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:	

Age		18-70
Gender		
Racial/Ethnic background		
Waist Circumference		≥ 94 cm
BMI		≥ 20 kg/m^2
Fasting dyslipidemia		HDL-C ≥ 40 mg/dL **OR** TG ≤ 150 mg/dL

OVERVIEW

You are being asked to participate in a research study because you are the *caregiver* of a person who has a disability from spinal cord injury or disease (SCI/D) (the 'care-receiver'). A caregiver is an individual who provides social and/or physical support including personal assistance, routine emotional encouragement and/or social interaction to the person with SCI/D. This study will enroll a person with SCI/D (care-receiver) and their caregiver as a team (partners), although the caregiver will undergo different types of testing and treatment than the care-receiver.

The purpose of this study is to address the serious problem of overweight/obesity and related health and behavioral problems occurring after SCI/D. It is known that people with SCI/D gain body weight after their injury, which makes daily activities more challenging to perform and increases the risk for medical conditions such as diabetes (a disorder of sugar metabolism) and cardiovascular (heart and blood vessel) disease, and pain. The Investigators want to better understand the impact of these complications on health, function, pain, and behavior (meaning, attitudes, beliefs, and acts) within the lives of persons with SCI/D. We also want to study the caregivers of people with SCI/D, who are also known to be affected by injury, poor health, and stress experienced by individuals with SCI/D that they care for.

A recent study conducted by the National Institutes of Health reported that the combination of nutrition, exercise, and behavioral interventions significantly reduced the risks for developing diabetes in a population of persons without disability. The current study will use similar methods from the National Institutes of Health *Diabetes Prevention Program* (*DPP*), and modify the exercise programs to fit the needs and abilities of people with SCI/D. The investigators have tested this treatment program and found it effective for improving fitness and reducing risks from diabetes in persons with SCI/D. The Investigators now want to know whether the treatments also improve life quality and reduce pain for people with SCI/D, and whether a combined program of *lifestyle management* with *exercise, nutrition, and behavioral counseling* can provide similar benefits of improved health and life-satisfaction for their caregivers.

Thus, the study will examine in *caregivers* of persons with SCI/D whether a twelve month (one year) program involving intensively supervised lifestyle treatment (6 months) and then minimally supervised treatment (6 months) can lower body weight, reduce body fat, reduce your risk factors for developing heart disease and diabetes, reduce pain and stress associated with being a caregiver, and improve your life quality and interactions with your care-receiver. The study will be coupled with care-receivers to see whether they also benefit from the treatments, and how the partnership of care-giver and care-receiver can be improved. The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) is the sponsor of this study and is providing the funding for it to be conducted.

A. STUDY PARTICIPANTS:

A total of 30 couples (30 people with SCI/D and their 30 caregivers) in the study are expected to participate in this study (60 individuals in total).

As the caregiver of a person with SCI/D you qualify to participate if ALL of the following are true for you:

- You care for a SCI/D individual that has also been enrolled in the study.
- you are 18-70 years old

You DO NOT qualify to participate if ANY of the following are true for you:

- you have been following a diet with caloric restriction for the past six months
- you have lost or gained 10% of your body weight within the past 6 months

- you have had surgery within the last 3 months
- you have pain in the arms, shoulders, or upper back that limits your ability to exercise
- you have diabetes
- you have taken medications for diabetes, or cholesterol within the past 6 months
- You have had a heart attack, stroke, or cardiac surgery that prohibits your use of exercise
- You have undergone a structured exercise conditioning program for leisure or competition within the past 3 months.
- You are pregnant

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. You were randomized (as by the flip of a coin) to one of two study groups. Your study group 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 (or other) 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 6th study month you will continue the exercise and diet at home (or other) for another 12 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).

Study Topic (Variable)		**How the Variable is Measured**	**Study Month**						**Time (Min)**
			-2	**0**	**2**	**4**	**6**	**12**	
Caregiver Fitness and Risk for Heart and Blood Vessel Disease									
	Body Weight	Weight Measured on a Scale	X	X	X	X	X	X	**5**
	Fitness - Endurance	Exercise test on a treadmill	X	X			X	X	**40**
	Fitness-Strength**	Ability to lift weights	X	X			X	X	**30**
	Heart Disease Risk and Sugar Metabolism	Blood Test from your arm	X	X			X	X	**10 minutes / taking blood**
	Dietary Record**	4-day list of all foods and drinks	X	X			X	X	**20**
Caregiver Function and Pain									

	Caregiver Function	How well you function in performing daily activities and how much pain you experience in daily life; Pen and pencil test	X	X			X	X	**<10**
	Multi-dimensional Pain**		X	X			X	X	**15**
Caregiver Quality of Life and Independence									
	Life Satisfaction	How satisfied you are with life: computerized test	X	X			X	X	**5**
	Anxiety and Depression	Whether you are stressed or depressed; computerized test	X	X			X	X	**20**
	Treatment Acceptance	How pleased you are with the study treatment: paper and pencil test	X	X			X	X	**5**

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 MEASURMENTS

The Investigators will ask you information about age and health. The study coordinator will go over your medical history to ensure that you are in good health, and that there are no reasons that you should not participate in the study. If any concerns arise the study physician will be contacted and your participation in the study will be depend on his approval.

A. **Height, Weight, and Waist Circumference -** Your height will be measured using a wall mounted measuring device. Weight will be measured on a digital scale. Waist circumference will be measured using tape measure at the level of your belly-button.

B. **Cardiovascular Fitness -** A treadmill exercise test will examine whether there are reasons that you should not undergo the exercise testing (such as abnormal responses to exercise) and determine your level of fitness. You will be prepared with a heart rate and blood pressure monitor to determine exercising heart rate. After preparation and instructions are completed you will start walking in a treadmill at a low level of exertion. The Investigators will be monitoring the rhythm of your heart and blood pressure 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. You will have a 3 minute warm-up after which the treadmill speed and inclination will be increased every 3 minutes making it harder to exercise. The investigators will also ask you to rate how difficult and how hard do you think you are exercising and ask you to rate this exertion on a scale from 1-10 before each stage. You will be instructed to work as hard and long as possible, but can stop the test at any time. After testing the Investigators will monitor your heart rhythm for 10 minutes and provide water and a towel.

C. **Strength Testing -** To determine how strong you are the Investigators will measure your maximum strength on a weight-lifting machine. Testing will be performed using weight-lifting maneuvers on the chest and leg press machines. The initial test for each station will be set at light weight. You will be instructed to perform seven repetitions of each maneuver at this weight, with each repetition lasting six seconds (3 seconds lifting, 3 seconds lowering). If you can perform 7 repetitions the resistance will be increased until you cannot lift the weight 7 times in a controlled fashion.

D. **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.

E. **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.

F. **Health Related Quality of Life -** Three computer tests will ask questions about how satisfied you are with life, whether you have stress and depression, and how optimistic you are that the treatments you are undergoing will improve your life.

G. **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.

H. **Other Assessment Information -** If the Investigators find during the initial exercise test that the exercise may pose a risk to your health you may be excused from the study. The same is true if the weight lifting causes pain, or if the test for diabetes (abnormal sugar metabolism) shows that you have a clinical condition that needs to be treated by a physician. If you have a mild form of diabetes you may still be enrolled in the study, although if it doesn't improve by month 2 of the intervention period you may be released from the study and referred to your physician for needed medical treatment of the condition.

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

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. **CORE INTERVENTION TRAINING CURRICULUM OUTLINE.**	
	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. There may be slight discomfort in your arm or hand during the insertion of the needle. Occasionally, a small accumulation of blood (hematoma) may form at the point of insertion of the needle. This may result in a small lump that will disappear. Occasionally, a small amount of bleeding may occur around the venipuncture site. On rare occasions, a local infection may occur around the site.
- You will be undergoing a series of assessments to test your strength and endurance, and you will also perform multiple weekly sessions of exercise including both strength and endurance exercises. It is possible that you will feel tired after the exercise sessions. During intense exercise you may fatigue or injure your hands, arms, shoulders, back, or legs, which may make your daily activities more difficult to perform.
- During exercise there is a risk of complications involving the heart. In exercise testing 1 in 3000 persons sustains symptoms (feelings or signs) that require them to been seen by a physician or to be transported to a hospital. One in 30,000 persons sustains permanent heart damage or dies.
- Answering questions about your health and quality of life 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 that you might have at any time during the testing or treatment periods.

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**.

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 PROGRAM FOR CAREGIVERS.

The six-month exercise training program includes a combination of cardiovascular and resistance exercise training performed three days per week. You will perform both modalities during each exercise training session. The following exercise training protocol are within the accepted guidelines established by the American College of Sports Medicine.

Initially, you will start exercising for 20 minutes and systematically progress to 40 minutes over the course of the three months. You will then maintain the latter intensity and duration for the remainder of their exercise training program.

The resistance training protocol consists of seven exercises (chest press, seated row, shoulder press, pulldown, bicep curl, seated dip and leg press) performed on selectorized resistance training equipment. During the first six weeks, you will be asked to complete one set of 12-15 repetitions of each exercise. When 15 repetitions can be completed comfortably, without fatigue, then the resistance will be increased. This progression will continue and adjusted throughout the intervention.

Exercise Intervention Summary

a. 3x week/ 72 visits (6 months)
b. Cardiovascular exercise is split into two bouts during each session starting at 10 minutes per bout and progressing to 20 minutes per bout.
c. In between the two bouts of cardiovascular exercise, the subject's participant complete seven resistance exercises with the following prescription.
    - Weeks 1 thru 6: 1 set of 12-15 repetitions
    - Weeks 6 thru 12: 1 set of 8-12 repetitions
    - Weeks 12 thru 24: 2 sets of 8 -12 repetitions.
    - Resistance increased by 10% when high end of repetition range can be completed before fatigue.

Cardiovascular Rx Suggested Progression

Initial intensity= 50% VO2R (as determined by submaximal treadmill test).

- VO2R is measured as METs.
- (Estimated MET max – 1 MET) x .5 + 1 MET

Initial duration=20 minutes (2 bouts of 10 minutes)