study doctor about any possible side effects you might have at any time during the study.

## **BENEFITS:**

No direct benefit can be promised by taking part in this study. However, it is likely that you will become more fit from undergoing exercise conditioning. It is possible that the diet being tested may cause you to lose body weight.

## **A. ALTERNATIVES:**

You have the alternative not to participate in this study. You can decide to stop participating in this study at any time. Not participating in this study will not affect your medical care. You can perform exercise and undergo diet without being part of this study.

## **B. COSTS:**

You will not have to pay for the study procedures. However, you will be responsible for costs associated with your transportation to the medical center, and costs for parking if you need to park your vehicle.

**C. INCENTIVES/PAYMENTS TO PARTICIPANTS:** You will be paid \$750 for your participation in the study. You must complete a W-9 form in order to receive payment for participation. This information will not be linked to any of the study data and will only be used for payment purposes. This information will not be linked to any of the study data and will only be used for payment purposes. You will receive \$150 after completing the screening and enrollment procedures, \$150 after 3 months of supervised clinical program, another \$150 after completing the supervised clinical program (6 months), and the balance of \$ 300 after the extension program and all data collection is completed at 12 months. Payment will be made in the form of a check, which you should receive about 2-3 weeks after your paperwork is submitted for payment.

## **D. COMPENSATION FOR STUDY-RELATED INJURY:**

You may be exposed to risk of injury from participation in this study. If injury occurs, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

## **E. VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THE STUDY:**

Your participation in this study is voluntary. You may refuse to participate, or withdraw from the study at any time, without penalty or loss of benefits to which you are otherwise entitled. This will not affect the medical care you receive from the study doctor or UM/Jackson Memorial Hospital. You must tell the study doctor if you wish to stop taking part in the study. Your participation in this study may be discontinued, without your consent, at any time by the study doctor, if he/she believes that participation in the study is no longer in your best interest. The Institutional Review Board (IRB), regulatory authorities, or the sponsor may also discontinue your participation in the study.

You can contact the study doctor at:

Mark S. Nash, Ph.D., FACSM  
Department of Neurological Surgery  
University of Miami Miller School of Medicine  
Lois Pope Life Center  
1095 NW 14th Terrace, R-48  
Miami, FL 33136  
304 243-3628 (Office)  
305 243-6946 (24 hour page operator)

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your health information. Although they will stop collecting new information about you they may need to use the information they have already collected to evaluate the study results. If you start the study and then you cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study findings.

#### **F. CONFIDENTIALITY:**

By signing this consent, you authorize the Investigator(s) and his/her/their staff to access your medical records and associated information as may be necessary for purposes of this study. This information will also be shared with the Sponsor of this study, (National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)) and persons working with the Sponsor to oversee the study.

Your records and results will not be identified as pertaining to you in any publication without your expressed permission.

The Investigators and their collaborators, staff will consider your records confidential to the extent permitted by law. The Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), and The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) may review these research records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.

Your paper records will be maintained in a locked file cabinet, placed within a locked office, which can only be accessed by a locked corridor at the Lois Pope Life Center. Electronic records will be stored on a computer at the Office of Research Information Management of the University of Miami, which is accessed by a password known to the Principal Investigator and his research staff, and to university computer maintenance personnel who are required to maintain the confidentiality of this information.

The study site personnel may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

#### **WHOM TO CONTACT:**

If at any time you have any questions about the study, you may contact Mark S. Nash, Ph.D. at 305-243-3628.

If you have any questions relating to your rights as a research subject, please contact **the University of Miami's HUMAN SUBJECTS RESEARCH OFFICE (HSRO)**, at [305-243-3195](tel:305-243-3195).

## WEIGHT MIRROR

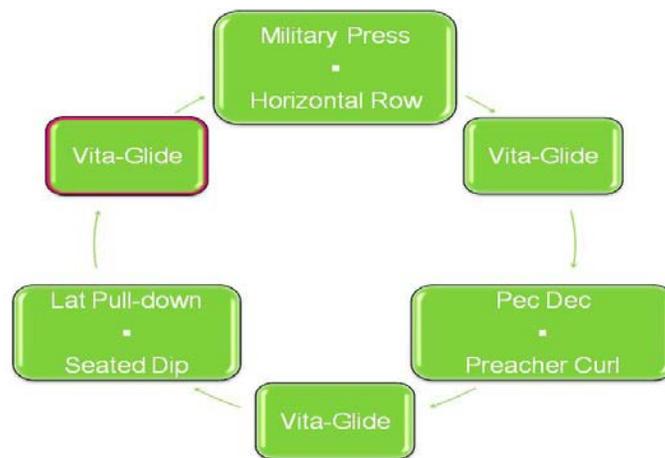
- As a component of the Behavioral Intervention, the Internet-based freeware, Weight Mirror, will be used to create a 'virtual image' of you which is 7% lighter than your actual weight at the onset of the study.
- Visualization of weight loss, in this manner, will be used as a motivational tool.
- A photograph will be taken of you at the onset of the study (Baseline), and uploaded to the Weight Mirror program for virtual image creation.
- The original photograph will be used as a reference along with the virtual image.
- NEW photographs will be updated at 6, and 12 months as a visual tool to monitor your progress.
- <http://makeovr.com/weightmirror/>

## A. DESCRIPTION OF EXERCISE MANEUVERS UTILIZED IN CRT.

Exercise Maneuver	Description
Military Press	Shoulder abduction with scapular elevation and upward rotation starting from the fully adducted and depressed position.
Horizontal rows	Shoulder horizontal abduction with scapular adduction starting from a position of maximum forward reach.
Pec dec	Should horizontal adduction while in external rotation to the midline, from the maximum tolerated horizontal abduction in external rotation.
Preacher curls	Elbow flexion supported on an inclined pad from the fully extended position.
Latissimus pull-downs	Shoulder adduction with scapular downward rotation and depression starting from the maximal upward reach position.
Seated dips ("Rickshaw")	Shoulder flexion, scapular depression, and elbow extension while maintaining arms as near the body as possible, from the fullest allowed point of shoulder joint extension, scapular elevation, and elbow flexion.

## B. CRT DESIGN:

- Each training session will be preceded by a 2-minute warm-up on a Vita-glide® arm ergometer.
- Resistance exercises will be performed in pairs (2 maneuvers in succession) each incorporating 10 repetitions of each maneuver lasting six seconds (3 seconds concentric, 3 seconds eccentric).
- Two minutes of endurance exercise is then interposed using a Vita-glide® arm ergometer at a cadence of 50 rpm without applied resistance
- Two more resistance maneuvers are performed.
- These activities are alternated until the participant has rotated through each resistance station **three times**.



Start/Finish

### Modifications to CRT for participants with tetraplegia:

- Adaptations to work-out for persons with tetraplegia as high as the C5 level.
- Resistance maneuver order is altered to reduce time needed for changing the resistance stations.
- Resistance and endurance exercises are performed in contiguous time blocks – order of exercise (i.e. resistance and endurance) are alternated on each training day.
- Each training session will be preceded by a 10-minute warm-up on a Vita-glide® arm ergometer.
- Each resistance station will be performed **twice only**.

