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

MULTI-CENTER CLINICAL TRIAL

OPERATIONS MANUAL

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GENERAL DESCRIPTION

A. OVERVIEW

Extensive evidence documents that people with physical disabilities (PWPD) are leading longer lives, yet experiencing aging trajectories that forecast earlier appearance of ill-health and functional decline. These health hazards and progressive dysfunction they foster test the ability of PWPD to maintain an active, productive, and vigorous lifestyle. They also make the maintenance of self-sufficiency, quality of life (QoL) and personal dignity more difficult as people age with disability.

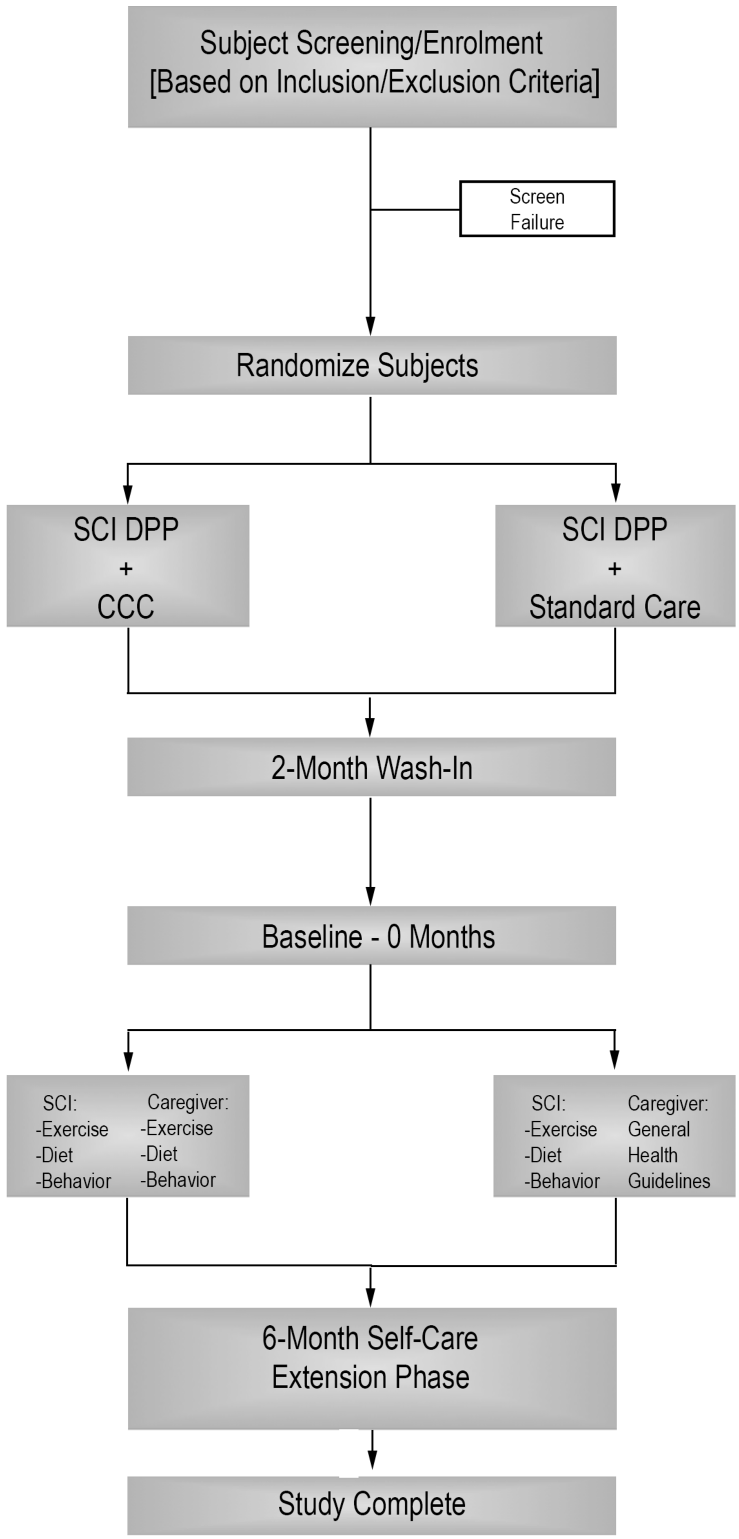
The current proposal will address the compelling problem of an overweight body habitus in persons with disability from spinal cord injuries (SCI). 'Obesity/overweight' represents the sole chronic condition whose speed of growth and widespread dispersion parallels pandemics of communicable diseases. Nearly 2/3 of Americans are currently overweight or obese, with a growth rate exceeding 10% in the past decade.3 The prevalence and impact of obesity is expected to worsen. Obesity-related health risks cross all lines of gender, geographic region, socioeconomic status, race, heritage, and educational level, and are strongly associated with 16 comorbid conditions including: cardiometabolic syndrome, hypertension, diabetes, inflammatory disease, coronary artery disease, congestive heart failure, stroke, osteoarthritis, sleep apnea, depression, cancer, respiratory failure, disorders of coagulation, and degenerative joint disease. All of these disorders are widely reported at elevated prevalence in PWPD.

While an overweight body has implications for health and function of PWPD, it also has an impact on their caregivers. Within the past quarter decade there has been a predictable shift of many health and function related responsibilities to adjuvant providers (i.e., healthcare provider extenders) -- so-called 'caregivers' – who are challenged to administer greater health and functional demands of aging PWPD while they are similarly experiencing health and functional decline accompanying their own aging. We have already started to observe - yet not fully comprehend - the many complex difficulties imposed by aging on PWPD and their caregivers, and speculate how to effectively intervene on them.

The current initiative is a randomized, controlled, multi-center intervention study aiming to a) address the concerning problem of overweight/obesity after SCI, b) better understand its impact on health and function of persons with SCI and their caregivers, and c) intervene on these hazards where inaction would forecast additional decline. We will use an intervention for all participants with SCI that is modeled after the Diabetes Prevention Program (DPP) that incorporates population-appropriate exercise, nutrition, and behavioral support.

This clinical trial manual describes the overall study design and details regarding the key components of the study such that effective execution of study objectives, appropriate data collection and outcome measures can be obtained.

B. STUDY DESIGN AND TIMELINE OF DATA COLLECTION



C. SUBJECT INFORMATION AND INCLUSION/EXCLUSION CRITERIA

Name:			☐
Code:			☐
D.O.B.			☐
Height:			☐
Weight:			☐

INCLUSION CRITERIA: SCI PARTICIPANT				
Injury level		AIS A-D **C5-L1**		☐
Injury duration		≥ 1 year		☐
Age		18-70 years		☐
Gender		Male 80%	Female 20%	☐
Racial/Ethnic background		All		☐
One or more of:				
i.	Waist Circumference	≥ 94 cm OR		☐
ii.	BMI	≥ 21 OR		☐
iii.	Dyslipidemia	HDL-C ≤ 40mg/dL (men); ≤ 50 mg/dL (women) OR TG ≤ 150 mg/dL		☐
INCLUSION CRITERIA: CAREGIVER PARTICIPANT				
Age		18-70 years		☐
Gender		Male	Female	☐
Racial/Ethnic background		All		☐
Caregivers are defined as: Family member, significant others or friends living with a disabled (SCI/D) partner who provide social and/or physical support including personal assistance, routine emotional encouragement and/or social interaction.				

EXCLUSION CRITERIA FOR BOTH SCI AND CAREGIVER PARTICIPANT:	
Structured exercise conditioning within 3 months of study entry	☐
Defined diet involving caloric restriction or nutrient modification	☐
Weight loss/gain of 10% within 6 months of study entry	☐
Surgery within 3 months of study entry	☐
Pressure ulcer within 3 months of study entry	☐
Upper limb pain that limits exercise	☐
Recurrent acute infection/illness requiring hospitalization of IV antibiotics	☐
Pregnancy	☐
Previous MI or cardiac surgery	☐
6 month history of glucose-lowering and/or lipid-lowering drug therapy	☐
Type I OR Type II diabetes (by World Health Organization [WHO] criteria)	☐
Contraindicated disorder/condition: ▪ Traumatic brain injury – residual cognitive/behavioral impairment ▪ Substance abuse/dependence ▪ Psychiatric condition	☐
Contraindicated drug therapy: ▪ β-adrenergic antagonists ▪ Maintenance α-blockers ▪ Methyldopa ▪ Thiazide and loop diuretics ▪ Parasympatholytics ▪ Zinc ▪ Estrogen/hormone replacement therapy (excluding oral contraceptives) ▪ Insulin-sensitizing drugs ▪ Lipid-altering agents	☐
We will exclude individuals with a diagnosis of pre-diabetes if, after 2 months of intervention, the following diagnostic criteria of the ADA are observed: FBG 110-126mg/dL after a fast of 8 hours OR 2 hyperglycemia symptoms (i.e. Polyuria, polydipsia and unexplained weight loss) and a causal plasma glucose ≥200 mg/dL. In the absence of unequivocal hyperglycemia, these criteria will be confirmed by repeat testing (per American Diabetes Association criteria). Should repeat testing confirm diabetes, subjects will be discharged and referred for medical treatment	☐

D. SPECIFIC AIMS AND HYPOTHESES

Specific Aim 1	A. To determine in people with chronic SCI the health and functional impact - and user acceptance and satisfaction - of a 6-month comprehensive LI program B. To determine whether these benefits are diminished following a 6-month period of minimal supervision and support
	Outcomes Focus 1: Fitness, Cardioendocrine Risk, and Inflammatory Stress
Hypotheses 1.1.1 A-E	Participants with SCI will have: A. Lower Body Mass B. Higher VO_{2Peak} and C. Higher 1-repetition maximum (1-RM) strength at 6-months compared to baseline assessments (-2 and 0 months) These effects will be: D. Preserved at 12-month follow-up and E. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
Hypotheses 1.1.2 A-D	Participants with SCI will have: A. Lower cardioendocrine risk as assessed by the surrogate marker of total cholesterol (TC) to HDL-C ratio (HDL-C) and B. Improved computed insulin sensitivity at 6-months compared to baseline assessments (-2 and 0 months) These effects will be: C. Preserved at 12-month follow up and D. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
Hypotheses 1.1.3 A-D	Participants with SCI will have: A. Lower fasting blood levels of pro-atherogenic inflammatory cytokines and B. Improved inflammasome activation at 2, 4, and 6-months compared to baseline assessments (-2 and 0 months) These effects will be: C. Preserved at 12-month follow up and D. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
	Outcomes Focus 2: Multidimensional Function and Pain
Hypotheses 1.2.1 A-D	Participants with SCI will have: A. Improved physical function and B. Increased participation at 6-months compared to baseline assessments (-2 and 0 months) These effects will be: C. Preserved at 12-month follow up and D. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
Hypotheses 1.2.2 A-C	Participants with SCI will have: A. Improved pain scores at 2, 4, and 6-months compared to baseline assessments (-2 and 0 months) These effects will be: B. Preserved at 12-month follow up and C. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
	Outcomes Focus 3: Life Quality – Independence
Hypotheses 1.3.1 A-D	Participants with SCI will have: A. Improved QoL and B. Increased independence at 6-months compared to baseline assessments (-2 and 0 months) These effects will be: C. Preserved at 12-month follow up and D. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
	Outcomes Focus 4: Self-efficacy, Acceptance and Satisfaction

Hypotheses 1.4.1 A-E	Participants with SCI will highly rate: A. Exercise Self-Efficacy B. Treatment acceptance and C. Life satisfaction at 6-months compared to baseline assessments (-2 and 0 months) These effects will be: D. Preserved at 12-month follow-up and E. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
Specific Aim 2	To determine the impact and user acceptance/satisfaction of a Complementary Caregiver Curriculum (CCC) on SCI caregiver health and function.
	Outcomes Focus 1: Caregiver Multidimensional Function and Pain
Hypotheses 2.1.1. A-D	Caregivers of persons with SCI will have: A. Improved caregiver function and B. Less pain at 6-months compared to baseline assessments (-2 and 0 months) These effects will be: C. Preserved at 12-month follow-up and D. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
	Outcomes Focus 2: Caregiver Quality of Life, Independence and Treatment Acceptance
Hypotheses 2.2.1. A-F	Caregivers of persons with SCI will have: A. Improved QoL B. Less caregiver burden C. Better life satisfaction and D. Less anxiety and depression at 6-months compared to baseline assessments (-2 and 0 months) These effects will be: E. Preserved at 12-month follow-up and F. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
Hypotheses 2.2.2. A-C	Caregivers of persons with SCI will highly rate: A. Treatment acceptance at 6-months relative to baseline assessments (-2 and 0 months) These effects will be: B. Preserved at 12-month follow-up and C. Will be significantly greater in the co-treated caregiver dyad partner than the control dyad partner
Specific Aim 3	To determine whether the complementary caregiver curriculum (CCC) enhances health and functional benefits obtained by the SCI dyadic partner enrolled in the LI program.
	Outcomes Focus 3: Crossover Benefit of Caregiver Intervention
Hypothesis 3.1	Participants with SCI will have better outcomes on all of their tested hypotheses (H1.1, H1.2, H1.3) if their caregiver partner received the CCC and not the control curriculum.

E. STUDY OUTCOMES

SCI Testing

Variable	Measure/Data Source	Outcome Sampling Time Points (By Month)			
		-2	0	6	12
Outcomes Focus 1: Fitness, Cardioendocrine Risk, and Inflammatory Stress					
Body mass	Calibrated Scale	▪	▪	▪	▪
Fitness – Endurance	Peak Oxygen Consumption	▪	▪	▪	▪
Fitness – Strength	Composite Strength; Mayhew Prediction Model	▪	▪	▪	▪
***Insulin Resistance	Homeostasis 2 Model (HOMA2) for IR	▪	▪	▪	▪
***Global CVD Risk	TC:HDL Ratio	▪	▪	▪	▪
***Inflammatory State	Inflammasome Activation; Cytokine (TNF-α, IL-1, IL-6) Production	▪	▪	▪	▪
Outcomes Focus 2: Multi-Dimensional Function and Pain					
SCI Function	SCI Functional Index (SCI-FI) – 6 Domains	▪	▪	▪	▪
Participation	Craig Handicap Assessment and Reporting Technique (CHART – SF)	▪	▪	▪	▪
Basic Pain and Classification	The International SCI Basic Pain Dataset (ISCIBDS)	▪	▪	▪	▪
Neuropathic Pain	The Neuropathic Pain Symptom Inventory (NPSI)	▪	▪	▪	▪
Multi-dimensional Pain	West Haven-Yale Multi-dimensional Pain Inventory (MPI-SCI)	▪	▪	▪	▪

Outcomes Focus 3: Life Quality - Independence					
Independence	Spinal Cord Independence Measure III (SCIM-III)	▪	▪	▪	▪
Self-Efficacy	SCI Exercise Self-Efficacy Scale (SCI-ESES)	▪	▪	▪	▪
Treatment Acceptance	Credibility and Expectancy Questionnaire (CEQ)	▪	▪	▪	▪
Life Satisfaction	Life Satisfaction Questionnaire-9 (LSQ-9)	▪	▪	▪	▪
Caregiver Testing					
Outcomes Focus 1: Caregiver Multi-Dimensional Function and Pain					
Caregiver Function	PROMIS – Physical Function – All Domains	▪	▪	▪	▪
Multi-dimensional Pain	West Haven-Yale Multi-dimensional Pain Inventory (MPI)	▪	▪	▪	▪
Outcomes Focus 2: Caregiver Quality of Life and Independence					
Anxiety and Depression	Hospital Anxiety and Depression Scale (HADS-A) Anxiety Subscale	▪	▪	▪	▪
Treatment Acceptance	Credibility and Expectancy Questionnaire (CEQ)	▪	▪	▪	▪

* We will take an additional dietary record after 3 months of intervention for both groups (SCI and caregivers).

** We will obtain a brief Pain History in addition to the MPI for caregivers at-2, 0,6,12 Months.

*** **These study outcome variables require blood sampling as outlined below:**

Study outcome	Whole blood volume per time point	Outcome sampling time points (by month)			
		-2	0	6	12
Insulin resistance	4 ml **Grey**, 4 ml **Lavender (EDTA)** (8 ml Total) (Fasting)	▪	▪	▪	▪
Global CVD risk	8 ml **Red** (8 ml Total)	▪	▪	▪	▪
Inflammatory State	4 ml **EDTA** (4 ml) (Fasting)	▪	▪	▪	▪
	Total blood draw (ml)	**20**	**20**	**20**	**20**

SHIPMENT OF SPECIMENS.

General Instructions:

Carriers:

- We recommend shipping FedEx Priority Overnight service.
- Other carriers are acceptable providing they offer overnight delivery service.
- If choosing an alternate carrier, verify policies regarding dry ice shipments (UPS does not accept boxes for shipment with greater than 5 lbs of dry ice.

Shipping Time:

- Please ship samples on Monday, Tuesday, or Wednesday to avoid transit delays over a weekend.
- The biochemistry lab is closed on weekends.

Notify us:

- Prior to shipment, send notice of sample shipment via email to: a.mendez@miami.edu
- Please include the following information:
  Sample log (used to compare with actual sample received)
  Shipment's tracking number

Shipping Address:

- Diabetes Research Institute Clinical Chemistry Lab
  University of Miami Miller School of Medicine
  Attention: Espy Perez
  1450 NW 10th Ave
  Miami, FL 33136
  305.243.5314

<u>Packing Instructions:</u>

These recommendations follow the US Center for Disease Control (CDC) guidelines for transport of biological specimens within the United States (Postal Law 18 USC, 1716) and should be strictly followed.

- <u>Supplies Needed:</u>
  - The shipping contained should consist of a corrugated cardboard box with an insulating Styrofoam box insert (1-2" wall thickness). These containers are available from scientific supply companies such as VWR.
  - Cryostorage storage boxes (cryovial size)
  - Large Ziploc freezer bags (gallon size)
  - Newspaper or other packing material
  - Paper towels or other absorbent material
  - Dry ice
- <u>Packaging Serum/Plasma Samples:</u>
  - Individual sample tube should have clearly indicated sample id numbers labeled directly on the tube.
  - Place cryovials (2 mL) into a 9 x 9 grid storage box (81 vials per box) into a 7" x 7" box. Box size should be modified as needed if sample aliquots are in larger tubes.
  - Cryostorage bags should be secured with rubber bands and place inside a large Ziploc freezer bag.
  - Place a minimum of 5 lbs (2.5 kg) dry ice on the bottom of the shipping container. Larger boxes will require additional dry ice. A good rule of thumb is at least ¼ of the available space should be filled with dry ice.
  - Place several layers of newspaper over the dry ice. This acts as a barrier and cushion between the dry ice and samples.
  - Place samples (boxed and bagged) on top of newspaper. Fill any remaining space with additional packing material (crumpled paper, packing peanuts, etc.) to prevent shifting. Please remember that as the dry ice sublimates your samples may begin to shift. It is a good idea to loosely pack the container to the top. (Don't crack the Styrofoam box!)
  - Place the sample log inside a Ziploc bag and lay this inside the box before you close the Styrofoam lid.
  - Seal the outer cardboard box with packing tape. Shippers (FedEx, DHL) require you to affix a black and white dry ice label to the outside of the box. For FedEx, check YES in the "Dangerous Goods" box and write in the weight of the dry ice enclosed.

PROCEDURES AND INSTRUCTIONS FOR STUDY OUTCOME MEASURES

A. Body Mass, Height, Waist Circumference and Body Mass Index – Body mass, in Kg, will be measured to the nearest 0.25 Kg on a calibrated scale that can accommodate the footprint of a wheelchair. Participants will be weighed both in and apart from their wheelchairs, with the outcome expressed as the average of two weightings. Height will be measured to the nearest 0.25 inch in the supine position using an individually calibrated Gulik II Plus tension regulated tape measure. Waist circumference will be measured using a Gulick II Plus tension regulated tape measure, at the level of the umbilicus and recorded to the nearest .25 inch. Body mass and height measures will be used to calculate body mass index.

B. Cardiorespiratory Endurance – will be assessed as VO2peak on an arm ergometer using open circuit spirometry. Participants will refrain from exercise 24 hours prior to testing. Ten minutes of quiet rest will precede exercise to acquire baseline values. A peak continuous graded exercise test. Participants will perform a VO2peak test using a calibrated electronically braked arm ergometer (Angio, Lode BV, Groningen, Netherlands). Heart rate and oxygen consumption will be recorded continuously from baseline through recovery. HR will be measured by standard 12-lead electrocardiography and expired respiratory gases will be collected and analyzed with an online open-circuit metabolic cart (Vmax ENCORE, CareFusion, San Diego, CA). Participants will position their wheelchair at such a distance from the ergometer that their arms are slightly flexed and wedges are placed under the rear wheels to restrict chair movement. Individuals with tetraplegia will have their hands affixed to the cranks with hand wraps and athletic tape. Participants will rest quietly in their wheelchairs for 10 minutes before the test to establish resting values. Thereafter, participants will began cranking on the arm ergometer at a starting load of 0 W and will be instructed to maintain a cadence of 55-65 rpm. A digital display will provide real-time revolutions per minute (rpm) feedback. Every minute, resistance will increase at a rate of 3-5 W for individuals with tetraplegia and all women or 10 W for individuals with paraplegia. Participants will continue until volitional fatigue, manifesting as either a nonverbal communication of the desire to stop or an inability to maintain cadence above 55 rpm. Upon cessation, participants will rest quietly for 10 minutes. Exercise termination will be based on the American College of Sports Medicine Guidelines for Exercise Testing and Training [ACSM, 9th Edition], with peak work defined as volitional exhaustion, inability to maintain targeted workload, or when increasing workload fails to further increase VO2. Expired gases will be continuously analyzed by an open circuit indirect calorimetry system (Encore®, with Cardiosoft® EKG monitoring, VIASYS, Inc., or equivalent). EKG rhythm will be continuously monitored to screen ischemia, rhythm disturbances, and signs/symptoms of exertional intolerance.

C. Composite Strength – To test strength we will measure upper extremity dynamic strength on a Helms Equalizer 7000 multi-station exerciser (Helms Distributing, Polson, MT, or equivalent resistance equipment) using the same maneuvers adopted for training. One-repetition maximum (1RM) testing will be carried out to assess upper extremity dynamic strength as follows:

- Subjects will be instructed to perform 8 repetitions of each maneuver with each repetition lasting six seconds (3 seconds concentric, 3 seconds eccentric).
- If 8 repetitions are completed in a controlled fashion, weight will be increased and the exercise repeated – incremental increases will be 5 kg (paraplegia) and 2.5 kg (tetraplegia) until 8 repetitions **cannot** be completed.
- 1RM will be calculated using the Mayhew regression equation:

$$\mathbf{1RM = Wt/(0.533 + 0.419e^{-0.055*REPS})}$$

where **1RM** is the calculated one repetition maximum strength, **Wt** is the resistance used in the last set where more than three repetitions but less than eight repetitions were completed, and **reps** equals the number of repetitions completed in the last set of testing.

D. Insulin Resistance, CVD Risk and Inflammatory State – participants will abstain from caffeine and alcohol consumption for 24 hours before testing, and will be tested in the post-absorptive state (10 hour overnight fast, and 48 hours after the last exercise bout.) Ten ml of whole blood will be drawn into citrate and Gel and Lysis Activator (serum) tubes between 8:00-10:00 AM. Blood will clot at room temperature for 30 minutes before centrifugation at 1500 x g, followed by serum recovery. Platelet poor plasma will be prepared from citrate tubes by centrifuging at 3000 x g for 30 minutes. Each site will prepare their own samples, and the -80o frozen samples from Craig Hospital will be shipped (on dry ice) in bulk via FedEx overnight priority. Fasting glucose assay will be performed on an auto-analyzer (Roche Cobas-Mira) using the glucose oxidase method and insulin assayed by Enzyme-Linked Immunosorbent Assay (ELISA) (Mercodia), as we have described.

I. <u>Insulin Resistance</u> – The internet freeware (www.dtu.ox.ac.uk/homacalculator/download.php) will be used to calculate the second generation Homeostatic Model Assessment 2 (HOMA2), a paradigm method for assessing β-cell function and insulin resistance (IR) from basal (fasting) glucose and insulin or C-peptide concentrations. The HOMA2 model has been validated against physiological methods, compares favorably with other models (i.e., euglycemic clamp, minimal model, ISI0-120) and requires only a single plasma sample assayed for insulin and glucose.

II. <u>Global CVD Risk</u> – The proxy of TC:HDL ratio [and secondarily the LDL:HDL ratio], which has predictive power for future CVD risk that is near equivalent to the Framingham regression equation will be used to asses CVD risk. Assays for TC, TG, and HDL-C will be performed as we have described using automated methods and commercially available kits according to manufacturers' instructions and run procedures. HDL-C will be assayed after precipitation of apoB-containing lipoproteins. LDL-C will be computed by the method of Friedewald.

III. <u>Pro-atherogenic Inflammatory Stress</u> – Inflammatory biomarkers will be assessed as surrogates for systemic inflammatory stress profiles as measured by cytokine and antibody production and gene expression in blood serum [inflammasome formation/ activation and cytokine (TNF-α, IL-1β and IL-6) production] using Western blotting and commercially available ELISAs, methods we described in studies from our laboratories.

E. SCI Function – we will operationalize 'function' as participant-reported outcomes (PRO) of physical function. This refers to an individual's capacity to carry out activities that require bodily movement. Most importantly, PROs capture their personal assessment of function. PROs are defined as "a measurement of any aspect of a patient's health status that comes directly from the patient," and capture the impact of a disease or condition on the individual. We will administer the SCI Functional Index (SCI-FI) computer adapted test (CAT). The SCI-FI is a PRO that captures activity limitations of persons with SCI. It has six domains; basic mobility, self-care, fine motor function, ambulation, manual wheelchair, and power wheelchair. We will assess basic mobility and self-care in all participants, and fine motor, ambulation, manual wheelchair and power wheelchair as befits the individual's injury and mobility characteristics.

F. Participation – We will also administer the Craig Handicap Assessment and Reporting Technique Short Form (CHART-SF), which was designed to measure the level of participation in a community setting. The CHART collects information on the degree to which the respondent fulfills the roles typically expected from people without disabilities. There are 5 dimensions that can be answered in quantifiable, behavioral terms (e.g., hours of physical assistance, how much time is someone with you to assist you, how many relatives do you visit, etc.). For each CHART dimension, a scoring procedure allows a score from 0 to 100 points, the latter being the maximum attainable, corresponding to a role fulfillment equivalent to that of most individuals without disabilities. We will focus our attention on the Physical Independence, Mobility, Occupation and Social Integration Subscales. Extensive research has shown good levels of reliability and validity.

G. Pain – For pain we will consider that pain is multidimensional, and this is reflected in our choice of tests for assessment and classification.

I. **Basic Pain** – The International SCI Pain Basic Data Set (ISCIPBDS) evaluates the worst, second worst and third worst pain when a person experiences one or more pains. The ISCIPBDS includes a pain classification made by a healthcare professional, and self-reported information regarding number of pain problems, location, intensity, and temporal pattern (i.e., onset, presence and number of days with pain over the last 7 days, duration, and variation in intensity). It also assesses pain interference with activities, mood and sleep for each specific pain problem. A self-report version of the ISCIBPDS was found to be valid with respect to questions about pain interference, intensity, location, frequency and duration of pain and time of day of worst pain. The ISCIPBDS was officially endorsed by major SCI and pain organizations (e.g., the International Spinal Cord Injury Society, the American Spinal Injury Association), and is now part of the NIH Common Data Elements (www.commondataelements. ninds.nih.gov). The ISCIPBDS was recently revised based on new developments in the field and on suggestions from the SCI and pain clinical and research community (version 2.0). The revisions include the updated SCI pain classification, omission of 3 questions regarding temporal pain pattern and 3 pain interference questions. The remaining 3 pain interference questions concern perceived interference with activities, mood, and sleep for overall pain rather than for individual pain problems and are scored on a 0 to 10 scale. The revised version has also been endorsed by all relevant organizations and is currently in press for publication in Spinal Cord.

II. **Neuropathic Pain –** The Neuropathic Pain Symptom Inventory (NPSI) is sensitive to change and evaluates five common features of neuropathic pain. The psychometric properties of the NPSI, including its sensitivity to change, provide useful evaluation in clinical practice and clinical trials. The NPSI shows many similarities among different patient groups with peripheral or central lesions, which supports its utility as a method for pain evaluation in diverse neurotrauma populations.

III. **Multi-dimensional Pain –** We will administer the Multidimensional Pain Inventory-SCI version (MPI-SCI), a psychometric instrument designed to assess pain and a range of psychosocial factors associated with chronic pain. Answers are given on a numerical rating scale ranging from 0 to 6. The MPI-SCI consists of three sections: (1) Pain impact; (2) Perceived Social support; and (3) Activities. The internal consistency, stability, and validity of the MPI-SCI have been demonstrated in the SCI chronic pain population.

An ASIA (international standards for neurological classification of spinal cord injury) will be administered before these assessments if we do not have one available within 2 years.

H. Quality of Life, Health Perceptions, Social Functioning and Vitality – We will administer:

I. **The Spinal Cord Independence Measure-III (SCIM-III) –** A 19-item questionnaire assessing domains of self-care, respiration and sphincter management, and mobility. The measure has been shown to have excellent internal consistency with α ranging from .77 to .85.188,189 The SCIM III correlates with Functional Independence Measure subscales with r values of .78 to .80.

I. Self-Efficacy, Treatment Acceptance and Life Satisfaction – We will administer:

I. **SCI Exercise Self-Efficacy Scale (ESES) –** A self-report to measure perceived exercise self-efficacy in individuals with SCI. The scale requires individuals to indicate their confidence in performing physical activities and exercise. The scale is SCI-specific and measures perceived self-efficacy for various types of physical exercise. The measure has acceptable reliability and validity in SCI populations.

II. **The Credibility and Expectancy Questionnaire (CEQ) –** Will measure treatment expectancy. The CEQ demonstrates high internal consistency, (a = 0.79–0.90). Retest reliability is r = 0.82 for the expectancy factor and r = 0.75 for the credibility factor. Items are rated based on cognitive appraisal and based on feelings about the therapy (e.g., how confident would you be in recommending this treatment to a friend who experiences similar problems?).

III. **Satisfaction Questionnaire 9 (LSQ-9) –** The nine-item version contains a single item assessing overall life satisfaction, along with eight additional items that are domain-specific. Normative data for chronic SCI has been obtained by Post et al. The measure has been used extensively in research with persons with SCI and has been shown to have excellent reliability and internal validity.

J. Caregiver Function – We will administer the four sub-domains of the PROMIS Physical Function CAT: mobility (lower extremity function), dexterity (upper extremity function), axial (neck and back function), and ability to carry out instrumental ADLs.

K. Caregiver Pain – We will obtain a brief Pain History and administer the:

I. **West Haven-Yale Multidimensional Pain Inventory (MPI),** which is a comprehensive instrument designed to assess a range of self-reported behavioral and psychosocial factors associated with chronic pain syndromes. The MPI comprises three sections: Section 1 (Pain Impact), Section 2 (Responses by Significant Others), and Section 3 (Common Activities). The Pain Severity, Life Interference Life Control, Affective Distress, Support, Negative Responses, from others, Solicitous Responses (SR) from others, and Distracting Responses from others subscales measure cognitive, affective, social and behavioral responses. The remaining subscales assess the degree of participation in various types of daily activities: Household Activities Away from Home, Social Activities and Outdoor Activities.

L. Life Satisfaction, Anxiety and Depression, and Treatment Acceptance – We will administer:

I. **Anxiety and Depression –** The **Hospital Anxiety and Depression Scale** (**HADS**) is commonly used to determine the levels of anxiety and depression that a patient is experiencing. The HADS 14-item scale – 7 relating to anxiety and 7 relating to depression – will generate ordinal data aimed at anxiety and depression detection in people with physical health problems.

II. **The Credibility and Expectancy Questionnaire (CEQ) –** For treatment acceptance as described above for SCI participants.

III. **PROMIS - Social Satisfaction Short Form**: The PROMIS adult Satisfaction with Social Roles and Activities short form item bank assesses satisfaction with performing one's usual social roles and activities (e.g., "I am satisfied with my ability to participate in family activities"). We will be using the subset banks Satisfaction with Participation in Social Roles (v1.0), with revised item pools.

M. Dietary Record – All Participants: To follow up caloric intake and expenditure, and ascertain potential dietary drift in the caregiver control arm, participants will be instructed to complete and return a sample 4-day dietary record. Habitual food and drink consumption are recorded and logs returned to study personnel. Dietary composition will be analyzed using a widely used nutritional software package (Food Processor II Windows v. 7.6; ESHA Research, Salem, OR). The collected data will provide a comprehensive food intake assessment for scrutiny by both investigators and study participants undergoing nutritional intervention.

EXERCISE PROGRAMS: CIRCUIT RESISTANCE TRAINING (CRT).

A. General principles:

- **CRT** is a mode of training that employs lockstep resistance maneuvers interposed with short periods of un-resisted, high velocity arm work.
- Study participants will undergo **CRT three times per week** on non-consecutive days for **24 weeks.**
- Resistive loads for training during weeks 1 and 2 of each month will be **50%** of the 1-repitiion maximal (1RM) values calculated during initial isoinertial strength testing.
- Resistive loads will be increased to 55% and 60% of the 1RM during training weeks three and four for each month, respectively.
- 1RM strength will be assessed as follows:
  - Subjects will be instructed to perform 8 repetitions of each maneuver with each repetition lasting six seconds (3 seconds concentric, 3 seconds eccentric).
  - If 8 repetitions are completed in a controlled fashion, weight will be increased and the exercise repeated – incremental increases will be 5 kg (paraplegia) and 2.5 kg (tetraplegia) until 8 repetitions **cannot** be completed.
  - 1RM will be calculated using the Mayhew regression equation:

$$\mathbf{1RM = Wt/(0.533 + 0.419e^{-0.055*REPS})}$$

where **1RM** is the calculated one repetition maximum strength, **Wt** is the resistance used in the last set where more than three repetitions but less than eight repetitions were completed, and **reps** equals the number of repetitions completed in the last set of testing. These loads will be increased to 55% and 60% of the 1-RM during training weeks three and four of each month, respectively. The 1-RM for each maneuver will be re-computed during the last training session every 4 weeks, which will correct for increasing strength.

- 1RM will be assessed in the following time schedule:

Exercise Maneuver	Upper extremity dynamic strength (1RM)								
	-2	0	1	2	3	4	5	6	12
Military press	▪	▪	▪	▪	▪	▪	▪	▪	▪
Horizontal rows	▪	▪	▪	▪	▪	▪	▪	▪	▪
Pec dec	▪	▪	▪	▪	▪	▪	▪	▪	▪
Preacher curls	▪	▪	▪	▪	▪	▪	▪	▪	▪
Latissimus pull-downs	▪	▪	▪	▪	▪	▪	▪	▪	▪
Seated dips (“Rickshaw”)	▪	▪	▪	▪	▪	▪	▪	▪	▪

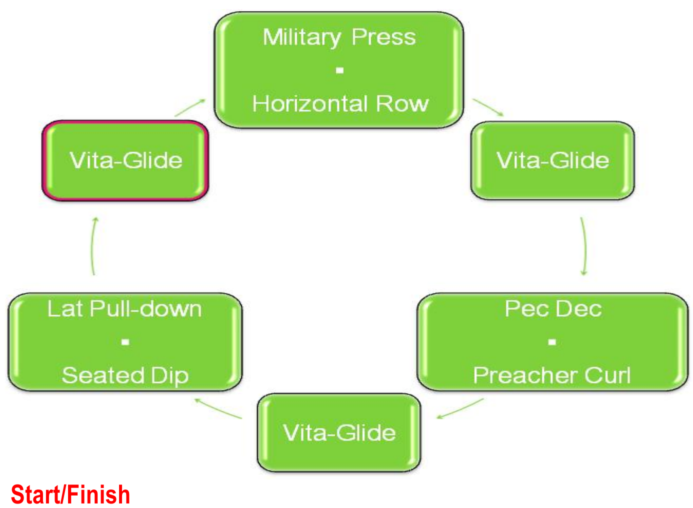
*Note: Red Cells denote data collection time-points for analysis; Black Cells denote monthly 1RM adjustments as described above.

B. Description of Exercise Maneuvers used 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.

C. CRT training session design for participants with paraplegia:

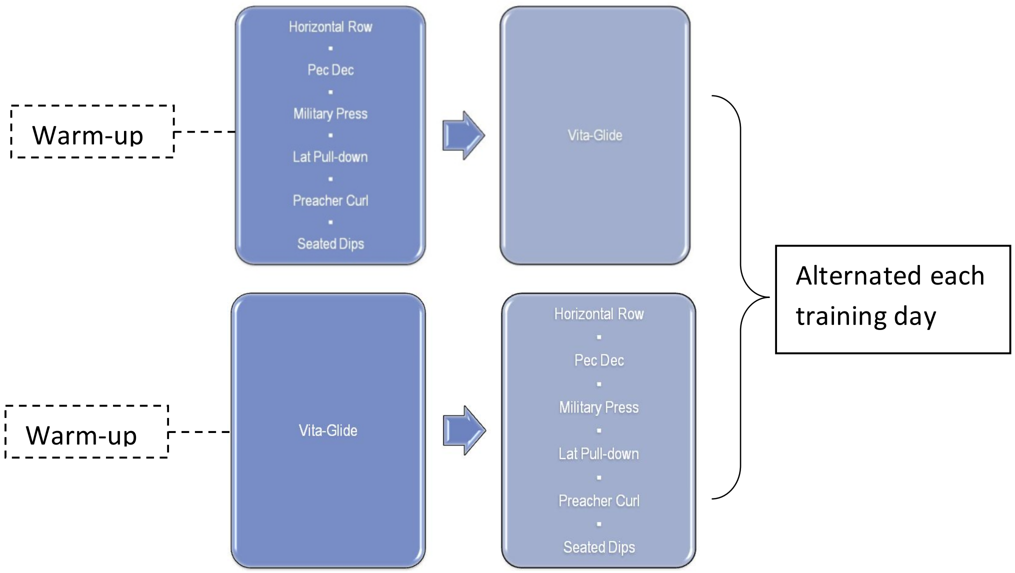
- Each training session will be preceded by a 2-minute warm-up on a Vita-glide® arm ergometer (or equivalent).
- Resistance exercises will be performed in pairs (2 maneuvers in succession) each incorporating 10 repetitions of each maneuver lasting six seconds (3 seconds concentric, 3 seconds eccentric).
- 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**.



D. 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**.



E. Exercise Program: Caregiver Participant

Resting Heart Rate and Blood Pressure: Subjects will rest for 5 minutes in a seated position prior to the initial reading. Blood pressure measurements will be measured with an appropriate size cuff and mercury sphygmomanometer in the non-dominant arm. Resting heart rate is measured by palpation of the radial artery for 60 seconds.

Body Mass, Height, Waist Circumference and Body Mass Index: Body mass will be measured to the nearest .1 pound using a digital platform scale. Height will be measured utilizing a wall mounted measuring scale and recorded to the nearest .25 inch. Waist circumference will be measured using a Gulick tension regulated tape measure, at the level of the umbilicus and recorded to the nearest .25 inch. Body mass and height measures will be used to calculate body mass index.

Fitness Assessment:

Prior to starting the exercise training program, each subject will complete a basic fitness assessment. Data collected will be used to assess program progress and develop the initial exercise prescription. Testing procedures and order are as follow:

Cardiovascular Fitness: Bruce Treadmill Protocol: Subjects will wear a heart rate monitor to accurately determine exercising heart rate. After a 3-minute warm-up at 2 mph/ 0% grade, the treadmill will be increased systematically as follows: speed

Stage	Speed (mph)	Incline (%)	Duration (min)
1	1.7	0	3
2	1.7	10	3
3	2.5	12	3
4	3.4	14	3
5	4.2	16	3

Heart rate, blood pressure and rating of perceive exertion (scale from 6-20) is measured 30 seconds prior to the end of each stage.

Test is terminated when two consecutive stages elicit heart rates above 60% of the subject's estimated maximal effort. Test is also terminated if subject's heart rate meets 85% of estimated maximal heart rate. Estimated maximal heart is calculated by the formula 208 – (age * .66) (ACSM, 2014).

Cardiovascular fitness (VO2 max) is estimated by extrapolating the VO2 estimates achieved at the two consecutive submaximal steady state heart rates to predicted maximum heart rate.

Exercise Training Program

The six-month exercise training program includes a combination of cardiovascular and resistance exercise training performed three days per week. Subjects 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 (*ACSM, 2014).

The cardiovascular exercise prescription ranges from 50%-70% of estimated VO2 max, 20-40 minutes. VO2 max is estimated from data collected during the submaximal treadmill protocol completed during the baseline fitness assessment. Initially, subjects start at 50% estimated VO2max for 20 minutes and systematically progress to 70% estimated VO2 max for 40 minutes over the course of the three months. They 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, subjects 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 by 5-10%. This progression will continue each time the upper end of the repetition range is successfully completed. After six weeks, the repetition range will be adjusted to 8-12 repetitions per set and finally increased to two sets of 8-12 repetitions for weeks 13-72.

*American College of Sports Medicine. *ACSM's Guidelines for Exercise Testing and Prescription*. Ninth edition. Wolters Kluwer/Lippincott Williams & Wilkins Health, 2014.

C. Fitness assessment protocol (-2, 0, 6 months, 1 year)
   a. Resting values
      - RHR
      - BP
      - Weight/Height: BMI
      - Waist circumference
   b. Cardiovascular Assessment
      - Bruce Treadmill Test – 5 stage protocol
      - Test terminated after 5 stages or when 85% APMHR is achieved
   c. Strength Assessment
      - Chest Press
      - Leg Press

D. Exercise intervention
   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.

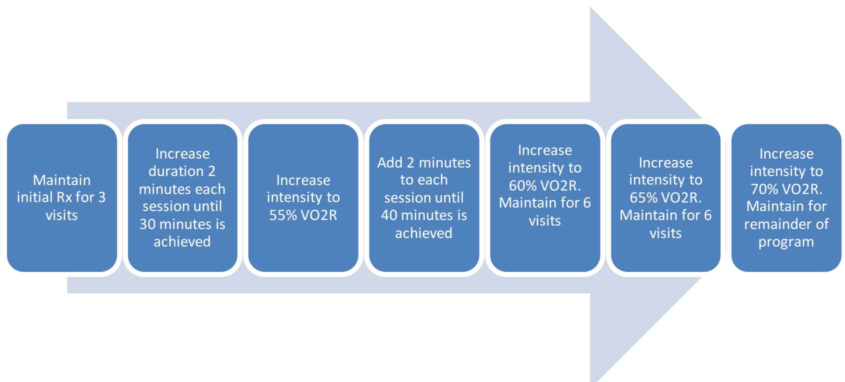
- Weeks 1 thru 6: 1 set of 12-15 repetitions
- Weeks 6 thru 12: 1 set of 8-12 repetitions
- Weeks 12 thru 24: 2 sets of 8 -12 repetitions.
- Resistance increased by 10% when high end of repetition range can be completed before fatigue.

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)



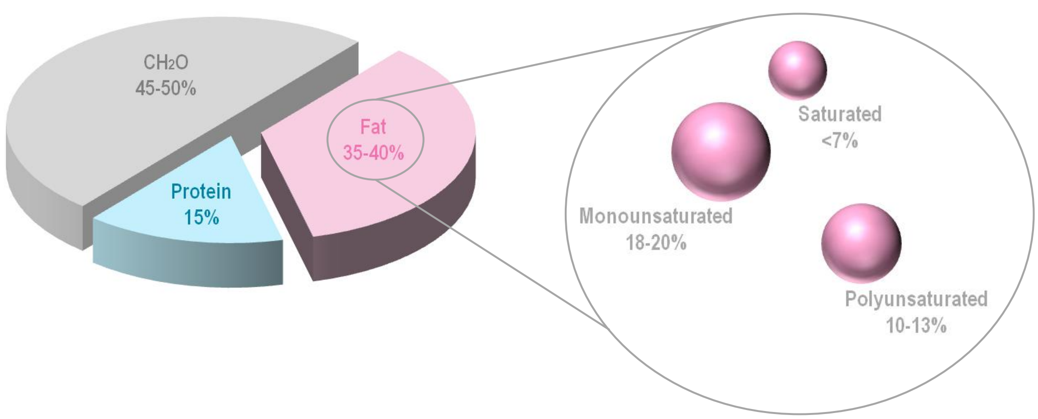
DIETARY INTERVENTION FOR SCI AND CCC: CALORIC RESTRICTION AND THE MEDITERRANEAN-STYLE DIET

A. General Principles:

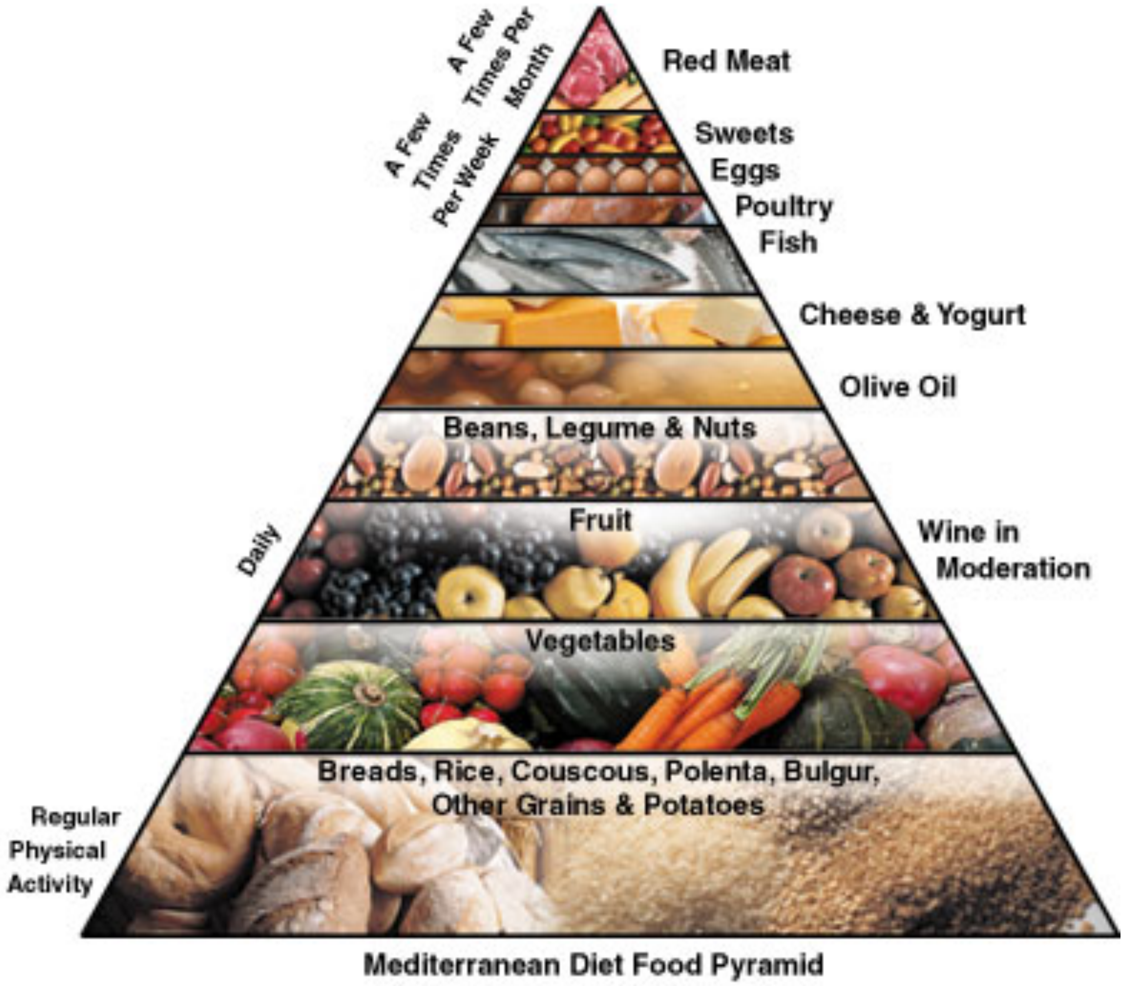
- Caloric restriction for SCI subjects will be **10-15%** less than the RDA for persons without disability **Consistent with DPP protocol**
- Sufficient to result in a weight loss of **1-2 lbs/week** and **~7%** of baseline body mass following 24-week intervention.
- Approximate target daily energy intakes prior to adjustment for physical activity are as follows:

Baseline weight (lbs)	Caloric Intake SCI (kcal/d)	Caloric Intake CCC (kcal/d)
120-170	1020-1080	1200
175-215	1275-1350	1500
220-245	1530-1620	1800
>250	1700-1800	2000

- Dietary intervention will follow the ***Mediterranean-style diets***, which recent evidence suggests may be optimal for weight loss and disease risk.
- Macronutrient composition of the Mediterranean-style diet is as follows:



B. THE TRADITIONAL HEALTHY MEDITERRANEAN DIET PYRAMID



- Example of serving breakdown of the major food groups in each weight defined calorie restricted group are as follows:

Caloric intake (kcal/d)	Food group (serving/day)					
	Fruit	Vegetable	Whole grain	Protein	Dairy	Oil
1200	2	2	3	2	1	4
1500	2	2	5	3.5	2	5
1800	2	3	6	4.5	2	7
2000	4	3	7	4.5	3	7

- A serving of each of the major food groups is as follows:

Fruit	1 serving = ½ cup **OR** 1 medium
Vegetables	1 serving = 1 cup leafy **OR** ½ cup raw/cooked
Whole grains	1 serving = 1 slice bread OR ½ cup rice/pasta/cereal
Protein-rich	1 serving = 1 oz OR ½ cup
Dairy	1 serving = 1 cup or 1½ oz cheese
Oil	1 serving = 1 tsp

C. FOOD INTAKE LOG – THE MEDITERRANEAN-STYLE DIET

S	M	T	W	Th	F	Sat
☐	☐	☐	☐	☐	☐	☐

BREAKFAST		
Food Group	**Food Item**	**Amount/Serving**
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

LUNCH		
Food Group	**Food Item**	**Amount/Serving**
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

DINNER		
Food Group	**Food Item**	**Amount/Serving**
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

SNACK		
Food Group	**Food Item**	**Amount/Serving**
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

D. IMPORTANT POINTS TO REMEMBER

- **Mediterranean**-style diets emphasize the consumption of **fish**, **seafood**, and **poultry** over red meats and beef
- All **dairy** products should be **low-fat** or **fat-free**
  - Low-fat or fat-free milk, cheese, yogurt
- Use healthy alternatives when experiencing milk-related intolerance (stomach/digestion problems):
  - Lactose free low-fat or fat-free milk and cheese
  - Fortified soymilk, rice milk, or almond milk
- Only use **unsaturated** oils or products with **unsaturated** oils
  - Olive oil – use for adding taste, salad dressings, sauces, and cooking
  - Canola oil – use for cooking or frying
  - Margarine: Smart Balance and Promise brands, for example
- Remember, **eggs** are very high in protein! **Watch your intake** throughout the day when having eggs for breakfast.
- Avoid having eggs and shrimp, or other shellfish, on the same day to moderate cholesterol intake
- All juices should be 100% fruit juice with no *added* sugar
  - Orange juice should be **fortified** with calcium and other vitamins
- Limit other sugary beverages
  - Use diet beverages instead
- Choose **whole wheat** or **whole grain** products instead of white
  - Brown rice
  - Whole wheat breads
  - Whole wheat pastas
  - Pancakes and/or waffles
- Choose iron-enriched wholegrain cereals that are low in sugar (oatmeal, cream of wheat, bran flakes) to meet your iron needs.
- Snacks can be eaten during main meals (breakfast, lunch, dinner) as a dessert, for example, or eaten in-between meals as snacks
- Refer to your diet recipes for our Mediterranean approved Caesar dressing!

INTENSIVE DIETARY EDUCATION WILL BE A PART OF THE BEHAVIORAL AND LIFESTYLE TRAINING CURRICULUM AS DESCRIBED IN THE FOLLOWING SECTION

E. DIETARY DETAILS FOR BEHAVIORAL CURRICULUM:

Specific Topics for Dietary Training Curriculum

Session 3 **Healthy Eating**	1. Learn about healthy eating by discussing the importance of using regular meal patterns and eating slowly. 2. Introduce the My Plate from MyPlate.gov. Give tips on specific foods, healthy alternatives, and portions. 3. Introduce all 5 food groups and show examples of foods within each group. **Activity**- Rate Your Plate: • Participant will pick 4 meals from the previous week. They will fill in the plate per meal for each serving of food they had and what food group it came from. • Participant will answer questions on how their plate looked in comparison to My Plate Sample and if there were any healthier options they could've chosen. 4. Learn how to read a basic food label. a. Go over serving size, servings per container, calories from fat, ingredient list and percent of daily values. b. Discuss limiting fat, cholesterol added sugar and sodium. **Activity:** Give sample food label and have participants fill in correct answers from the label provided. 5. To do next week they will: • Keep track of weight • Fill out rate your plate forms everyday • Answer questions before next session.
Session 4 **Get to know your Fats**	1. Learn about Unsaturated Fat= *"The good guys"* a. Monounsaturated fat b. Polyunsaturated fat **Activity:** Have participants write down 3 healthful fats they eat daily. 2. Learn about Saturated Fat= *"The bad guys"* a. Saturated fat b. Trans fat

	Activity: Have participants write down 3 harmful fats they eat daily then circle one to try to change for the following week. 3. Learn how to read Fat on a food label • Teach what manufactures are required to list on the food label as to what manufactures are voluntarily allowed to list on food labels. **Activity:** Give 2 sample food labels. Have participants fill in correct answers about fat from the label provided. 4. To do next week • Keep track of the kinds of fat they eat everyday • Write down everything they eat, drink and all daily activity • Make a plan to change a habit and reach a goal • Answer questions before next session.
Session 7 **Tip the Calorie Balance**	1. Learn about the two components of the calorie balance: a. Calories consumed (food, beverages consumed) b. Calories expended (metabolic process and physical activity) 2. To reinforce the importance of maintaining a calorie balance in the weight loss process a. Balancing food calories with activity calories 3. Learn how many calories it takes to lose/gain a pound 4. Reinforce positive changes made so far a. Changes to be more active b. Changes to eat fewer calories 5. **Activity** for next week: a. Plan physical activities for the upcoming week b. Monitor calories consumed c. Reinforce portion control using portion size guide
Session 10 **Four Keys to Eating Out**	Learn strategies for a successful dining experience outside the home 1. Plan Ahead a. Steps to take charge of your eating out experience 2. Ask for what you want a. Strategies to be firm and assertive

	3. Take charge of what's around you 4. Choose foods carefully a. Healthy eating pitfall and success clue words 5. What's on the menu a. Healthy restaurant menu options b. Fast food options **Activity** – Describe a problem when you eat out: • Identify triggers and proactive solutions 6. To do next week • Continue to self-monitor weight, physical activity • Critique action plan

Session 3: **Healthy Eating**

We'll begin today to keep track of your weight:

At every session, mark it on the How Am I Doing.

Your starting weight was ________ pounds.
Your weight today is ________ pounds.
Your goal weight is _____ pounds.

Write your weight down in one place. Keep a track book or your Journal.

Some parts of healthy eating include:

... the way you eat.

A regular pattern of meals is important.

A regular pattern will keep you from getting too hungry and losing control.

Eat slowly. If you eat slowly, you will:

a) Digest your food better.
b) Be more aware of what you're eating.
c) Be more aware of when you're full.

Try pausing between bites. Put down your utensils. Enjoy the taste of your food!

Don't worry about cleaning your plate.

Serve yourself smaller portions to begin with.

... what you eat overall.

Let's start with the Food groups from My Plate.

Balancing Calories

- Enjoy your food, but eat less.
- Avoid oversized portions.

Foods to Increase

- Make half your plate fruits and vegetables.
- Make at least half your grains whole grains.
- Switch to fat-free or low-fat (1%) milk.
- Drink water instead of sugary drinks.

Tips for Foods:

- Buy fresh fruits and vegetables in season. They cost less and are likely to be at their peak flavor.
- Buy packages of fruits or veggies for quick snacks.
- Include a green salad with your lunch and/or dinner every day.
- Try brown rice or whole-wheat pasta instead of white rice or pasta.
    - Check the ingredient list for the words "whole grain" or "whole wheat" to decide if they are made from a whole grain. (Some foods are made from a mixture of whole and refined grains).
- Buy the leanest meat cuts and lean ground meats such as boneless skinless chicken breasts and turkey cutlets.
    - Choose lean or low-fat luncheon meats for sandwiches instead of luncheon/deli meats with more fat, such as regular bologna or salami.
    - Trim away all of the visible fat from meats and poultry before cooking.
    - Drain off any fat that appears during cooking.

Vegetable Group Vegetables may be raw or cooked; fresh, frozen, canned. Any vegetable or 100% vegetable juice counts as a member of the Vegetable Group.	Lettuce, spinach, broccoli, carrots, peppers, green beans, cauliflower, celery, cucumbers, Plantains, mushrooms, zucchini, onions, potatoes, and corn. Some Juices like tomato juice or V-8.
Grain Group Any food made from wheat, rice, oats, or other cereal grain is a grain product. Grains are divided into 2 subgroups: Whole grains Refined grains.	**Whole grains:** brown rice, oatmeal, popcorn, wheat tortillas, wild rice, whole wheat bread and breakfast cereals like whole wheat cereal flakes **Refined grains:** white bread, corn & flour tortillas, couscous, crackers, grits, white noodles and pastas, pitas, pretzels and Breakfast cereals like corn flakes.
Fruit Group Fruits may be fresh, canned, frozen, or dried, and may be whole, cut-up, or pureed. Any fruit or 100% fruit juice counts as part of the Fruit Group.	Apples, apricots, bananas, berries, grapes, kiwi fruit, lemons, limes, mangoes, melons, oranges, peaches, pears, papaya, pineapple plums, prunes, and raisins. 100% Fruit juices like orange, apple, grape, and grapefruit.
Milk Group All fluid milk products and many foods made from milk are considered part of this food group. Most Dairy Group choices should be fat-free or low-fat. Foods made from milk that retain their calcium content are part of the group.	**Milk:** fat-free (skim), low fat (1%), reduced fat (2%), whole milk, lactose-reduced or lactose free milks **Cheese:** cheddar, mozzarella, Swiss, parmesan, ricotta, cottage, American **Yogurt:** fat-free, low fat, reduced fat, whole milk yogurt **Milk-based desserts:** puddings, ice milk. frozen yogurt, ice cream
Protein Group All foods made from meat, poultry, seafood, beans and peas, eggs, processed soy products, nuts, and seeds are considered part of the Protein Foods Group. Beans and peas are also part of the protein group.	Meats, game meats, lean luncheon or deli meats, organ meats, poultry, and eggs. **beans and peas:** soy beans, split peas, tofu (bean curd made from soybeans), veggie burgers, texturized vegetable protein (TVP), nuts and seeds, seafood
Remember: The amount of each group you need to eat depends on your age, sex, and how physically active you are!	

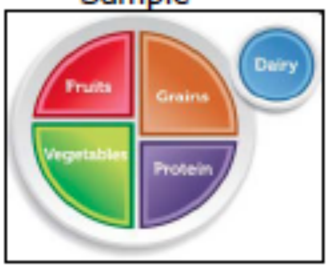
Rate Your Plate (Y)

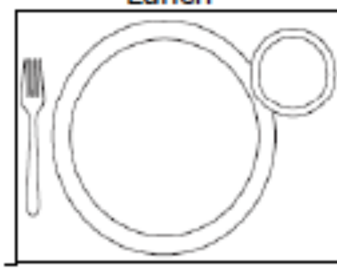
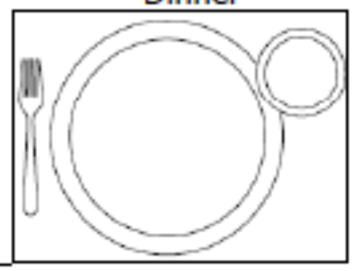
1. Pick four meals from last week's Keeping Track. Fill in the dates.

2. Fill in each plate for every serving you ate from each food group. The plate beside shows you the minimum number of servings recommended.

Date: ___/___/______

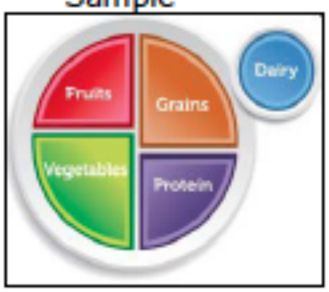
Sample | Lunch | Dinner

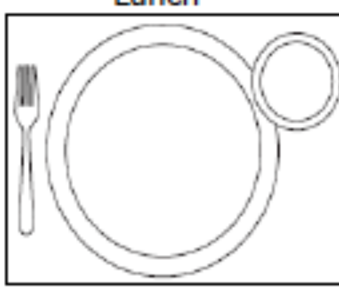
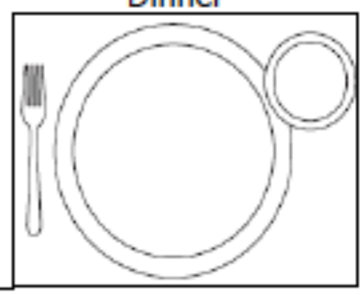


Date: ___/___/______

Sample | Lunch | Dinner



What could *you* do to better to match My Plate?

____

____

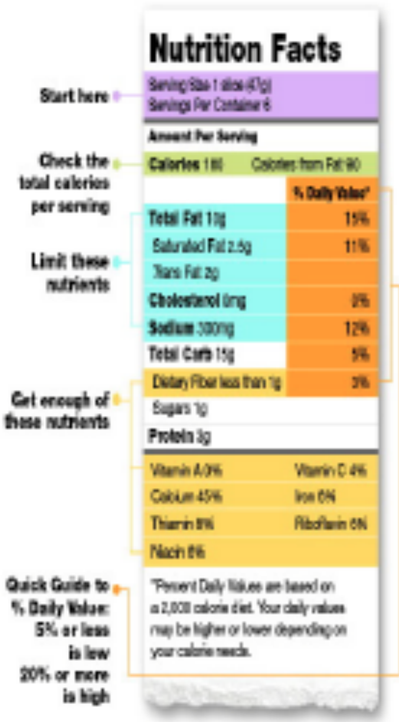
Are there healthier options to any foods that you ate? If so, what are they?

____

____

Learning how to Read a Food Label

Become a smart shopper by reading food labels to find out more about the foods you eat. The Nutrition Facts panel found on most food labels will help you:



- Find out which foods are good sources of fiber, calcium, iron, and vitamin C

- Compare similar foods to find out which one is lower in fat and calories

- Search for low-sodium and low sugar foods

- Look for foods that are low in saturated fat and trans fats

Serving Size & Servings per Container or Package

- Look here for both the serving size (the amount for one serving), and the number of servings in the package.

- Remember to check your portion size to the serving size listed on the label. If the label serving size is one cup, and you eat two cups, you are getting twice the calories, fat and other nutrients listed on the label.

Calories and Calories from Fat

Find out how many calories are in a single serving and the number of calories from fat. It's smart to cut back on calories and fat if you are watching your weight!

Let the Percent Daily Values Be Your Guide

Daily Values (DV) are average levels of nutrients for a person eating 2,000 calories a day. A food item with a 5% DV means 5% of the amount of fat that a person consuming 2,000 calories a day would eat.

- 5 percent or less is low — try to aim low in total fat, saturated fat, cholesterol, and sodium

- 20 percent or more is high — try to aim high in vitamins, minerals and fiber

Ingredients are listed in order so you get an idea of how much of each ingredient is in the food. When something is listed first, second, or third, you know that this food probably contains a lot of it.

Tips on Food Labels:

Limit Fat, Cholesterol and Sodium:

Eating less of these nutrients may help reduce your risk for heart disease, high blood pressure and cancer:

- Total fat includes saturated, polyunsaturated and monounsaturated fat. Limit to 100% DV or less per day.
- Saturated fat and trans fat are linked to an increased risk of heart disease.
- Sodium — high levels can add up to high blood pressure. Try to stay below 1500 mg per day, and NO higher than 2300 mg per day!

Additional Nutrients

Carbohydrates — there are three types of carbohydrates: sugars, starches and fiber. Select whole-grain breads, cereals, rice and pasta plus fruits and vegetables.

Sugars — simple carbohydrates or sugars occur naturally in foods such as fruit juice (fructose), or come from refined sources such as table sugar (sucrose) or corn syrup.

Now that you know a little more about food labels, you can read up on what you're eating!

Ingredients: Dehydrated Potatoes, Modified Food Starch, Corn Oil, Sugar, Salt, Soy Lecithin, Leavening (Monocalcium Phosphate and Sodium Bicarbonate), and Dextrose.
No Preservatives.

Nutrition Facts
Serving Size 1 oz. (28g/About 10 crisps)
Servings Per Container 10

Amount Per Serving	
Calories 120	Calories from Fat 30
	% Daily Value*
Total Fat 3g	5%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 200mg	8%
Total Carbohydrate 21g	7%
Dietary Fiber 2g	8%
Sugars 2g	
Protein 2g	

Vitamin A 0%	Vitamin C 6%
Calcium 4%	Iron 0%
Thiamin 4%	Niacin 6%
Vitamin B6 4%	Phosphorus 8%
Zinc 2%	

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Let's try this label:

What is a serving of this item? _______

How many servings are there? ________

How many calories are for one serving? ___

How many calories would you eat if you ate 3 servings? _______

Is this a lot for one food item? ______
(Yes! We will explain in a later session)

How much sodium would you get if you ate 3 servings of this item? ________

Is this a lot for one food item? ______

What ingredient does this product have the most of? ________________________

To do next week:

I will:

☐ Keep track of my weight and what I eat.

☐ Fill out the Rate Your Plate form every day.

☐ Answer these questions before our next session:

Did you make any changes during the week to better match My Plate?

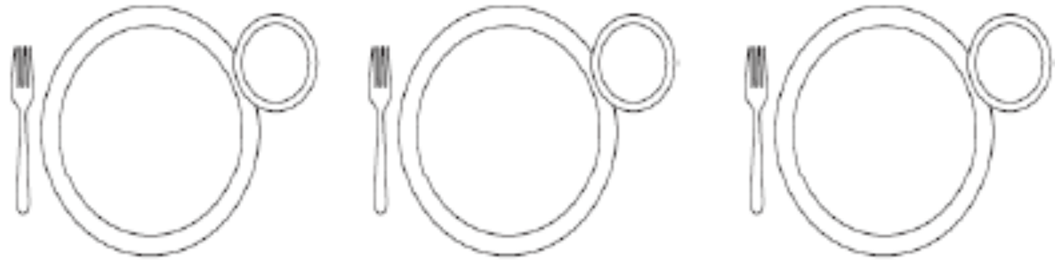
If yes, what were they?

What problems did you have? How did you solve them?

For next week:

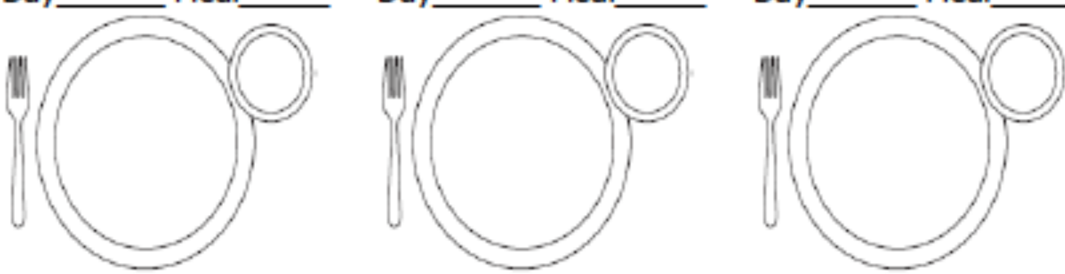
Keep track of my food groups by filling in my plate. Fill in the day of the week. For the meal place B- for breakfast, L- for lunch, or D for Dinner.

Day______ Meal_____ Day______ Meal_____ Day______ Meal_____

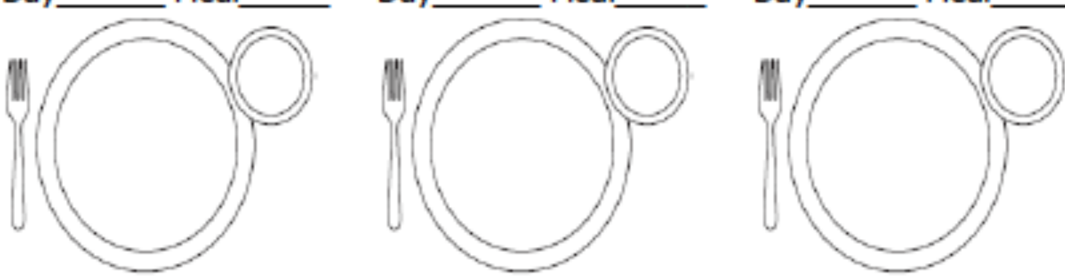


Day Meal _ Day Meal _ Day Meal _

Day______ Meal_____ Day______ Meal_____ Day______ Meal_____



Day______ Meal_____ Day______ Meal_____ Day______ Meal_____



Session 4: **Get to know your Fats**

Fats, or lipids, are nutrients in food that the body uses to build nerve tissue (like the brain) and hormones. Fats and oils are important parts of a healthy diet, but the type of fat you choose can make a big difference for the health of your heart. By understanding how fats work in the body, knowing the difference between the good guys (unsaturated fat) and the bad guys (saturated fat), you can eliminate excess fat from your diet and eat better for your health.

Two Types of Healthy Fat:
"The Good Guys"

- **Monounsaturated fat.** This is a type of fat found in a variety of foods and oils. Studies show that eating foods rich in monounsaturated fats (MUFAs) improves blood cholesterol levels, which can decrease your risk of heart disease. Research also shows that MUFAs may benefit insulin levels and blood sugar control, which can be especially helpful if you have type 2 diabetes.

  Foods that are rich in Monounsaturated fat are: · avocado · canola oil · olives and olive oil · cashews and cashew butter · sesame seeds · almonds and almond butter · peanuts, peanut butter and peanut oil

- **Polyunsaturated fat.** This is a type of fat found mostly in plant-based foods and oils. Evidence shows that eating foods rich in polyunsaturated fats (PUFAs) improves blood cholesterol levels, which can decrease your risk of heart disease. PUFAs may also help decrease the risk of type 2 diabetes. One type of polyunsaturated fat, omega-3 fatty acids, may be especially beneficial to your heart. Omega-3s, found in some types of fatty fish, appear to decrease the risk of heart disease. They may also protect against irregular heartbeats and help lower blood pressure levels.

  Foods that are rich in Polyunsaturated fat are: · some salad dressings · walnuts · corn oil · sunflower oil · some tubs of margarine · pumpkin and sunflower seeds

Name 3 kinds of healthful fats you eat? (Unsaturated)

1. ____________________

2. ____________________

3. ____________________

Two Types of Harmful Fat:
"The Bad Guys"

- **<u>Saturated fat.</u>** This is a type of fat that comes mainly from animal sources of food. Saturated fat raises total blood cholesterol levels and low-density lipoprotein (LDL) or "bad" cholesterol levels, which can increase your risk of cardiovascular disease. Saturated fat may also increase your risk of type 2 diabetes.

Foods that are high in saturated fat are:

· skin from chicken and turkey · lard · butter · chocolate

· high fat dairy products such as cream, whole milk, cheese, regular ice cream and sour cream

· high-fat processed meats like ground beef, bologna, hot dogs, sausage, bacon, and spareribs

- **<u>Trans fat.</u>** Most trans fats are made during food processing through heating up of unsaturated fats. Some occur naturally in foods, especially foods from animals. These trans fats are "chemically-altered fats" (companies use them to increase the shelf life of their products).

  - **Research studies show that trans fat can increase "bad" cholesterol (LDL) and lower the healthy "good" cholesterol (HDL). This can increase your risk of heart disease.**

Foods that are high in trans fat are:

· processed foods like crackers, snacks, breads, chips, and baked goods

· candy like caramels and chocolates · shortening like Crisco

· some fast foods such a French fries and biscuits · dips

Most of the fat we eat (70% of it) is hidden in foods.

Let's uncover it! Here's a lunch menu:

Fried fish sandwich	5 teaspoons of fat
Large French fries	6 teaspoons of fat
Apple turnover, fried	4 teaspoons of fat
Milkshake, with ice cream	5 teaspoons of fat
Total:	20 teaspoons of fat **(That's about 1 entire stick of butter or margarine!)**

To help you stay on your weight goal, we'll help you **eat healthy.**

Make a plan to eat less harmful fat and follow it.

Write down 3 foods you eat that are high in Saturated or Trans fat. Circle one.

1. ____________________

2. ____________________

3. ____________________

Now, what is one way you can cut your saturated fat intake for next week? (There are examples below) Be sure it is something you can do!

1. ____________________

Instead of…		*Replace with…*
Bologna, beef or pork, 1 ounce	→ Lower the fat in meats.	Turkey breast, 1 ounce
American cheese, 1 ounce	→ Use low-fat substitutes.	American cheese, low-fat, 1 ounce
Potato chips, 1-ounce bag	→ Eat smaller amounts.	Potato chips, ½ of a 1-ounce bag
Fish, flounder, deep fried, 3 oz	→ Cook in healthy ways.	Fish, flounder, baked, 3 oz.
Mashed potatoes, ½ cup, whole milk and butter	→ Use low-fat flavorings and substitutes.	Mashed potatoes, ½ c, skim milk, and margarine
Green beans, w/bacon, ½ cup	→ Use low-fat flavorings.	Green beans, steamed, ½ cup
Ice cream, premium, ½ cup of ice cream [for a rare treat.]	→ Eat less often.	Frozen yogurt or sherbet ice cream
Regular margarine or butter	→ Eat light option.	Light-spread margarines, or diet margarine
Chicken Nuggets	→ Cook in healthy ways.	Chicken breast, broil, or grill, 3 oz

Now that you know how to read a food label… what does "Total Fat" mean?

Nutrition Facts	
Serving Size	4 cookies (30g)
Servings Per Container	4
Amount Per Serving	
Calories 220	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 6g	30%
Trans Fat 0.5g	
Cholesterol 10mg	2%
Sodium 70mg	4%
Total Carbohydrates 25g	8%
Dietary Fiber 1g	4%
Sugars 20g	
Protein 3g	
Vitamin A 0% • Vitamin C 8%	
Calcium 2% • Iron 4%	

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram
Fat 9 • Carbohydrates 4 • Protein 4

Total Fat on the food label represents the amount of fat in one serving of the product.

Remember Total Fat comes from four sources:

- Monounsaturated Fat
- Polyunsaturated Fat

> Good Guys

- Saturated Fat
- Trans Fat

> Bad Guys

Note: Manufacturers are ***required*** to list saturated fat and trans fat as subcategories of total fat and can ***voluntarily*** list monounsaturated fat and polyunsaturated fat.
There are 12 grams of total fat in one serving of this product

6 grams = saturated fat & 0.5 grams = trans fat.

You can assume the remaining 5.5 grams of fat come from monounsaturated and/or polyunsaturated fat, even though it's not listed on the label.

Question: What if you eat a larger serving than is listed on the label?

Answer: You will be eating more fat (grams) than is listed on the label!!

Read this Food Label:

Nutrition Facts

Serving Size 1 oz. (28g/about 21 pieces)
Servings Per Container 10

Amount Per Serving

Calories 150	Calories from Fat 80
	% Daily Value*
Total Fat 9 g	**14%**
Saturated Fat 2g	**10%**
Cholesterol 0mg	**0%**
Sodium 300mg	**12%**
Total Carbohydrate 16 g	**5%**
Dietary Fiber less than 1g	**1%**
Sugars less than 1 g	
Protein 2g	

Vitamin A	0%	Vitamin C	0%
Calcium	0%	Iron	2%

* Percent Daily Values are based on a 2,000 Calorie diet. Your daily values may be higher or lower depending on your calorie needs.

☐ **Look at the Serving size**

☐ **Look at the Total Fat in grams:**

How much is Saturated Fat _______g

How much isTrans Fat _________g

How much Polyunsaturated and Monounsaturated Fat ________g

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 250	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 1.5g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Let's Try Another Label:

What is the Serving size?___________________________

What is the Total Fat?____________g

How much Saturated Fat _______g

How much Trans Fat _________g

How much Poly and Monounsaturated Fat ________g

If you had the whole container how much fat is that?

______Total fat in 2 servings
______Saturated fat in 2 servings
______Trans Fat in 2 servings

For Next Week:

Keep track of the fat you eat every day:
"Good Guys vs Bad Guys"

1. Write down everything you eat and drink.

It's the **most important** part of changing your behavior.

Spelling is NOT important. What IS important is to:

→ Be honest (write down what you really eat).
→ Be accurate (measure portions, read labels).
→ Be complete (include everything).

Remember: Your lifestyle coach is here to help you!

Next week I will:

Keep track of my weight, what I eat, drink, and my daily activity.

Be active for ________________ .

Make a plan to change your habit and follow it.

→Write down in your journal or food diary the foods you circled during today's session.

→ Write down what you will do this week to achieve your goal.
Again, be sure it is something you can do.

What I will need to do to reach this goal:

____

____

Problems I might have and what I will do to solve them:

____

____

Last week we talked about four types of Fat.

Before the session today, answer these questions:

Did you follow your plan? ___Yes ___No ___ Almost

What problems did you have following your plan?

____

____

What could you do differently next week?

____

____

What I will need to do to reach my goal of eating more healthy fat:

____

____

Problems I might have doing this and what I will do to solve them:

____

____

____

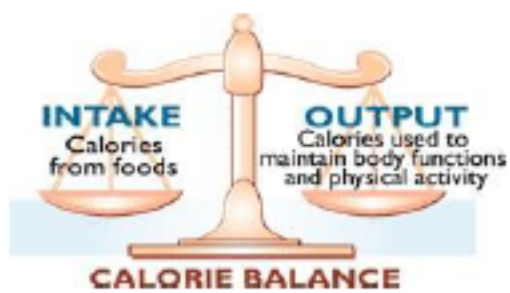
Session 7: Tip the Calorie Balance

This session focuses on the TWO main elements in calorie balance:

- calories consumed or eaten
- calories expended

Calorie balance over time is the key to weight management.

Calorie balance refers to the relationship between calories consumed from foods and beverages and calories expended in normal body functions (i.e., metabolic processes) and through **physical activity**. People cannot control the calories expended in metabolic processes, but they *can* control what they **eat** and **drink**, as well as how many calories they use up during **physical activity**.



Calories in food		Calories burned during activity	
2 Apples	160	30-45 minutes of upper body circuit training*	170*
Slice of bread w/ 1 Tbsp peanut butter	160		

*PatrickL.Jacobs; Edward T. Mahoney; Mark S. Nash; Barth A. Green. Circuit resistance training in persons with complete paraplegia. *J of Rehab Res Dev.* 2002; 39(1): 21-28.

Your weight is a result of the **balance** between food (calories in) *and* activity (calories out)

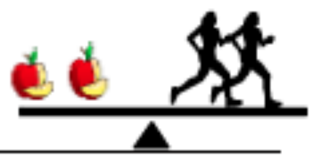
Food Calories Activity Calories

1. Your weight can stay **the same.**

2. You can **gain weight.**

3. You can **lose weight.**

4. You can reach a **new balance** at a **new weight**



Remember:

- Foods eaten and being active work together.
- To lose weight, it's best to eat less **and** be more active.

- **By TIPPING the balance you can lose the weight you want!**
- Over time, you can reach a new balance at a new, lower weight.
- **You will keep the weight off by making changes part of your new lifestyle**

How much to tip the balance?

- 1 pound of body fat stores equals about 3,500 calories.
- Slow, steady weight loss (1-2 pounds/week) is the best way to lose body fat.

To lose:	Tip the balance by this number of calories:
1 pound/week	3,500 per week or **500 each day** for 7 days
1-1/2 pounds/week	5,250 per week or **750 each day** for 7 days
2 pounds/week	7,000 per week or **1,000 each day** for 7 days

For permanent weight loss, it's best to eat less AND be more active!

Changes you've made so far

To be more active (both to reach your goal and be active in general)

- ______________________
- ______________________
- ______________________

To eat fewer calories

- ______________________
- ______________________
- ______________________

Have these changes *tipped the balance*?

Your weight at the start of Lifestyle Balance:
Weight now:
Expected weight by this time:

You have:

Stayed at the same weight, or gained weight

- To lose weight, try something else to tip the balance
- We'll work together to find what works better for you

Lost some weight, but not as much as expected

- Good. You've made some progress
- To lose more weight, try something else to tip the balance *further*.

Lost as much weight as expected (or more)

- Great! You've tipped the balance
- Keep tipping the balance, and you'll keep losing weight

To do next week

I will:

1. Keep track of my weight, eating, and activity.

2. Be active for ______________________.
    - Try setting aside one block of time OR find 2-3 shorter time periods.
    - Plan other activities you LIKE to do.

	What I will do	When	Minutes
Mon			
Tues			
Wed			
Thurs			
Fri			
Sat			
Sun			
		Total minutes for the week:	

3. Make active lifestyle choices throughout the day

4. To tip the balance further, I will:
    - Keep track of calories every day
    - Watch out for foods that are high in empty calories
    - Be sure to record *everything*
    - Watch portion sizes

Portion Size Guide

4 dice = 1 oz of cheese

4-oz individual applesauce = ½ cup

1 small potato = 1 computer mouse = or 1 cup vegetables

Small apple = 1 cup of fruit

8 oz yogurt = 1 cup of milk

School milk carton of milk = 1 cup

½ medium bagel = 1 hockey puck = 1 oz grain

2 Tbsp peanut butter = 1 golf ball

1 cup pasta = 1 baseball

Session 10: Four Keys to Healthy Eating Out

1. **Plan Ahead**
   - Call ahead to ask about low-fat choices
   - Pick where you eat out carefully.
   - Go somewhere that offers low-fat choices.
   - Eat less fat and fewer calories during other meals that day.
   - Eat a little something before you go out or drink a large, low-calorie beverage
   - Plan what to order without looking at the menu
   - Don't drink alcohol before eating
   - For parties or dinner parties: Bring something from home to share with others.

2. **Ask for what you want. Be friendly and firm**
   - Ask for the foods you want
     - Ask for lower-fat foods
     - Can foods be cooked in a different way?
   - Don't be afraid to ask for foods that aren't on the menu.
   - Ask for the amounts you want
     - Ask how much is usually served.
     - Order salad dressing, gravy, sauces, or spreads "on the side."
     - Ask for less cheese or no cheese.
     - Split a main dish or dessert with someone
     - Order a small size (appetizer, senior citizen's, children's)
     - Before the meal, have the server pack ½ of your order to take home.

3. **Take charge of what's around you**

- Ask for one piece of bread per person instead of a bread basket
- Use olive oil instead of butter for your bread

4. **Choose foods carefully**

- Watch out for these high-saturated fat words on

- Au gratin
- Breaded
- Buttered or buttery
- Cheese sauce
- Creamed, creamy, cream sauce
- Fried, deep fried, pan fried
- Gravy
- Hollandaise
- Parmesan
- Pastry
- Rich
- Sautéed
- Scalloped
- Southern style

- Look out for these healthier alternatives

- Baked
- Broiled
- Boiled
- Grilled
- Poached
- Roasted
- Steamed
- Stir-fried

- Think about what you really *need* to eat
- Trim visible fat off meat
- Take skin off chicken
- Split main dishes with someone to control portion sizes
- Skip the mayonnaise. Use olive oil instead
- In general:
    - Lunch meals should contain no more than 400 calories
    - Dinner meals should contain around 500 calories

What's on the menu?

- You can make healthier choices no matter what kind of restaurant you go to
  - Be sure to ask the waiter how the food is prepared.
    - Note: Most restaurants serve a tossed salad—top with a dash of olive oil and lemon juice or vinegar.

GO! Healthy choices	CAUTION!
Pizza • Plain cheese pizza (ask for half the cheese or low-fat cheese). • Onions, green peppers, mushrooms, tomatoes • Grilled chicken	**Pizza** • Meat toppings (sausage/pepperoni, ground beef) • Extra cheese
Burger Place (fast food) • Grilled, broiled, or roasted chicken, without sauce or mayonnaise • Broiled, extra lean burger.	**Burger Place (fast food)** • Regular hamburger, cheeseburger. • French fries. • Fried fish or chicken. • Mayonnaise-based sauces.
Mexican • Heated (not fried) tortillas. • Grilled chicken or beef fajitas • Soft tacos (corn or flour tortillas). • Salsa or Pico de Gallo	**Mexican** • Enchiladas. • Chili con queso • Fried tortillas, tortilla chips • Sour cream, guacamole • Crispy or crunchy tacos
Chinese and Japanese • Stir-fried chicken. • Stir-fried vegetables. • Steamed rice. • Soup. • Teriyaki.	**Chinese and Japanese** • Egg foo yung. • Fried chicken, beef, or fish. • Fried rice or noodles. • Egg rolls. • Fried won ton. • Tempura.
Italian • Spaghetti with meatless tomato sauce • Minestrone soup	**Italian** • Sausage • Lasagna, manicotti, other pasta dishes with cheese or cream • Fried or breaded dishes (like veal or eggplant parmesan)

GO! Healthy choices	CAUTION!
Seafood • Broiled, baked, or boiled seafood with lemon • Plain baked potato	**Seafood** • Fried fish • Fried vegetables • French fries
Steakhouses • Shrimp cocktail • Broiled chicken or fish • Plain baked potato	**Steakhouses** • Steak (except trimmed lean cuts). • Fried fish or chicken • Onion rings, other fried vegetables • French fries

Fast Food Options

As you embark on your journey towards a healthier lifestyle it is important to be prepared for the occasional obstacle or bump on the road. Although eating fresh, home prepared meals is always best, below are some convenient options that can fit into your healthy plan for those days when you are *on-the-go*.

Arby's		Boston Market	
Menu Item	**Calories**	**Menu Item**	**Calories**
Roast Turkey and Swiss Sandwich (1/2)	340	Qtr. White Rotisserie Chicken (1/2 order) with Steamed Veg and New Potatoes	360

Burger King		Domino's	
Menu Item	**Calories**	**Menu Item**	**Calories**
BK Veggie Burger (no cheese)	410	Hand tossed Chicken and Veggie (per slice, small)	210
BK Big Fish Sandwich (1/2 order)	320	Hand tossed Pepperoni Pizza (per slice, small)	238
Spicy Chick'n Crisp Sandwich	300		

KFC		McDonald's	
Menu Item	**Calories**	**Menu Item**	**Calories**
KFC Snacker with Crispy Strip	290	Filet O Fish	380
Grilled Chicken Breast (1/2 order) with Green Beans and Mashed Potatoes n' gravy	240	McChicken	360

Pollo Tropical CHICKEN ON THE GRILL		TACO BELL	
Menu Item	**Calories**	**Menu Item**	**Calories**
Chicken TROPICHOP w/ rice and beans (½ order)	265	Fresco Crunch Taco	150
Chicken TROPICHOP w/ rice and vegetables	165	Fresco Soft Taco – Beef	180
Pork TROPICHOP w/ rice and beans (½ order)	340	Fresco Bean Burrito	350
Pork TROPICHOP w/ rice and vegetables (½ order)	245	Fresco Burrito Supreme – Chicken	350
¼ Chicken, white meat (no skin), w/ rice and beans (½ order)	350	Fresco Burrito Supreme – Steak	340

Describe a problem you have when you eat out

____

____

____

1. Make a positive action plan using one of the **4 keys to eating out**

   I will: ____

   When? ____

   I will do this first: ________________________________

2. **I will handle roadblocks that may come up by:** ____________________

   ____

   ____

3. I will do this to make my success more likely: ______________________

4. How can we help you? ______________________

To do next week

1. **Keep track of my**
   i. Weight
   ii. Eating
   iii. Physical activity

2. **Try my action plan.**
   i. Did it work?
   ii. If not, what went wrong? ______________________

BEHAVIORAL INTERVENTION FOR SCI AND CCC- TIMELINE AND PROTOCOL

A. General Principles:

- 16-session protocol aimed at behavior modification through: education, stress management, problem solving skills training, and cognitive restructuring.
- Delivered by a ***Lifestyle Coach*** selected with consideration to gender, and injury level.
- 16-session core curriculum training will be scheduled within the 24-week core intervention time frame.
- Individual sessions will be 30-60 minutes in duration.
- Following core curriculum training participants will be contacted monthly for the duration of the extension period.
  - *Face-to-face* contact with the life-style coach will occur bi-monthly.
- A ***Lifestyle Manual*** will be provided for each participant.
- *Language in the curriculum has been adapted to better reflect the SCI population and should be adjusted accordingly for the caregiver in the dyad if they are also randomized to the full intervention.

	B. 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.

C. Session Outlines

Session 1A:
Welcome to the Lifestyle Balance Program

Objectives:

In this session, the participant will:

- Meet the lifestyle coach and study team.
- Review the Standard Healthy Lifestyle Guidelines, if not presented at randomization.
- Be given the Lifestyle Balance notebook.
- Discuss the participant's 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 and sign a related agreement.
- Choose to focus either on the weight loss or the physical activity goal first.

To Do Before the Session:

Get materials ready:

- Keeping Track book (or two, if the next session is scheduled more than 7 days later).
- Pages for participant notebook.
- Video or photographs of local study team members, if not present in person.
- Measuring cups, spoons, and scale (for participants who focus on weight loss first).
- Map to the supervised activity sessions (for participants who focus on activity first).

Invite family member to attend (if, during the run-in period, it was determined that a family member's attendance would enhance adherence).

On the Lifestyle Balance Update page, pencil in tentative appointment dates (schedule sessions 1-8 for one week apart, 9-16 for either one or two weeks apart). Insert this page in to the inside front pocket of the participant's notebook. Also, keep a copy of the Lifestyle Balance
Update page in your notes for each participant.

Fill in the activity session schedule on page 1 of Getting Started Being Active.

Introduce yourself and the other members of the local study team.

Greet the participant. Also welcome family member or other support person if present.

Hello. I'm delighted to meet you. My name is [ ]. As you know, you've been assigned to the group in the SCI Weight Loss Program that will be making lifestyle changes to try to prevent diabetes. The lifestyle changes *will be to lose weight through healthy eating and to be more physically active. We've called this group the "Lifestyle Balance Program" because we'll be helping you reach a healthy balance between what you eat and how active you are.*

I will be meeting with you often during the next several years, so we will get to know each other very well. I'm looking forward to working with you as a team to make our time together a success. There are many people on the study team; we're all resources for you.

Introduce the study team members, or use a video or photographs to introduce them if not present. Explain the role of each member of the team, and stress that during the upcoming years of the study, all of the members of the team will be available to support the participant.

Give the participant the Lifestyle Balance Notebook.

Here is the notebook we'll use throughout the study. It's yours to keep. At every session I'll give you some handouts to put into the notebook and we'll go over them together. Feel free to write notes or questions on the handouts, and take the notebook home. Just be sure to bring it with you to every session. Here is my name, address, and phone number for your records [give other team members' phone numbers, as appropriate].

It's very important that we stay in touch. Feel free to call me or stop in at the clinic whenever you have questions or need to talk. It's also important to call if you cannot come to a session.

Discuss the participant's initial reactions to being assigned to the Lifestyle Balance Program.

Some people who have been assigned to the Lifestyle Balance Program wanted to be in this group from the beginning; some hoped they would be assigned to another group in the study.

- **What do you think about being in the Lifestyle Balance Program?**
- **Are there some things about this group that seem good to you, and some things you're not so excited about?**

The participant may express disappointment about not being randomized to another arm of the study, fears of failing at the lifestyle intervention, memories of past failures at weight loss efforts, and so on. Recognize concerns, promote confidence that the participant can succeed, and give support.

If the participant is very negative, help him or her to identify *some* positive things about being assigned to this approach. Stress that the Lifestyle Balance Program is "state-of-the-art." It has been carefully designed based on many research studies about the best ways to help people change.

Complete the work sheet "Remember Your Purpose" with the participant.

Emphasize the positive aspects of the intervention, relating them whenever possible to issues of personal value to the participant, and encouraging the participant to provide specific details, in images or words (such as the names of people) that can be recalled later as a source of motivation. Examples:

- Has the real potential to prevent diabetes.
- No drugs, no drug side effects.
- Will reduce his or her risk of heart disease and stroke.
- Will help him or her look and feel better, have more energy.
- Make her or his family and friends proud.
- Set a good example for children, spouse, friends, and community.
- Will contribute to scientific research findings that will then improve health care practices for the community.

Explain that you may review this work sheet with the participant later in the program as a source of motivation.

Receive an overview of the Lifestyle Balance Program.

As I said earlier, the Lifestyle Balance goals will be to:

1. Lose weight through healthy eating, and
2. Be more physically active.

We strongly believe that making these lifestyle changes and keeping them up over time will prevent diabetes in people like you who are at risk of diabetes.

The Lifestyle Balance program has been carefully designed. It is based on many research studies of the best ways to help people change.

In this program we will help you:

- **Learn the facts about healthy eating and being active.** Our staff is experts in nutrition, exercise, and helping people develop healthy habits. We will give you the most up-to-date and accurate information.

  But knowing the facts, or what to change, isn't enough. You also need to know **how to change.** So we will help you:

- **Learn what makes it hard for you to eat healthy and be active.**
  - And learn **how to change these things so they work *for* you**, not against you.

For example, you'll learn how to:

- Find the time to be active.

[Review the rest of the items on the work sheet.]

We will also give you the **long-term support** you need to stick with the changes you make. We will be your **"coaches."**

Review the Lifestyle Balance Goals.

These are Lifestyle Balance goals:

1. **Lose 7% of your weight through healthy eating**. Your goal will be to weight xxx pounds or less.
2. **Do 2-1/2 hours of brisk, physical activity each week** (this would be like doing brisk exercise for 30 minutes on five days of the week).

We will help you to reach these goals one step at a time and keep them up over time.

We'll go over each of these goals in detail, and exactly what they mean for you, as we go along. You may also have your own specific goals you want to reach, but these are the goals for the study as a whole. I will do everything I can to help you reach the study goals, and so will the rest of the study team.

Refer to the Manual of Operations for how to respond to participants who have their own personal goals, for example, who want to lose less or more weight, who are already very active, or who wish to do less than 2-1/2 hours of activity. Briefly address their concerns, then move onto the study goals. For example:

- If the participant wants to lose less weight or be less active than the study goal: "We'll work toward this goal slowly, one step at a time. It's a safe and reasonable goal for you, and I'm very confident that you can do it."
- If the participant wants to lose more weight or be more active than the study goal: "Let's work toward this goal first. When you reach this goal, we'll talk about going further."

Discuss the rationale for the goals.

The Lifestyle Balance goals are **safe and can be reached.**
We will help you reach the goals by making:

- **Gradual (made one step at a time),**
- **Healthy, and**
- **Reasonable changes in your eating and activity.**

Nothing extreme. For example, you won't need to do very vigorous exercise, although you can if you want. "Being active" doesn't mean you need to be a marathon runner. We will just gradually increase your general activity and help you develop a more active lifestyle.

Reaching the Lifestyle Balance goals:

1. **May prevent diabetes.**

Research has shown that leaner and more active people are less likely to get diabetes. Also, moderate weight loss and physical activity have been shown to improve the body's use of insulin (the hormone that regulates the amount of sugar in your blood). This can reduce the chance of getting diabetes.

We believe that lifestyle changes can indeed prevent diabetes, if you make these changes and keep them up over time.

That's why you and I will work together to do everything we can to help you lose weight and be more active.

2. **Reaching the Lifestyle Balance goals will also help you look and feel better and be more healthy in general**. Research has shown that losing weight and being active can:

- Relieve tension, help you relax and sleep.
- Give you more energy, make it easier to get around (for example, if you're more active on a regular basis, your joints will be more flexible and you'll be less likely to injure your back).

Many of you may have health problems like high blood pressure or high blood cholesterol. Research has shown that losing weight and/or being active can:

- Lower blood pressure.
- Lower blood levels of LDL or "bad" cholesterol (the kind linked to the risk of having a heart attack or stroke).
- Raise blood levels of HDL or "good" cholesterol (the kind that reduces your risk of heart attack or stroke).

3. **In addition, reaching the Lifestyle Balance goals will set a good example for your family, friends, and community.**

Many of us live in a family or a culture that practices high-fat eating and inactivity. You will face a challenge as you work at doing things differently. But you will also set a good example of what it's like to live a more healthy lifestyle, which can be inspiring and encouraging to everyone around you.

I know that losing weight and being more active takes a lot of effort. **Changing behavior takes work.** It takes dedication and hanging in there and doing what needs to be done every step of the way.

We are here to help. I'll be meeting with you often, and I will do everything **I** can over the next four years to help you reach and stick with your Lifestyle Balance goals. I am confident that **you can do it!**

Discuss key aspects of the lifestyle coach-participant relationship.

It is very important that we work together throughout the study as a **team**. I will count on you to:

- **Come to sessions and bring your Lifestyle Balance notebook.**
  Call 24 hours ahead if you must miss a meeting. For example, call before Monday afternoon if you must miss a Tuesday afternoon appointment.
- **Do your best to reach your eating and activity goals.** That includes doing home activities to practice what you learn.
- **Keep track of your eating and activity 7 days a week.** I'll talk with you more about this in a few minutes. **Be honest.** Don't try to "please" me. I will count on you to write down what you are really eating, and how active you really are, not what you think I want to hear or what would make me happy.
- **Keep track of your weight at home.** We will also weigh you here at each session. By weighing yourself at home, you will be able to see the pattern of your weight from day to day and see how your changes in eating and activity affect your weight.
- **Let me know if you have any problems.** Ask questions when you don't understand something. I am here to help and I need to know when you're having any difficulties. There's no such thing as a "stupid" question--it's *smart* to speak up when you have a question.

Some participants, because of their cultural heritage or personal history, may consider it rude to ask questions or to bring up difficulties. This is true, for example, of many Hispanics. With these participants in particular, be sure to express your acceptance and appreciation when they voice their questions and concerns.

- **Stay willing and open to change. Always "hang in there."**
  - We will sometimes run into problems, and I will count on you to hang in there and give it your best until we solve the problems together. This is a "can do" study. You can count on me to:
- **Go over your records of what you eat and your activity.**
  Notice what you are doing well and what can be improved.
  Noticing what you're doing **well** is one of my most important jobs. I will encourage you and build you up and appreciate your efforts.
- **Answer your questions.**
  It's important that you feel free to ask me any questions you have, and I will get the answers for you. Please remember that the staff are experts, and our job is to make our expertise available to you in any way we can.
- **Be honest.**
  We will both need to "say it like it is." I will count on you to be honest about how you are doing. And you can count on me to tell the truth about how *I* think you are doing and what I think needs to be done to solve any of the problems we run into.
- **Stand by *you* during hard times,** and
- **Believe you can reach your eating and activity goals**. We all need someone to believe in us when we are making changes for the better. I know you can do it, and when you get discouraged, I will be here to believe in you. **Always "hang in there" for you,** and **support and help you** continually.

Is there anything else you'd like me to do to help you? (Write any appropriate suggestions that the participant makes on the work sheet.)

Let's sign this as a way of remembering how we agree to work together.

Sign the agreement and have the participant sign it as well.

We want to be sure this program works for you. No two people are alike. So at different times during the study, you'll be able to choose *when* you want to focus on a certain topic, depending on what will be most helpful to you.

Overview the session topics.

This page shows you the topics for Sessions 1 through 16. As we've said before, you are welcome to invite a family member or friend to any or all of the sessions.

Session 1B:
Getting Started Losing Weight

Objectives:

In this session, the participant who has chosen to focus on the weight loss goal first 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.
- Receive weighing and measuring tools.

Review the reason for self-monitoring foods eaten and the basic principles of self monitoring.

You've decided to start with the weight loss goal. To help you lose weight, our goal is to help you to **eat healthy.** And healthy eating involves **eating less fat.**

This is because **eating too much fat is fattening (makes us fat) and is related to heart disease and diabetes**. (We'll go over this in more detail next week.)

The first step to eating less fat is to **figure out how much fat you are eating now**. To do this, I want you to **write down everything you eat and drink every day**. This is something we're going to do throughout the first 24 weeks of the study. It's the **most important part of changing your behavior.**

For right now, I just want you to write down what you ate, like you did during the run-in.

Keeping track of what you eat will help you and I see, in black and white:

- What foods you eat,
- How much you eat,
- When and where you eat, and
- How your eating habits change over time.

Your Keeping Track records will be the very basis for our working together. You and I will be the only ones to see them, so **spelling is NOT important.**

You can make up **abbreviations** or use your own shorthand if that makes it easier and faster for you to keep track, just so we both know what you mean.

Note: The use of abbreviations may also help those participants who have difficulty spelling feel less self-conscious.

What IS important is to:

- **Be honest.** That means to **write down what you really eat**, not just what you think will please yourself or me.
- Also, **be accurate**. It's best to write down what you eat as soon as possible after you eat it, because it's easy to forget. For example, count the number of slices of cheese you eat and write down the kind of cheese.
- And **be complete**. **Include everything.** The butter on the toast, the cream in the coffee, and the mayonnaise on the sandwich.

It may seem hard to write down all of your foods, especially at first. And it does take some time. But it's worth its weight in gold. **Being aware of what you are eating is the first step toward changing your eating habits.**

Assign self-monitoring of foods eaten and circling of high-fat foods.

To get you started I want you to do several things during the coming week. They're listed on this part of the work sheet called "To do next week." At every session you'll get a list of one or two things to do during the week. There are square boxes beside each item *[indicate boxes]* so you can put a check beside each one after you do it. That way you'll have a record of what you still need to do before the next session.

For this week, I want you to:

- **Write down everything you eat and drink every day.**

  Use this "Keeping Track" book. Give the participant a Keeping Track book and indicate where in the book to record food intake.

  Write down the time you eat something, the amount, and the name of the food or drink and a description. **Skip the other columns for now** *[indicate the grams of fat and calories columns].* Use one line for each food. And **skip activity for now.**

- **Circle some of the foods or beverages you think are highest in fat**. Over time you will learn exactly what foods are high in fat. For now, just guess what some of the foods are. The idea is get you thinking about fat and looking for some of the high-fat foods in your meals and snacks.

Note: You do not want the participant to return with a book more than half filled with circled foods, which would be discouraging. This should be a positive beginning experience.

- Finally, be sure to **bring your completed Keeping Track books and your**
  - **Lifestyle Balance notebook back with you** to every meeting.

Have the participant practice self-monitoring foods eaten and circling high-fat foods.

> Let's take a minute to **practice Keeping Track on this page.** Think about a few of the foods you ate earlier today or yesterday. What was the first thing you ate? When did you eat it? Write the time here, the amount here, and the food here. Just skip the other columns.

Have the participant demonstrate. Be sure the participant understands what to do.
Do you think that food is high in fat? Just guess. If so, circle it.

Continue with several additional foods. Point out, as you go along, examples of accuracy (e.g., give brand name and type of food); honesty (e.g., include nibbles or very large amounts); completeness (e.g.; include % fat of milk); and the use of abbreviations.

Just skip the section for physical activity.

Any questions?

Give the participant weighing and measuring tools.

> **If you want to, you can start to measure the amount of food you eat using these.**

Get out the measuring tools.

> Here are some **measuring cups and spoons** for you to start to use, just to get an idea of the amount of different foods you usually eat. We'll talk in more detail about measuring in the coming weeks.
>
> For now, you might want to pour your breakfast cereal into the bowl you typically use, just as usual, and then measure the cereal before you eat it. Or put the amount of margarine you usually spread on toast onto the knife and measure it using the measuring spoons before you spread it. You can also use a glass measuring cup, if you have one at home, for liquids and a ruler for measuring things like pizza, pieces of pie, and cookies. This **scale** is for weighing meats and cheese *(briefly demonstrate how to use it)*.
>
> As I said, you don't need to measure amounts this week, unless you want to.

Any questions?

Discuss appointment schedule.

We will meet *every week* for the first 8 sessions. On this “Lifestyle Balance Update” page, which we’ll keep in the front of your notebook, I've used a pencil to write down some possible appointments for this same time and this same day of the week. Is this a good time for us to keep meeting?

If not, make changes to the penciled-in dates and on your copy of the Lifestyle Balance Update.

For sessions 9 through 16, we’ll meet *[explain the frequency that your clinic has decided to hold these sessions, whether every week or every other week.]* And then, after session16, we’ll meet once every month or two months.

Session 2:
Be a Fat Detective

Objectives

In this session participants will:

- Begin to graph weight and be assigned self-monitoring of weight.
- Learn the reason for and basic principles of self-monitoring fat grams.
- Receive the participant's 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.
- Learn to use the Fat Bank (optional).
- If this is Session 4: Receive weighing and measuring tools. Also, develop an activity plan for the coming week (for most participants, a weekly total of 120 minutes).

To Do Before the Session

Review the participant's self-monitoring records from the run-in period, noting specific examples and general types of high-fat foods consumed.

Get the participant's "How Am I Doing?" graph for weight. The graph should show the participant's weight goal and expected rate of weight loss from randomization weight to the goal.

Using the participant's randomization weight, determine the participant's fat/calorie goals.
Refer to the Manual of Operations.

Get materials ready:

- Measuring cups, spoons, ruler, and scale.
- Fat Counter.
- Keeping Track book.
- Pages for the participant notebook.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

Review the participant's Keeping Track for food intake. Notice many good things, and make only one suggestion for improvement.

> Were you able to write down anything this week about your eating?
> What did you learn by Keeping Track? What difficulties did you have?

If the participant has not self-monitored, ask, "Tell me a little about that." Do your best to uncover some of the barriers that prevented the participant from Keeping Track without making him or her defensive. Problem solve with the participant to address the barriers.

Take a minute to page through the completed Keeping Track book, if available, from front to back. Comment briefly, as described below. (Also, keep the record until the next session or Xerox it. After the session, do a more careful review, make written comments, and return to the participant at the next session.)

Be positive and nonjudgmental. Emphasize what an important learning tool this will be throughout the study. Praise all efforts to keep track, no matter how small, and any level of accuracy or completeness. For example, praise any and all of the following efforts. The participant was able to [this list is for your reference, not to be reviewed with participants]:

- Record anything at all.
- Record something each day.
- Record throughout the day, each day.
- Note time of day.
- Describe kinds of foods (cuts of meat; parts of poultry; label information from packaged foods)
- Describe methods of food preparation: baked, broiled, steamed, stir-fried, fried, barbecued, etc.
- List additions to foods at the table: butter, margarine, cream, sugar etc.
- Give simple details about portion size: counts; cups; bowls; spoonfuls.
- Give actual weights and measures of portion size: package weight ounces, measuring spoons and cups, ruler measurements, food scale measurements.

Examples:

- "Great! I see here that you wrote down eating 13 cheese crackers with your soup."
- "It's really useful that you noted adding 2 teaspoons of butter to your beans."

Point out no more than one area for improvement, preferably starting with the most simple.

Example:

- "I see you were able to record all weekdays. Fantastic! In the coming weeks it will be useful for you to try and record on weekends too so we can learn about how your eating and exercise might be different then."

Weigh the participant. Introduce the How Am I Doing? Graph for weight and self monitoring weight at home.

Today's session is called "Be a Fat Detective" because we'll talk about how to become more aware of the amount of fat you eat and how that can help you lose weight through healthy eating.

Today's session is called "Be a Fat Detective" because we'll be talking about how to become more aware of the amount of fat you eat and how that can help you lose weight through healthy eating.

But before we talk about fat, let's begin today to **keep track of your weight** and your progress toward your weight loss goal.

In the first session we said that one of the study goals was to lose 7% of your weight, which means that, since your **starting weight was xxx pounds**, your **goal is to weigh xxx pounds**. Let's see what you weigh today.

Weigh the participant. See instructions in the Manual of Operations.

To keep track of your weight, we'll do two things. First, at every session we'll **mark your weight on this graph, called "How Am I Doing?"**

Insert the "How Am I Doing?" graph for weight into the front of the participant's notebook.

Here is your "starting weight," what you weighed when you first joined the study, and here is your goal weight. This line shows what a steady and gradual weight loss might look like for you. Of course, most people's weight goes up and down from week to week, and yours will probably do that, too, sometimes above this line, sometimes below it. Many people lose weight faster at first and then the rate levels off. We won't pay as much attention to each weight but rather to the pattern over time. We want you to stay under this line as much as possible and reach your goal weight by Week 24, or six months from now. That will be in *[name the month and mark on the graph at 24 weeks].* After that we will help you to stay under your goal weight for four years. Maintaining your weight loss will be very important which is why we will teach you not only how to lose weight, but also how to keep it off!

Let's mark your weight for today on the graph.

Have the participant mark it on the graph. Provide help as needed.

When you weigh yourself at the center record your weight here...

Indicate the weight column on the back of the Keeping Track book, and circle the day(s)on which you want the participants to weigh themselves. See Manual of Operations for guidelines.

Introduce the rationale for and the basic principles of self-monitoring fat.

Now let's move on to the topic for today.

To help you lose weight, our goal will be to help you **eat healthy.** And **healthy eating involves eating less fat**, for several reasons.

- First of all, **eating too much fat is "fattening" (makes us fat). So by eating less fat, you can lose weight.**

  In fact, fat is the most fattening of all the things we eat. Fat contains more than twice the calories (9 calories per gram) than the same amount of carbohydrate (starch or sugar) or protein (4 calories per gram). So **even small amounts of high fat foods are high in calories.**

  Review the example on the worksheet (a lot of calories in a small amount of peanuts versus fewer calories in a large amount of popcorn) and/or other examples that are relevant to the participant's eating pattern.

- **Fat is also related to heart disease and diabetes**. Research has shown that eating a lot of fat can increase your cholesterol level. Cholesterol is one measure of the amount of fat in your blood. The higher your cholesterol, the greater your chance of having a heart attack. There is also some evidence that eating a lot of fat may increase your chances of getting diabetes.

For participants who want more information:

> The recent Surgeon General, C. Everett Koop, MD, had this to say about the importance of eating healthy: "If you are among the two out of three Americans who do not smoke or drink excessively, your choice of diet can influence your long-term prospects more than any other action you may take." In other words, healthy eating is one of the most important steps you can take to improve your health.
>
> And in his recent report to the nation, the Surgeon General named eating less fat as our country's number one dietary priority, more important than sodium, sugar, or additives. In fact, all of these important national organizations recommend eating less fat: the National Heart, Lung, and Blood Institute, the American Heart Association, the American Diabetes Association, the American Dietetic Association, and the American Cancer Society.

What kind of foods do you eat that are high in fat?

Let's look at some of the high-fat foods you circled in your Keeping Track. [Write on the work sheet a few of the foods that the participant correctly circled as high in fat.]

What kind of foods do you eat that are high in fat? [If the participant doesn't mention any high-fat foods, briefly look with the participant a this or her self-monitoring records from the run-in period. Write on the work sheet some of the high-fat foods noted.]

Make some general points about the food groups or types of food that tend to be high in fat, such as:

1. Meats (Meats contain both fat that you can see and fat that you can't see.)
2. Dairy foods (whole milk, regular cheese, ice cream) (Many Americans get most of their fat from meats and dairy products, including cheese.)
3. Snacks (such as potato chips)
4. Butter, margarine (Many people add fat to foods to flavor them.)
5. Gravy, mayonnaise
6. Baked goods (such as cookies, cake, muffins)
7. Fat added in cooking (oil, lard, shortening) such as deep-fat frying (fried chicken, French fries, doughnuts).

Keep in mind that the purpose of this list is **not** to give the participant detailed information about where fat is found in foods. Rather, the purpose is to begin to show them that many different foods that they eat are high in fat and to provide a rationale for self-monitoring. The facts about where fat is found in foods should come later as a byproduct of their own discovery through self-monitoring.

These are the kinds of foods you will have to watch out for as you become a "fat detective." They are also the kind of foods that are widely available, tempting to many of us, and they may even be traditional foods in your family or culture.

Many people aren't aware that most of the fat we eat (70% of it, in fact) is hidden in foods.

For example, fat is hidden in:

- The marbling of meats,
- Baked products,
- Sauces, and
- Batter coatings on deep fried foods.

Here's an example. *[Review the example on the worksheet.]* That's a lot of fat, a total of22 teaspoons or about 1 entire stick of butter or margarine.

The best way to learn how much fat is in food is to **keep track of the amount of fat you eat every day**.

You will need to adapt the following section depending on the participant's literacy level, willingness to self-monitor, and comprehension of the self-monitoring process. If this is Session2, some of the following will be a review of points made at the last session; when possible, make these points using examples from the abbreviated self-monitoring the participant did during the previous week.

The first step is to:

1. **Write down everything you eat and drink in your Keeping Track books.**

This is something we're going to do throughout the first 24 weeks of the study. It is the **most important part of changing your behavior.**

Keeping track of what you eat will help you and I see, in black and white:

- What foods you eat,
- How much you eat,
- When and where you eat, and
- How your eating habits change over time.

Your Keeping Track records will be the very basis for our working together. You and I will be the only ones to see them, so **spelling is NOT important.** You can make up **abbreviations** or use your own shorthand if that makes it easier and faster for you to keep track, just so we both know what you mean.

Note: The use of abbreviations may also help those participants who have difficulty spelling feel less self-conscious.

What IS important is to:

- **Be honest.** That means to **write down what you really eat**, not just what you think will please yourself or me.
- Also, **be accurate**. It's best to write down what you eat as soon as possible after you eat it, because it's easy to forget. For example, count the number of slices of cheese you eat and write down the kind of cheese. Measure portions and read labels (we'll talk in more detail about these things next week).
- And **be complete**. **Include everything.** The butter on the toast, the cream in the coffee, and the mayonnaise on the sandwich.

It may seem hard to write down all of your foods, especially at first. And it does take some time. But it's worth its weight in gold. **Being aware of what you are eating is the first step toward changing your eating habits.**

2. **Figure out how much fat is in every food and write it down.**
   To do this, you will need to:

   1. Figure out the amount of the food you ate.
   2. Look up each food in the Fat Counter, which is a book I'll give you that lists foods and the grams of fat in each one.
   3. Compare the amount of food YOU ate with the amount in the Fat Counter to see how much fat you ate. And third,

3. **Add up the fat grams you eat during the day.**

I'll show you how to do each of these things in just a minute.

Give the fat gram goal.

Everyone in the Lifestyle Balance Program gets a fat gram goal or "budget." It is based on body size and the amount of calories needed to lose weight. So everyone has a different goal.

Your fat gram goal or "budget" is to stay under xx grams of fat each day. You can think of it as a budget because you need to stay *under* it every day. *[Fill in the blank with the participant's fat gram goal (refer to the Manual of Operations).]*

A gram is the way fat in food is measured. A gram is a unit of weight. One paper clip weighs about 1 gram. *[Note: Be careful not to go into too much detail here because some participants may be easily confused by the differences between grams of weight and grams of fat.]*

We don't expect you to stay under your fat gram goal right away or be able to stay under it every day. It may be hard to reach your fat gram goal at first. For now, just try to **get as close to your goal as you can.** During the next few weeks, we will teach you how shop for food and cook and serve it so that it is easier for you to reach your goal. Overtime we'll work together so that you can consistently stay *under* your fat gram goal.

Give the participant the Fat Counter. Demonstrate and practice how to use it and food labels to figure out how much fat the participant eats. *[If this is Session 4, also give the participant measuring tools.]*

This is a Keeping Track of Fat "practice page." Let's write down some of the foods you ate yesterday and figure out the grams of fat in those foods.

Write on the work sheet a variety of foods that the participant ate yesterday. If possible, include both high- and low-fat foods and several foods with portion sizes that might require some calculation on the part of the participant. Show the participant how to look each food up in the Counter and calculate the number of fat grams in the amount that the participant ate.

Exactly how you do this will vary from participant to participant. The key is not to overwhelm those participants who may find calculations difficult and confusing. Assure these participants that you will continue to help them with this in the upcoming sessions and that the **important thing for now is to begin looking foods up in the Counter and getting an idea of the amount of fat in different foods and in various serving sizes.**

As you look foods up in the Counter, give the participant the weighing and measuring tools and make the following points:

> **Here are some measuring cups and spoons for you to start to use**, just to get an idea of the amount of food you usually eat. **Next week we'll go over measuring in more detail and practice it together.**
>
> For now, you might want to pour your breakfast cereal into the bowl you typically use, just as usual, and then measure the cereal before you eat it. Or put the amount of margarine you usually spread on toast onto the knife and measure it using the measuring spoons before you spread it. The glass measuring cup is for liquids. This scale is for weighing meats and cheese (briefly demonstrate how to use it). The ruler is for measuring things like pizza, pieces of pie, and cookies.

Here are some things to keep in mind **when you use the Fat Counter.**

If you can't find a food:

- Look for one that is the most like that food. (Don't assume that a food doesn't contain fat because it's not listed in the Fat Counter.) For example, use nut bread for zucchini bread.
- Write the name of the food in the back of your Fat Counter. There is a section there for listing additional foods. Then ask me about it next week, and I will help you find the fat grams.
- If you are having trouble figuring the grams of fat:
- Just write down the food and the amount you ate. I will help you figure the fat grams when you come in.

If you make a recipe:

- For many recipes, you can simply write down how much of each ingredient you ate. For example, in a stew, write down the amount of each ingredient that was in the amount you ate. For example, how much beef you ate, how much carrots, and so on. Include any fat that you used in cooking.

- If you cook from recipes often, bring in some favorite recipes next week. I will help you count the grams of fat in them.

An optional handout is available on counting fat grams in more complicated recipes. We think that this handout should be saved for a later session, and at this point it would be more appropriate to ask the participant to bring in any recipes he or she uses often and help the participant estimate the fat grams. Remember that the participant is self-monitoring, not recording dietary data for nutrient analyses, and the point is to learn to distinguish high fat from lower-fat foods and make dietary changes toward the fat gram goal.

If you do use the handout at some point, use it to demonstrate how to count the fat grams in one of the participant's own recipes, rather than alone.

The bottom line for this week is to just get started and do your best. If you run into any problems, I'll help you with them next week.

If you eat a packaged food:

- Look on the label for the fat grams. (Even if it is listed in the Fat Counter, the grams on the label are more accurate.) First, find the Nutrition Facts on the label, and look at the serving size. Is this the amount you ate? And look at the total fat grams per serving.

- What if you eat a larger serving than is listed on the label? You will be eating more fat grams than are listed on the label.

Review the sample label on the work sheet. Be sure that the participant understands that the serving size on a label may be very different from what most of us consider a serving.

Demonstrate and practice how to add up fat grams during the day.

Some participants may be confused and overwhelmed at this point because of difficulties with calculations. Do **not** review adding up fat grams with these participants until the beginning of the next session. Instead, simply use the "Adding up the fat grams" worksheet to practice again how to look up fat grams and calculate the number of fat grams in the amount eaten by the participant. As before, tailor this to the participant's skill level.

> The final step in keeping track of fat is to add up the fat grams you eat during the day.
> There are two ways you can do this in your Keeping Track.
> *[Turn to Adding Up the Fat Grams work sheet.]* Imagine that this is your Keeping Track.
> Let's write in some of the foods you ate last week, the amounts you ate, and the grams of fat. In the Grams of Fat column, you can put a slash mark after the number of grams of fat and write down a "running total" (keep adding up the grams of fat throughout the day).

Demonstrate or have the participant calculate several running totals.

> A running total is like a subtotal or running balance in a checkbook. The purpose of keeping a running total is so you know just how much fat you've eaten as you go along. You can use this to plan what foods you choose for the rest of the day. For example, "What should I have for lunch? Well, I've eaten x grams of fat so far. My fat gram goal is x grams. So I'd better eat less than x grams of fat for lunch to stay under my fat goal for the day." This is like using a budget to manage how much money you spend.
>
> Another way to add up the fat grams is to use what we call the Fat Bank, these columns that look like rulers. The left column is the Fat Budget. The right is Over Budget.
>
> I'll show you how to use it.

Have the participant do as much of the following as possible. Provide help as needed.

a. **Your fat goal is x grams. Find that number on the Fat Budget column and put an arrow beside it**. Cross through all of the notches above your goal.
b. **Then fill in or cross through one notch for each gram of fat you eat.** Start at your fat budget and go DOWN.

Demonstrate or have the participant cross through the notches for the breakfast foods.

> You can easily see about how much fat you have left for the day in your budget.

c. **If you cross through all of the notches in the Fat Budget column, start at the bottom of the Over Budget column and go UP.** This will let you see how much over your fat gram goal you are.
d. **Write the total fat grams for each day on the back of your Keeping Track booklet** (show the participant where the totals should go). This will help us both to see at a glance how you've done during the entire week.

Have the participant complete the grams of fat, running total, and Fat Bank columns for the rest of the foods on the sample. Also, show the participant where to transfer the total fat grams for the day to the back of the Keeping Track book. Again, be careful not to overwhelm the participant.

> Changing the way we eat is a gradual process and it will take time. I don't expect you to be perfect. During the next few months you will learn many different ways to help you eat less fat. For now, I want you to be the best fat detective you can be, looking for fat everywhere. And just do your best to **come as close to your fat gram goal as you can.**

Do you have any questions?

Participants should leave this session aware that:

1. We are more interested in their efforts to be honest and complete about their eating habits than to present us with picture-perfect Keeping Track records, and
2. We consider self-monitoring a very important tool and expect everyone to do some monitoring.

Assign home activity.
For next week:

- Keep track of your weight.
  Weigh yourself at home every day at this time of day.
  Record your weight on the back of the Keeping Track book.
- Keep track of what you eat and drink.
  Write down everything you eat and drink in your Keeping Track books.
  - Do this every day, as soon as possible after you eat.
  - Be honest.
  - Measure portions as much as you can and start reading labels.
  - And be sure to include everything you eat.

  Use the Fat Counter to figure out how much fat is in what you ate, and write it down in your Keeping Track books. Keep a running fat gram total throughout the day. Try using the Fat Bank, too. Come as close to your fat gram goal as you can.
  If this is Session 4:

Keep track of your physical activity, as you have been. And be a little more active this week-- your goal is (for most participants, it will be 120minutes).

Session 3:
Three Ways to Eat Less Fat

Objectives:

In this session, the participant will:

- Review self-monitoring skills, and learn in more detail how to weigh and measure foods, by estimating 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.
- If this is Session 5: Develop an activity plan for the coming week (for most participants, a weekly total of 150 minutes).

To Do Before the Session

Get materials ready:

- Measuring cups and spoons, glass measuring cup, scale, and ruler.
- Fat Counter.
- Pages for participant notebook.
- Optional handouts that are appropriate for a specific participant (e.g., the blank "Menu Make-Over" work sheet).
- Food models or actual foods for weighing and measuring demonstration. Include a selection of common high-fat foods, plus enough food models of teaspoons of fat (1teaspoon = 4 grams of fat)--or test tubes filled with measured amounts of shortening — to show graphically the fat content of the foods. If possible, choose actual foods that you know the participant eats often. If this isn't possible, try to use food models that weigh close to what the actual food would weigh to avoid confusing the participant (for example, regarding the weight of various portion sizes of meats). For the actual foods, weigh or measure them in advance. For the food models, tape the amounts on the bottom. Some foods that may be suitable:

To weigh on the scale:

- 3 oz (after cooked) regular (25% fat) hamburger patty (keep frozen) to weigh on scale. 19 grams of fat (equivalent to 5 teaspoons of fat).
- 4 ounces cheddar cheese, thinly sliced by a deli (keep refrigerated). 28 grams of fat(equivalent to 7 teaspoons of fat).

To measure in metal or plastic measuring cup, teaspoon, tablespoon:

- 3 teaspoons of soft margarine in a tub (keep refrigerated). 12 grams of fat (equivalent to 3 teaspoons).
- 4 tablespoons of oil in the bottom of a frying pan, plus same amount in a small jar or bowl. (Ask the participant to guess the amount in the pan first, then bring out the jar or bowl of oil for the participant to measure with a tablespoon). 48 grams of fat
(equivalent to 12 teaspoons of fat).

- 1-3/4 cups macaroni and cheese made from a mix (keep refrigerated). 34 grams of fat (equivalent to 8 teaspoons).
- 3 cups of "butter-flavored" movie popcorn. 29 grams of fat (equivalent to 7teaspoons of fat).

To measure in the glass measuring cup:

- 1-1/2 cups of whole milk in a large cereal bowl (keep refrigerated). 12 grams of fat(equivalent to 3 teaspoons of fat).

Weigh the participant. Mark weight on the How Am I Doing? Graph for weight.

If the participant has lost weight, congratulate him or her, but don't go overboard. Stress the fact that he or she must already be making some changes in **behavior.**

If the participant has not lost weight, mention it but stress that little by little as she or he makes behavior changes, the numbers on the scale will change.

Check if the participant weighed himself or herself at home. Discuss the fact that the two scales may differ. Patterns of change should be similar on both (if gain weight on clinic scale, home scale should show a weight gain, also).

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. [If this is session 5, graph activity, also.]

> Were you able to write down anything this week about your eating?
> What did you learn by Keeping Track? What difficulties did you have?
> Were you surprised by the amount of fat in some foods?
> How did using the Fat Counter go?
> Were you able to keep a running total of fat grams or use the Fat Bank?
> How close did you come to your fat gram goal?

Refer to the script for the 'Be a Fat Detective" for guidelines on how to review the Keeping Track records.

Review self-monitoring skills using the Fat Counter, weighing and measuring tools, and actual foods or food models.

> We've given you measuring cups and spoons and a scale because **weighing and measuring foods is important**. Today we're going to start with something a little more "hands-on" than we've done so far and practice weighing and measuring together. First, let me go over some details about how to use the cups and scale and so on. You may be doing these things already.

> **Metal or plastic measuring cups and spoons**

Use these for solid foods like margarine or mashed potatoes. Fill the cup or spoon and then level it off before you record the amount.

Demonstrate how to level.

Leveling can make a big difference. For example, even two extra tablespoons of granola on top of a cup that hasn't been leveled will add about 3 grams of fat.

Glass measuring cup (demonstrate this, although the study does not provide one)

Use a glass measuring cup, if you have one at home, for liquids like milk or soup. Pour the liquid in the cup, then read the line at eye level. If you read it from above, your eyes can fool you.

Demonstrate measuring liquids and reading the amount from eye level. Use any liquid. Water is fine.

Scale

The best way to measure meat and cheese is on a scale. Even a small amount can make a big difference in fat. Scales can measure very small amounts.

Demonstrate the use of the scale by weighing an actual food or food model. Have the participant weigh another food or food model. Make sure the participant can use the scale and read the results.

It's important to **weigh meats after they are cooked**. They lose about a quarter of their weight in cooking. So 4 ounces of raw meat weighs about 3 ounces when it's cooked. Three ounces of meat is about the size of a deck of cards or your palm, minus the fingers.

When you weigh cheese, you'll notice that one slice might look like another but not weigh the same. For prepackaged slices, you can check the label for the weight.

Most people are surprised when they begin to weigh and measure foods. Our eyes can play tricks on us.

Here are some common high-fat foods that someone might easily eat in a day.

Show the participant food models or actual foods for common high-fat foods. Review the instructions on the work sheet and have the participant complete the chart except for the column "Teaspoons of Fat." If possible, use some actual foods that the participant eats often and observe the participant using the weighing and measuring tools so you can check her or his technique. Note: It may be helpful to repeat this activity at various points during the intervention, particularly after the Progress Review during Session 7 or

8, 12, and 16, as a way to review measuring skills and demonstrate the importance of accurate portion estimation.

Were you surprised by the actual amounts? Even small mistakes in estimating amounts can make a big difference in the fat grams.

Eventually you will get better at judging food amounts by looking. **For now, weigh and measure foods as often as you can.**

Last week we talked about the fact that most of the fat we eat is hidden in foods (70%, in fact). For example, fat is hidden in:

- The marbling of meats,
- Baked products,
- Sauces, and
- Batter coatings on deep fried foods.

Let me show you what the fat in these foods would look like if we could see it as teaspoons of butter, margarine, or oil. *[Fill in the last column of the worksheet and if possible, illustrate using food models of teaspoons of butter or test tubes of measured amounts of shortening.]* That's a lot of fat, a total of x grams and x pats (or x sticks) of butter or margarine altogether *[note: one stick of butter or margarine = 1/2 cup or 24teaspoons].* Pretty amazing.

Introduce the three ways to eat less fat.

Many different kinds of foods are high in fat, but there are only three basic ways to eat less fat.

1. **Eat high-fat foods less often.** *[Review the example on the work sheet.]*

2. **Eat smaller amounts of high-fat foods**. Cutting back even a little can make a big difference. *[Review the example.]*

3. **Eat lower-fat foods instead.**

In the coming months, you'll discover a number of ways to "eat lower-fat foods instead." Here are a few examples of the difference you can make. *[Review the examples on the work sheet, including the warning about the calorie content of low-fat or fat-free products. Use other or additional examples if they would be more relevant to the participant's eating pattern.]*

Review the "menu make-over."

These menus show examples of small changes that make a big difference in fat grams saved. These are examples of the different ways to eat less fat, not menus for you to follow.

You will make your own food choices to reach your fat gram goal.

Review the examples on the worksheet. Mention that potato chips appear in both menus, and explain that there are no "good" or "bad" foods (the participant can eat any food in a small amount now and then and still reach his or her fat gram goal).

A blank "Menu Make-Over" work sheet is available if at this or other sessions the participant would benefit from recording personal examples of high-fat menus and corresponding make-overs.

Assign home activity.

Let's focus now on what you can do next week.

- Keep track of your weight and what you eat. Keep a running fat gram total throughout the day, and try to stay under your fat goal (budget).
  [If this is Session 5] And continue to keep track of your physical activity. This week be a little more active, for a total for the week of. *[Fill in the blank. For most participants, the goal will be* ***150 minutes****.*]
- Make a plan to eat less fat and follow it.

Let's make the plan right now using this chart. First, write down 5 foods you eat that are high in fat. These should be foods that you eat often (not, for example, birthday cake that you eat only rarely). Now circle one of these foods and pick one of the three ways to eat less fat from that food.

Complete the rest of the work sheet with the participant, and assign the questions at the bottom as part of the home activity. Stress that the plan to eat less fat should be specific and realistic.

Session 4:
Healthy Eating

Objectives:

In this session, the participant 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 the participant's 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.

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Poster of Food Guide Pyramid.
- Optional handouts that may be appropriate for a specific participant (for example, one on low-fat recipe substitutions for participants who cook from recipes often).
- Individual samples of low-fat foods to taste (optional).

Weigh the participant. Mark weight on the How Am I Doing? Graph for weight.

If the participant has lost weight, congratulate him or her, but don't go overboard. Stress the fact that he or she must already be making some changes in **behavior.**

If the participant has not lost weight, mention it but stress that little by little as she or he makes behavior changes, the numbers on the scale will change.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. [If this is Session 6, graph activity.]

If this is Session 6:

> Were you able to follow your activity plan from last week?
>
> Discuss any barriers and problem solve with the participant. Graph on the How Am I Doing? Graph for activity.
>
> What did you learn by Keeping Track last week? What difficulties did you have?
> Were you surprised by the amount of fat in some foods?

How did using the Fat Counter go? Did you keep a running total for fat grams?
Did you follow your plan to eat less fat? How close did you come to your fat goal?

Refer to the script for the ‘Be a Fat Detective” for guidelines on how to review the Keeping Track records.

Discuss how eating less fat fits into the overall context of healthy eating. Introduce the Food Guide Pyramid.

In the past few weeks, we've talked quite a bit about eating less fat. **Eating less fat is essential to losing weight. It's also one important part of healthy eating in general.** Today we're going to talk about some of the *other* parts of healthy eating. We'll look at your overall eating pattern to see how healthy it is and how you might improve it.

What exactly is "healthy" eating?

One part of healthy eating is the *way you eat.*

- **A regular pattern of meals is important.** Try to eat 3 meals each day. This will keep you from getting too hungry and losing control.
- **Eat slowly.** You will digest your food better if you take small bites and chew your food well. Also, you'll be more aware of what you are eating and more aware of when you are full. Try pausing between bites, putting down your utensils, and enjoying the taste of your food and the company who may be present.
- **Don't worry about cleaning your plate.** The greatest waste of food is to eat more than you want or need. Practice serving yourself smaller portions to begin with.

Another part of healthy eating is *what you eat*. One way to define what's included in a healthy eating pattern is by using the **Food Guide Pyramid.** Have you heard of the Food Pyramid? *[Tailor the following discussion based on what the participant already knows about the Food Pyramid.]*

The Food Pyramid is a **general guide to healthy eating** that's based on the latest findings about nutrition and health.

Turn to the Food Pyramid work sheet and point out the base of the pyramid.

The pyramid image is used because at the bottom is the **foundation**, the largest part of the structure, what the rest of the eating pattern is built on.

The foundation of the Food Pyramid is grains, or the **bread, cereal, rice, and pasta group**. These foods should be the main part of your diet. A healthy eating pattern includes **6 to 11 servings** from this group. A generation ago, many families built their meals around meat: the "meat and potatoes" eating style. Now we know that most Americans eat too much fat and protein, and much of it comes from big servings of meat.

So in the Food Pyramid, the foundation is not meat, but rather breads, cereals, and other grain foods.

After naming the group and stating the recommended number of servings, ask the participant the following questions for every group except fats, oils, and sweets. As you do so, write on the work sheet a few examples of low-fat choices for each group, including serving size.

If possible, use example foods mentioned by the participant. Keep the discussion simple and tailor it to the individual (use examples that match the participant's eating preferences and ethnic background). A Food Pyramid handout on the next page will provide more details for participants who want them about the types of foods and serving sizes in each group. Ethnic variations are available. Do not review the entire Food Pyramid if it would be overwhelming to the participant.

1. **What are some low-fat foods that would fit into this group? What do you think would be considered one serving of these foods?**

2. **Can you think of any high-fat foods that would be in this group? These would be the foods for you to avoid.**

3. For the breads and cereals group: Many people think bread and potatoes and other starchy foods are high in fat, but actually it is the fat added to them in cooking or at the table that makes them high in fat. Potatoes are a good example: plain potatoes are low in fat, but by adding butter or sour cream, they become high in fat.

4. For the meats group: Nuts are included in this group (for example, peanut butter). All nuts are very high in fat. And many meats are high in fat, too. Americans tend to eat too much meat. We used to think we needed to eat a lot of meat to get enough protein, but now we know that Americans tend to eat *too much* protein. The Food Guide Pyramid recommends only two to three servings from the meat group and the portion size for a serving of meat is only 2 to 3 ounces. (Use a food model to illustrate this.) The meats group also includes dried beans. Have you tried dried beans, like kidney beans in chili? Unlike most meats, dried beans are high in protein but low in fat, unless you cook or serve them with added fat.

5. For the milk group: Some people have trouble drinking milk because it gives them gas, bloating, and diarrhea. Is that a problem for you? If so, milk products that are lactose-free may help you get rid of these problems.

6. The smallest part of the Pyramid is at the top, fats**, sweets, and alcohol.** These foods should be eaten **only in small amounts**. In general they don't provide vitamins and minerals, and they are high in calories, "empty" calories. {Remember that fat contains 9calories per gram and alcohol contains 7 calories per gram, compared to carbohydrates and protein at 4 calories per gram. Small

amounts of sweets won't add many calories, but many sweets, like cakes and chocolate, are also high in fat.)

a. What are some lower-fat alternatives for foods in this group?
b. What are some of the high-fat foods to avoid?

Have the participant compare his or her eating pattern to the Food Pyramid recommendations.

Let's look at one or two days from your Keeping Track book and compare what you ate to the guidelines given on the Food Pyramid. *[Turn to Rate Your Plate page.]* Let's start with breakfast and look at how many breads, cereals, rice, and pasta you had.

Move on throughout the day's record, and check off on the Rate Your Plate chart each serving from the food groups. Don't worry about being precise. This is not a self-monitoring record but a general guide to healthy eating. Clarify in simple terms any questions that come up regarding serving sizes.

- Consider one fat serving to be: one teaspoon of butter, margarine, oil, or regular mayonnaise; 1 tablespoon of cream cheese or salad dressing; or 10 peanuts.
- Consider one sweets serving to be: ½ cup of ice cream, 1 small cupcake or piece of cake, or 2 small cookies.
- If the participant drinks alcohol, explain that a) the recommendation is that if you choose to drink alcohol, do so in moderation, and b) alcoholic beverages are high in calories.
- Consider one serving to be one can (12 fluid ounces) of beer (150 calories), one glass (5fluid ounces) of dry wine (115 calories), or 1.5 fluid ounces (one "shot") of liquor (105calories). Mixers, such as tonic or a regular soft drink, add more calories.

Continue with a second day if appropriate.

What could you do to better match the Pyramid?

It looks like you could eat more *[vegetables*]. Let's think about tomorrow. If you want to eat 3 to 5 servings of vegetables, how could you do it?

Write example food choices and amounts on the work sheet, total the servings, and compare to the goal number of servings. E.g., 2 servings of salad with nonfat salad dressing for lunch, 1cooked vegetable and 1 serving salad with nonfat salad dressing for dinner = 4 servings. **Emphasize the importance of increasing grains, vegetables, and fruit.** It is not necessary to complete the rows for every food group.

Provide more examples of ways to "eat lower-fat foods instead."

Last week we talked about the three ways to eat less fat, one of which is to "eat lower-fat foods instead." The Food Pyramid and "eating lower-fat foods instead" work together. Here are some examples. *[Review the guidelines on the work sheet, highlighting those that are particularly relevant to the participant and reviewing examples from all of the Food Pyramid groups.]*

Do you **cook from recipes?** Or does your spouse? What are some examples?

If the participant does a *great deal* of cooking from recipes, review the guidelines on the optional handout, **Build a Better Recipe**, highlighting those that are particularly relevant to the participant. If the participant only uses recipes occasionally, save the optional handout for a later session because this session is so full of information.

If the participant wants help in lowering the fat in a favorite recipe, have the participant bring the recipe to the next session and modify the recipe with the participant at that time.

Don't review recipe substitutions or modifications at all if the participant seldom cooks from recipes.

For some participants, recipe modification may be helpful as a small part of several future sessions, and it may be important to include other family members who cook for the participant. Regardless, remember that this is an early session and don't try to do too much at this point. Demonstrations of low-fat cooking can be done in future sessions during the maintenance phase of the trial.

Assign home activity.

For next week, I want you to:

- Continue to Keep Track of what you eat [*if this is Session 6, also assign Keeping Track of activity.]*
- For this week only, we're adding one more simple form, the same one we used today to Rate Your Plate. Use the two pages after this one to go over your Keeping Track records and compare what you ate to the Food Pyramid. [*Review the instructions on the forms.]*

Completing the Keeping Track booklet is much more important than completing the Rate Your Plate form. If the participant seems very reluctant to complete the Rate Your Plate forms, mention that you can complete them together at the next session and that the priority is to Keep Track.

Also, answer these questions before our next meeting:

- Did you make any changes during the week to better match the Food Pyramid? If yes, what were they?
- What problems did you have? How did you solve them?

Any questions?

Session 5:
Move Those Muscles

Objectives:

In this session, the participant 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 exercise that the participant enjoys.
- Discuss the importance of wearing appropriate clothing.
- Develop an activity plan for the coming week (for most participants, this will be a total for the week of 150 minutes of activity) that includes the Lifestyle Balance activity sessions and other moderate activities that the participant enjoys.

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Schedule and map for the supervised activity sessions.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

> Were you able to come to the Lifestyle Balance activity sessions last week?
> Were you able to do something active on 3 to 4 days during the week?

Be positive and nonjudgmental. Praise all efforts to be more active, no matter how small. If the participant did not attend the sessions and/or did not do at least some activity during the week, ask, "Tell me a little about that." Do your best to uncover some of the barriers that prevented the participant from attending or being active without making him or her defensive. Problem solve with the participant to address any barriers. Stress again the important reasons for attending the activity sessions, particularly at the beginning of the study, and for taking steps to be active to some degree on a regular basis.

If this is Session 5 (the last session was “Healthy Eating”):

> How did Keeping Track go last week? Did you “Rate Your Plate?” Did you make any changes during the week to better match the Food Pyramid? If yes, what were they? What problems did you have? How did you solve them?

Review and comment on the participant's self-monitoring records. If the participant did not complete the "Rate Your Plate" form, complete the form for one or two days with the participant. Praise all improvements, no matter how small. Problem solve with the participant to address any barriers.

Weigh the participant and graph.

Introduce the Lifestyle Balance activity goal.

So far you've focused on losing weight through healthy eating. This week and next week we'll focus on the other goal of the Lifestyle Balance program: being more active.

> The Lifestyle Balance activity goal is to **do a total of 2-1/2 hours of physical activity each week.** This will burn about **700 calories per week**.

Assess participant's current level of activity.

Now, before we can make an activity plan for you, I need to know **how active you are now.**

The purpose of the following discussion is to get a general idea of how active the participant is and to get the participant talking about his or her personal preferences and experiences with physical activity. Record the participant's answers on the work sheet, and make notations of pertinent details in the participant's progress notes so that you will be able to understand the situations (cues) that promote or derail a participant's physical activity. For example, if a participant has been able to exercise regularly in the past, primarily by doing it at lunch with a coworker, then this valuable piece of information can be highlighted from the start and the participant can be helped to arrange his/her environment accordingly.

- **Do you do any kind of regular physical activity that lasts at least 10-15minutes?** (Examples: work out at a health club, etc.) Where do you do these activities? With whom?
- How many **times each week** do you do these activities? And when you do, **for how long are you usually active?**
- Have you done any **activities in the past** that you no longer do? Why did you stop? Have you thought about starting to do them again?

If the participant names one or more activities, use them as a starting point when planning for next week.

- **What do you like or dislike about being active or being inactive?** (Record.)

Provide the rationale for the activity goal.

I want to be sure you understand why being more active is so important. **Being more active will:**

- **Help you feel and look better.**
  Being active can:

- Improve your mood,
- Counter depression and anxiety,
- Give you more energy,
- Help reduce stress,
- Be a way to meet new friends,
- Help you sleep better,
- Improve your self-esteem (help you to feel better about yourself in general),
- Improve your muscle tone and body measurements.

Many people report that they simply **feel good** when they're more active, and they really miss it if they've been active for a while and then stop.

- Regular physical activity will **make you more physically fit.** It will:

  - Strengthen your heart, lungs, bones and muscles,
  - Make your joints more flexible,
  - Reduce pain and injuries,
  - Make it easier for you to do your daily work, like carrying groceries,
  - Make it easier for you to play with your children or grandchildren.
  - **Help you lose weight and keep it off.**
  - Research has shown that the best way to lose weight is to eat a healthy diet **and** be more active. A combination of both is also the best way to keep weight off.

  In addition to helping you lose weight, be more fit, and feel better in general,

- Physical activity will **lower your risk for heart disease, some kinds of cancer, and may help prevent diabetes.**

  Being more active:

  - Raises HDL cholesterol (the good cholesterol),
  - Lowers triglycerides, and
  - Lowers blood pressure if it is elevated.
  - Being more active also lowers blood sugar by making the body more sensitive to insulin. This reduces the risk of diabetes.

Describe the Lifestyle Balance activity sessions.

It's not easy to start being more active. We are here to help. Some things that can help you are to:

- **Come to the Lifestyle Balance activity sessions!**

List other activities that the participant enjoys that can be counted toward the activity goal.

- It will also help if you **plan activities you LIKE to do**.

After all, the point is to make physical activity a regular part of your lifestyle, and that will never happen unless you enjoy the activities you do. Exercise should be intense **enough to breathe heavier than usual and to consider that you are working hard, but not so fast that you can't carry on a conversation or have trouble breathing.**)

Many kinds of activity are good. **What other activities might you like to do?**

Write on the work sheet **only the activities the participant should count toward the activity goal,** that is, those that are equivalent to brisk exercise, as indicated in the Lifestyle Intervention.

Manual of Operations. Don't review the list of activities in the Manual of Operations with participants, but use it as your own reference only.

From time to time, the activities you like may change. Just let me know, and we can make changes to this list.

Develop an activity plan for the coming week.

Now let's make a **plan for next week.**

- During the week I want you to **be active for**.

Fill in the blank on the work sheet with the total number of minutes of activity per week (for most participants, this should be **60 minutes**).

For example, you could do xx minutes of activity on 3 different days of the week. We'll gradually increase this over the next three weeks until you're up to 2 ½ hours of new activity per week.

- **Include a friend or family member if you would like.** Some people like to be active alone, as a time to do something special for themselves. But many people find it helpful to be active with someone else. Is there anyone you would like to invite to exercise with you?
- **Include the Lifestyle Balance activity sessions.**
- And remember to **plan activities you LIKE to do.**

Okay. Let's write down the activities you will do on which days of the week. How many minutes will you do them? It should be for **at least 10 minutes.**

- Also, **keep track of your physical activity every day** *[or, if this is Session 5, keep track of your weight, eating, and activity].* Use your Keeping Track books. Keeping track will help us both to know how you are doing from week to week.

Show the participant where in the Keeping Track book to self-monitor activity. If this is Session 2, you have already shown the participant how and where to self-monitor activity, so the following will be somewhat redundant.

> Write down what the activity was and how long you did it. Also, if you're exercising and know the distance in miles, write that down too if you want to. Use one line for each time you're active, even if it's the same kind of activity. For example, if you go around the block at 8:00 in the morning and again at 7:00 in the evening, write both down separately.
>
> It's also important to **record only the amount of time you were actually *doing* the activity.** By that I mean don't include the time when you may have been taking a short break. For example, if you exercised and after 10 minutes you ran into a friend and stopped to talk for 5 minutes before exercising for 10 more minutes, you should only write down 20 minutes of exercise, not 25 minutes. The same is true for when you go swimming. If you are in the water for 60 minutes but only swim laps for 10 of those minutes, then you were only active for 10 minutes and that is what you should write in your Keeping Track.

Session 6:
Being Active: A Way of Life

The script for this session is written as if the participant has been relatively sedentary before this time. Use your judgment to change your presentation of the session for those participants who have already been fairly active.

Objectives:

In this session, the participant 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).

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook, including individualized How Am I Doing? graph for activity.

Weigh the participant. Graph the weight in the participant's notebook.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

> Last week we made a plan for your physical activity. **How did it go?**

Review the participant's Keeping Track records for activity. Praise any physical activity that was done, whether or not the participant reached his or her weekly goal.

If this is Session 6: Also review the participant's dietary self-monitoring and progress toward fat and/or calorie goals and weight loss.

Did you attend any of the activity sessions?

Emphasize again the importance of these sessions, especially at the beginning of the program. If the participant did not attend, try to uncover and address anything that got in the way.

> Did you have any trouble Keeping Track of your activity? *[If "yes," review.]*

Graph participant's activity.

> Every week we'll **mark your activity on this graph** *[show the participant the How Am I Doing? graph for activity].* We'll use the graph to see your progress over time and how you are doing compared to your activity goals.

Mark the participant's recorded activity from last week on the graph, or if possible, have the participant do so.

Discuss barriers to activity.

> It's important that we try to **solve any problems you're having following your activity plan.** Let's take last week. Did anything get in the way of your plan for activity?

Discuss whatever problems the participant brings up and brainstorm possible solutions. Consider any additional difficulties, such as upcoming cold weather, that the participant may face in the next few weeks and make plans to cope with these. Keep the examples relevant to the present or very near future. Examples:

Problem:	Children.
Solution(s):	Get a baby sitter or other family member to watch them.
	Include the children in the activity (e.g., going for a exercise).
Problem:	Hot weather.
Solution(s):	Exercise early or late in the day when it is cooler.
	Exercise indoors
Problem:	Cold weather or rain.
Solution(s):	Wear appropriate clothing.

Optional participant handouts are available on various barriers to activity, such as cold or hot weather. Give the participant only those that are relevant at this time.

Discuss time as a barrier.

One of the most common problems is lack of time. Everyone's busy these days.

But **you *can* find the time to be active.**

Here are two different ways.

- **Set aside one block of time for planned activity every day.**
  Make being active a predictable part of your daily routine, like taking a shower may be a predictable part of your morning.

Use an example that is particularly relevant to the participant's lifestyle. For example, businesspeople may relate to an example of making a "standing appointment" for physical activity. Mothers may relate to an example of planning time to read a bedtime story every night to a child.

When can you set aside 20 to30 minutes to do an activity you like? Are you a morning person? Or would you enjoy getting out for exercise during lunch? How about after dinner? *[Complete the work sheet.]*

Some people can't find one big block of time to be active. Either their schedules vary a lot from day to day, or they're so busy that there isn't a 20-30 minute period that's free on most days. For some people, this might be the case during certain seasons of the year, for example, during the fall when after-school schedules begin to get hectic for their kids.

In these situations, it's usually easier to use a different approach.

- **Be on the lookout during the day for 10 to 15 minutes of free time. Use the time to be active.**
  For example, you might be able to take a 10-minute break between meetings at work and go for exercise. Then later, take another 10-minutes to exercise after lunch. In the evening, take 10-minute exercise before you pick your son up from soccer practice. By the end of the day you've done 30 minutes of activity.

In a way, you really can't "plan" for these times, but you can think ahead about when to be on the lookout for them. Or seize the moment! Sometimes all the best planning in the world falls apart. There's still the "spontaneous approach." On some days you might look at the work or housekeeping you have ahead of you and realize, "I'm not going to finish all of this today, no matter what I do." So plan your exercise and JUST GO!

Can you think of any times during the day when you have 10 or 15 free minutes?
[Complete work sheet.]

Discuss lifestyle activity.

We've been talking about the kind of activity you will be recording in your Keeping Track books, whether you do it in one block of time or at several times during the day. Another important kind of activity is called "**lifestyle activity**." It involves **making active choices throughout the day.** It's hard to record this kind of activity, so **we aren't asking you to write it down in your Keeping Track books**. But it is just as important as what you do record.

An example of an inactive choice is when you shop, park your car as close as you can to the entrance to the store. An active choice is to park your car further away and wheel/walk. This may only take a minute or so to do, but every minute of activity has an impact on your overall health and it adds up to a "more active you."

Our parents, and especially our grandparents, didn't have a choice about being active throughout the day. They were active because they had to be. There weren't elevators in every building. They had no car or only one car for the entire family. They had no phone or only one phone and so they ran up or down the stairs to answer it. They did the dishes and laundry by hand. It was simply their way of life. By contrast, most of us now have so many conveniences that our lives are almost guaranteed to be inactive unless we **consciously make active choices.**

What are some active choices you could make during the day? What are some inactive choices you could limit?

Add examples to the chart. Possibilities include:

- Wheel/walk to a nearby store rather than driving.
- Go for a 2-minute exercise session during TV commercials (especially food commercials!).
- Do stretching exercises while watching TV.

Turn inactive time into active time.

Many people say they have no time exercise but they watch several hours of television in the evening. **Try cutting your TV time in half and turn it into exercise time.** Or be active while you watch TV. Lift weights, or exercise with your arms.
At first, you may think of exercise as a way to relax after along day. But when you get used to it, you'll discover that exercise is a great way to relax and unwind, and you may feel much more rested and refreshed than you would have had you spent that time on the couch in front of the TV.

Discuss ways to prevent injury and give the participant some handouts on simple stretches and when to stop exercising.

- Build up your activity *slowly.* Start and end each session *slowly.* Exercise at a less intense pace is a fine way to warm up and cool down. If you want, you can also do some simple stretches like those on these handouts.

  These handouts also tell you what to do if you get a cramp or a muscle strain or pull and when to stop exercising. So look the handouts over at home and we can discuss any questions you have at the next session.

Note: Don't review these handouts during the session. Most participants will simply be wheeling/walking as their form of physical activity, so it is not necessary to emphasize stretching. Just suggest that they start and end their exercise at a slower pace. For those participants who begin doing more intense activity later on, review these handouts at that time.

If a participant starts doing stretches, make sure they do not include stretching time in their 21/2-hour goal.

Develop an activity plan for the week.

Now let's make an activity plan for next week.

- The goal is to do a little more than last week, for a weekly total of**.** *[Fill in the blank on the worksheet. For most participants the goal will be **90 minutes** of activity per week.]*

Try setting aside one block of time, or plan to use several 10-15 minute periods during the day. Include the activity sessions, and be sure to plan activities you LIKE to do. *[Complete the chart.]*

- Also, **keep track** of your physical activity every day. *[If this is Session 6, assign weight and dietary self-monitoring also.]*

  Record only the time when you are **doing** the activity. (That is, don't include breaks.) And **don't record activities that last less than 10 minutes.** *[Give the participant a Keeping Track book.]*
- **Include lifestyle activity throughout the day.**
  You won't record this, but it is still very important. What active choices do you plan to make during the week?*[Record on the blank line.]*

  Next week we'll talk about the lifestyle activity you did.

Any questions?

Session 7:
Tip the Calorie Balance

Objectives:

In this session, the participant will:

- Discuss how healthy eating and being active are related in terms of calorie balance.
- Discuss how calorie balance relates to weight loss.
- Review the participant's 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, make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

To Do Before the Session

Review some of the participant's past Keeping Track records. Make brief notes of some of the positive changes the participant has made to eat less fat and be more active.

For participants who have not lost weight as expected or have gained weight:

Determine the participant's daily calorie goal (refer to the Manual of Operations).

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Meal plans appropriate for the participant's calorie goal. Tailor to the participant's food preferences as much as possible before the session.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

> Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? (Graph activity.)

If this is Session 8 (the last session was "Take Charge of What's Around You"):

Were you able to get rid of the problem food cue and add the positive cue for being more active? What problems did you have? What could you do differently next week?

If this is Session 7 (the last session was "Being Active: A Way of Life"):

Were you able to make the active lifestyle choices you had planned?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Explain how healthy eating and being active are related in terms of calorie balance.

Everything we've covered so far fits together. It fits together because of what's called the "calorie balance." That's what we'll talk about today.

We've said many times that the Lifestyle Balance Program involves **two kinds of lifestyle changes:**

1. Healthy eating. This includes eating less fat and more grains, vegetables, and fruits, and
2. Being active.

These changes are important in and of themselves. They may prevent diabetes and lower your risk of other diseases. They are also important because they're **both related to weight loss** and that's because of what's called "**calorie balance.**"

Calorie balance is the balance between the calories (or energy) you take in by eating and the calories (or energy) you use up by being active.

When you eat **food,** you take in calories or energy.

- Calories in food come from **fat, carbohydrates (starches, sugar), protein, or alcohol.** Other ingredients in food, like vitamins, minerals, and fiber, don't have calories. (For example, green leafy vegetables are mostly vitamins, minerals, and fiber--and they have very few calories).
- The **number of calories in any food you eat depends on what's in that food. Fat is the most concentrated in calories, with 9 calories per gram.** That's more than twice the number of calories in starches, sugars, or proteins, and even more than alcohol. So foods that are high in fat are high in calories. That's one important reason why our emphasis has been on eating less fat.

  For example, many people think of meats as being "pure protein" but actually most meats contain protein plus a lot of fat, which is where most of the calories in meats come from.

Calories also measure the energy you **use up**.

- You use calories **for just staying alive** (like breathing) and **by any activity** you do.
- The **number of calories you use** in a certain activity depends on several things, including the type of activity, the amount of time you are active, and how much you weigh (basically, the amount of energy used is determined by the amount of weight carried and the distance over which you carry it. When you wheel/walk for a distance of a mile, for example, you are carrying a lot of weight (your body) over a long distance (1 mile).

If the participant is doing a different type of planned activity, check with the exercise physiologist on staff to convert minutes or distance into calories.

Explain how calorie balance is related to weight loss.

Your **weight** is determined by the **balance between food (calories in) and activity (calories out).**

Let's look at four ways the calorie balance can work.

1. Your weight can **stay the same**. In this case, "calories in" from food equal "calories out" from activity. Food and activity are at about the same level on both sides of the scale.
2. Second, you can **gain weight**. In this case, "calories in" from food are higher than "calories out" from activity. Either calories have increased or activity has decreased or both. The balance has tipped this way *[indicate direction of balance]*.
3. Third, you can **lose weight.** "Calories in" from food are lighter than "calories out" from activity. You've eaten less food (by less I mean fewer calories, not less in volume--remember, we said early in the program that you can actually eat more food for the same number of calories by eating lower-fat foods), or you've done more activity, or both. The best way to lose weight is to do **both** at the same time and **really tip the balance** this way *[indicate direction].*
4. And finally, you can reach a **new balance at a new weight.** You have developed new food habits and new activity habits and they are balanced again. This is what happens when you lose weight and keep it off. You've reached a new balance over time.

The important thing to **remember** is that:

- **Food and activity work together** to determine how much you weigh.
- To lose weight, it's **best to eat less *and* be more active.** That way, you are changing both sides of the energy balance at once. **By TIPPING the balance, you can lose the weight you want.**
- Then, over time, you can reach a new balance at a new, lower weight. We will help you to **make the changes part of your lifestyle, so you will keep the weight off.**

Explain calorie requirements for weight loss.

How much do you need to tip the balance in order to lose weight?

The number of calories you need to eat, or the amount of activity you need to do, varies from person to person. But in general, there is a formula we can use. It's based on two facts:

- **1 pound of body fat stores about 3,500 calories,** and
- **Slow, steady weight loss (1 to 2 pounds or so a week) is the best way to lose body fat.** (Quick losses of large amounts of weight can mean that water or muscle are being lost rather than fat, and that's unhealthy.)

So **to lose 1 pound in a week, you need to tip your energy balance by 3,500 calories** in the week. Or 500 calories each day for 7 days. Or to lose 1-1/2 pounds in a week, you need to tip your energy balance by 5,250 calories in the week. Or 750 calories each day for 7 days. For a 2-pound weight loss per week, you need to tip the balance by 7,000 calories in the week, or 1,000 per day.

Again, for weight loss, the best way to tip the balance is to change both food **and** activity.

Review the participant's 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.

Now let's take a minute to review some of the **changes you've made so far** on both sides of the balance.

- First, **what changes have you made to be more active**? We've talked about increasing both planned activity, the kind you've been recording in your Keeping Track books, and lifestyle activity, like taking the stairs instead of an elevator.

Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

- **What changes have you made to eat less fat (and fewer calories)?** We've focused on eating less fat because fat is the most concentrated source of calories.

Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

Have these changes tipped the calorie balance?

The answer is in how the scale has responded.

- At the **start of the Lifestyle Balance program, you weighed** ... *(refer to the How Am I Doing? graph for weight at randomization visit and record that weight on the work-sheet*
- **Your weight now is...** (record on work sheet).
- And **we expected your weight by this time would be ...** *(record the weight indicated on the graph by the expected weight loss line at this week).*

So you have ...

Check one of the three boxes on the work sheet. Be as positive as possible, stressing the accomplishments the participant has made so far, no matter how small, and express your confidence in the participant's future success.

- **Stayed at the same weight, or gained weight.**
  - To lose weight, you need to try something else to tip the calorie balance. We'll work together to find out what will work better for you.
- **Lost some weight, but not as much as expected.**
  - Good. You've made some progress.
  - To lose more weight, you need to try something else to tip the calorie balance *further.*
- **Lost as much weight as expected (or more).**
  - Great! You've tipped the calorie balance.
  - If you keep tipping the balance, you will keep losing weight.

Develop an activity plan for the coming week.

For next week:

- Continue to keep track of your weight, eating, and activity.
  Be active for__________ **.**

Fill in the blank on the work sheet, depending on how active the participant has been until this point. For most participants, *if this is Session 8,* the goal should be **150 minutes** per week; *if this is Session 7*, the goal should be **120 minutes** per week.

By doing more activity, you will use more calories.

As before, try setting aside one block of time each day, or look for 10 to 15 minutes that open up during the day and use them to be active. Include the Lifestyle Balance activity sessions. And plan other activities you LIKE to do. *[Complete the chart.]*

- **Make active lifestyle choices throughout the day.** As we've said before, every minute of activity is helpful. So keep moving as much as you can.
  What are some of the active choices you plan to make this week? *[Fill in the blank.]*

If weight loss has not been as expected, make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

The following is a requirement for participants who have not lost as much weight as expected. It is an option for successful participants who want to lose more weight or express an interest in learning more about the calorie content of foods.

- And **to tip the calorie balance further, one of two things will be helpful:**

  - **Keep track of calories every day, just like you've done for fat grams.**

  Sometimes it isn't enough to just look at fat grams. You may be eating some foods that are relatively low in fat but still high in calories. (For example, many of the new fat-free frozen desserts and cookies are just as high (or higher) in calories than the original versions because of added sugar.) Or you may be eating large enough portions of some foods that the calories are adding up. By keeping track of calories, you'll learn which foods are higher in calories and find ways to save calories. So this week, we want you to look up the calories in every food you eat, just like you've been looking up the fat grams.

Try to stay under calories each day. You should lose weight if you eat that number of calories. Also,

- Watch out for the foods that are high in calories.
- Be sure to record *everything.*
- And watch portion sizes.

Or it might be most helpful for you to:

- **Follow a meal plan for calories per day.**

  A meal plan is a model or good example of what to eat. A meal plan will:

  - **Show you exactly what foods and amounts to eat.** You won't be faced with a lot of decisions and temptations about food.
  - A meal plan will also **make it easier for you to record what you eat.** In fact, if you follow the meal plan *exactly*, you won't need to record anything.

Which do you think would be most helpful, keeping track of calories or following a meal plan? Or would you like to try both?
Check the box or boxes on the work sheet.

- If applicable, give the participant the appropriate meal plans. Tailor the meal plan to suit the participant's food preferences, and answer any questions or concerns the participant has regarding following the meal plans as closely as possible for the coming week. Present the meal plan as a flexible model from which the participant can develop an individualized eating style, rather than as a rigid prescription. (See How to Use the Lifestyle Balance Meal Plans for further information on how to introduce the meal plans to participants.)
- With some participants, you may need to practice calorie monitoring using an example and/or briefly double-check and correct portion estimation skills using food models.

For the rest of the study, we'll keep working together to bring you closer to your weight loss and activity goals. **We'll keep trying to tip the calorie balance and see how the scales respond.** Over time, you'll reach a new balance at your goal weight and then we'll work together to help you maintain that weight.

Note: The following explanation is for only those participants who express interest in how their calorie goal has been calculated. Do not give this text to participants.

Question: How did you determine the number of calories I should be eating to lose weight?
Answer: The number of calories you need for weight loss depends on many things, including how active you are, how old you are, and so on. But we can make a good guess and then see how the scale responds. We like to begin by estimating what you ate when you entered the program.

1. Estimate of what you ate when you started:

   Starting weight x 12 = calories/day (estimate)

2. A slow, steady weight loss of 1 to 2 pounds per week is the best goal.

- To lose 1 pound, you must eat 3,500 calories less. If you want to lose 1 pound in 1week, you would need to eat 500 fewer calories each day for 7 days.
- To lose 2 pounds, you must eat 7,000 calories less. If you want to lose 2 pounds in1 week, you would need to eat 1,000 fewer calories each day for 7 days.

We recommend that heavier people aim to lose 2 pounds per week, and that thinner people lose 1 pound per week. No one should eat fewer than 1,000 calories/day.

3. Estimated calories at start: calories/day for maintenance

To lose 1 pound per week, subtract 500 to get calories/day.
To lose 2 pounds per week, subtract 1000 to get calories/day.

So your daily calorie goal for weight loss is ______________.

Session 8:
Take Charge of What's Around You

Objectives:

In this session, the participant 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 forfood, 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).

To Do Before the Session:

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that may be appropriate for specific participants (for example, the "Am I Really Hungry?" sign to post on the refrigerator door).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

> Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? (Graph activity.)

Did you "Rate Your Plate?" Did you make any changes during the week to improve the way you eat (eat more slowly, follow a regular pattern of meals/snacks)? Did you make any changes to better match the Food Pyramid? If yes, what were they? What problems did you have? How did you solve them?

If the participant did not complete the "Rate Your Plate" form, complete the form for one or two days with the participant.

> Were you able to make the active lifestyle choices you had planned? Keep track of calories and stay under your calorie goal and/or follow the meal plan *(if applicable)*? Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the concept of eating and activity cues.

Today we're going to talk about **taking charge of what's around you**, or **how to make what's around you support your Lifestyle Balance goals** to lose weight by healthy eating and to be more active.

First, we'll talk about cues for eating, and later, go on to activity cues.

What "cues" you (or makes you want) to eat?

- Of course, one reason we eat is because of **hunger.** But what about those times when you have an "appetite" or desire to eat without physically being hungry?
- You might eat because of **what you're thinking or feeling**. For example, you might eat some ice cream because you feel lonely, bored, or happy.
- You might eat because of **what other people say and do.** You might eat chips at a party because a friend offers them to you.
- Or you might eat because of **the sight or smell of food, or**
- **Certain activities that make you think about food** (like watching TV or reading magazines). This is what we'll focus on today. In later meetings we'll talk about eating in response to thoughts, feelings, or what other people say and do.

The **sight of food** is one of the most powerful food cues. For example, you may see a carton of ice cream in the freezer and soon you'll be eating ice cream, even though you're not hungry. The **activity of watching TV** is also a powerful food cue for many people. You may turn on the TV and find yourself eating potato chips, even though you're not hungry.

Another example is **eating popcorn at the movies.** Do you eat popcorn when you go to the movies?

If not, probe for another example that is relevant for the participant, such as eating hot dogs at a sporting event or buying cookies after passing a bakery. Use the example in the discussions that follow.

Why do you eat popcorn in that situation? Do you think it's because you're hungry?
Most likely, it's because eating popcorn at the movies is a **habit** for you.

When you respond to a food cue in the same way over and over again, you build a habit. The food cue becomes paired with the way you respond, and your response becomes more and more automatic.

Let's say that since childhood, you've gone to the movies many, many times, and you've eaten many boxes of popcorn there. Now you find yourself eating popcorn whenever you go to the movies, even though you're not hungry. You responded to the cue (going to the movies) in the same way (buying popcorn), over and over again. Buying popcorn became a habit. And since it's a habit, it may be hard for you to sit through a movie and not have popcorn.

Food cues and eating habits are not harmful by themselves. But they can be a problem if they get in the way of your efforts to eat less fat and calories.

Discuss two ways to change problem food cues and habits.

How can you change problem food cues and habits?

1. One of the best things you can do is to **stay away from the food cue. Or keep it out of sight.** For example, you may not be willing to stop going to the movies, but you can stay away from the concession stand. If you keep going to the movies and don't let yourself have popcorn, slowly you will stop thinking about popcorn. The connection between the movies and the popcorn will have been broken.

2. Or you can **build a new, healthier habit. Practice responding to the cue in a healthier way.** An excellent way to support yourself as you do this is to **add a new cue that helps you lead a healthier life.** For example, you might take a package of sugar-free gum with you when you go to the movies. When you enter the theater, take out a piece of gum. After a while, you will connect going to the movies with chewing gum.

   It's important to remember that **it takes time to break an old habit or build a new one.** Change doesn't happen overnight. If you wanted to stop eating popcorn at the movies, you would need to see a lot of movies without popcorn. Eventually, you will enjoy the movie and forget about the popcorn.

Note: Some participants will find it hard to accept the idea that cues in the environment make them want to eat certain things. Try to find some ways (for example, as in the bullets below) to show the participant that there are many food cues around us all the time and that this phenomenon is so common that we are usually unaware of how powerful it is.

These ideas are powerful, and they work. Also, they're nothing new. People use them every day, sometimes very consciously and sometimes without even thinking about it. Some examples:

- Food companies deliver samples of new breakfast cereals right to your door by mail. They know that if they can get the food into your house, you'll eat it.
- For generations, mothers have put leftover snacks in the front of the refrigerator so their teenagers are more likely to eat them before the foods spoil.
- Supermarkets put new products on the shelves that are the easiest to see and reach.

In this session, we want to help you learn to make changes in what's around you to encourage healthy eating and being more active.

Identify specific food cues at home that are a problem for the participant. Discuss ways to change them.

Let's talk about **some of the problem food cues in your life and some ways you can change them.**

Note: A few common food cues are listed at the top of the second work sheet. Do not turn to this yet.

Let's start with **where you live.** Imagine that we've just opened the front door. We have a video camera, and we start taking a video of what's in the room. Which room would it be? Do you see any actual food in the room? Do you see anything else that might make you think about eating, like a TV or a comfortable chair? What is a change you could make to stay away from that cue or to build a new, healthier habit?

Move from room to room ("Are there other rooms that are a problem for you?"), asking for cues and discussing possible ways to either stay away from the cue or to build a new, healthier habit. If the participant has no response, refer to previous Keeping Track records and/or turn the page in the participant's notebook to the list of common problem food cues and ask if one or two of the examples apply to the participant (possible solutions are given below). Don't give too many examples. Some will undoubtedly come up at future sessions and can be addressed in detail at that time. The purpose of discussing specific examples is to make the "remember" points that follow of relevance to the participant.

Living room (or bedroom)

Cue: *TV (or computer, telephone).*
Solution(s): One way to break the connection between eating and the TV is to make it a rule never eat while watching TV (or on the computer or phone).
Keep an exercise band near the TV.
Keep a pack of sugar-free gum near the TV (or computer). Allow yourself only gum while watching TV (or working on the computer).

Cue: *Candy dishes (for serving candy, chips, and nuts) on an end table.*
Solution(s): Don't buy the candy, chips, or nuts.
If you must buy these foods, hide them. Keep them out of sight.

Kitchen

Cue: *High-fat/calorie foods, **especially those that are ready to eat**. In the freezer (e.g. ice cream), refrigerator (e.g., cheese, lunch meats, whole milk, pie),* kitchen cupboards (e.g., cookies, chips), or on counter tops (e.g., cookie jar, food packages).

Solution(s): Stop buying these foods altogether.
Store them out of sight, in a brown bag or other unattractive, opaque container.
Make them hard to reach.
Keep lower-fat/calorie choices easy to reach, in sight, and ready to eat.
Examples: Fresh fruits, raw vegetables (already washed and prepared), non fat dips, pretzels, low-fat popcorn, diet drinks.
Limit high-fat/calorie choices to those that require preparation.

Cue: *Foods you are cooking or leftovers, on the stove or counter.*

Solution(s): Make it a rule not to eat while cooking.
Taste foods only once, then rinse your mouth with water or a breath mint immediately.
Rinse off any utensils used in food preparation immediately after each use.
Ask someone else to taste the food.
Put leftovers away **before** meals.
Ask someone else to put the leftovers away.
Put leftovers in individual serving containers right away, and freeze them for future meals.

Dinner Table

Cue: *Serving dishes or packages of food on the table during meals.*

Solution: Serve foods from the kitchen.
Store food only in the kitchen. Put packages away immediately after use.

Cue: *Large dinner plates (or large glasses, bowls, serving spoons and forks).*

Solution(s): Serve yourself small portions using a smaller plate or bowl. Or ask someone who is supportive to do so. Spread the food attractively over the plate.

Cue: *Leftovers on plates.*

Solution(s): Remove your plate from the table as soon as you're finished.
Don't eat the food that your children leave on their plates.

Identify specific food cues at work that are a problem for the participant. Discuss ways to change them.

Let's do the same thing with **where you work.** Are there any things on your way to work, around you at work, or on your way home that have become paired with eating high-fat/calorie foods?

Cue: *Fast-food restaurant (or bakery, hot dog stand, candy store, etc.) on the way to or from work.*

Solution(s): Take a different way to work.
Make it a rule to never eat in the car.

Cue: *High-fat/calorie foods in public areas* (doughnuts or high-fat coffee creamers near the coffee pot, candy on secretary's desk, etc.).
Solution(s): Stay away from those areas.
Buy or make your own coffee in a different place.
Bring a low-fat/calorie snack to share with co-workers.
See if there's a way to keep these foods out of sight (other co-workers may appreciate it, too).

Cue: *High-fat/calorie foods on your desk, in your desk drawer, or in your locker.*
Solution(s): Don't bring high-fat/calorie foods to work. Keep low-fat/calorie snacks like apples, raw carrots, pretzels, low-fat popcorn, or diet beverages on hand instead.
Make it a rule not to eat at your desk.

Cue: *Vending machines.*
Solution(s): Stay away from the vending machines.
Bring a low-fat/calorie snack from home. Or buy juice or pretzels, if available in the machine. Ask a friend to go get them for you, so you won't be tempted by the other foods.

The important thing to **remember**, whether you are at home or at work, is:

1. **Keep high-fat/calorie foods out of your house and work place. Or keep them out of sight**. *Out of sight is out of mind.*

   Keep lower-fat/calorie choices easy to reach, in sight, and ready to eat.
   Examples: Fresh fruits, raw vegetables (already washed and prepared), non fat dips, pretzels, low-fat popcorn, diet drinks.

2. **Limit your eating to one place.** Where do you eat most of your meals at home? Limit all eating to this place. When you are hungry, go to this place to eat. This will help you to distinguish between hunger and other cues to eat.

   At work, a particular table in the cafeteria or kitchen area may be a good choice. Do not eat at your desk or computer. This is an open invitation to become distracted from eating.

3. **When you eat, limit other activities**. The rule is simple: No TV, driving, or talking on the phone while you are eating. Focus on enjoying the meal. In the future, these other activities will not cue you to eat.

Identify specific food cues while shopping for food that are a problem for the participant. Discuss ways to change them.

Finally, let's take the video camera to **where you shop for food.** Move around the store as you usually do. What do you see that's a problem for you?

You don't have as much control over what foods are in the grocery store as you do over what foods are in your house. But you do have some control. Here are some tips:

- **Make a shopping list ahead of time.** Make it a rule not to buy anything that's not on the list.
- **Don't go shopping when you're hungry.** Have a low-fat/calorie meal or snack first.
- **Avoid sections in the store that are tempting** to you, if possible. For example, go down a different aisle to avoid the bakery.
- **Ask the grocery store manager to order low-fat/calorie foods t**hat you want to buy. Remember, that is their business, to please you, the customer.
- **Don't be a slave to coupons.** Only use the coupons that are for low-fat/calorie foods, not for high-fat foods.

Identify specific positive cues for activity that the participant could add to his or her home.

Now let's turn to **physical activity.** For most people, there are many things around them that lead to being inactive. For example, after dinner, you may automatically position yourself in front of the TV. This is because the end of dinner and TV have been paired together many times in the past. But remember, you do have a choice. You could just as easily choose to exercise after dinner.

If you have been inactive, you probably have many cues around you that are associated with inactivity and few that would cue you to be active. To be active regularly, it's important to add positive activity cues to your life. Over time, the cues will become paired with being active, and you will develop new activity habits that will become more and more automatic.

What are some positive activity cues that you could add to your life? Let's pick up our imaginary video again, and start with **where you live.** What could you add to the living room that would prompt you to be active?

Move from **room to room**. Mention a few examples from the handout and add some that are particularly relevant to the participant.

In the living room or bedroom:

- Keep exercise equipment in sight, not in the closet.
- Hang an activity calendar and graph of your activity in a visible place.
- Keep an exercise band near the TV. (Why not make TV a positive cue?)
- Hang a photo or poster of people being active or of outdoor scenes in a visible place.
- Subscribe to a health or exercise magazine. Keep it in a visible place.
- Buy a home exercise video and leave it on the coffee table or on the TV.
- Put a note on the TV reminding you that a half hour of TV time could be used for exercise instead.

In the kitchen:

- Post motivational photos, outdoor scenes, or reminders to be active on the refrigerator.

In the bathroom:

- Post a reminder on the mirror before breakfast.

Identify positive cues for activity that the participant could add to his or her work place.

> **What are some positive activity cues that you could add to your work place?** Let's pick up our imaginary video again. *[Mention a few examples from the handout and add some that are particularly relevant to the participant.]*

- Put your exercise band in a visible place in your office.
- Put a note on your office door reminding yourself to exercise during your lunch break before eating.
- Set an alarm on your watch to remind you to exercise.
- Make a regular, daily appointment with yourself to be active. Write it in your date book. Keep your appointments with yourself--they are as important as your other appointments.
  Emphasize two cues that can prompt activity either at home or work.

- Set up a **regular "date" to be active with a friend or family member.** When she or he arrives at 7:00 for exercise, you'll probably go even if you don't feel very energetic.
- **Use a timer or alarm on your watch to remind you to be active.**

Discuss some ways to remove cues for inactivity.

Another approach is to remove the cues for being inactive.

- **Watch less TV.** Keep the TV behind closed doors in a cabinet. Or get rid of your TV. Or be active while you watch TV (for example, use your exercise band or system).
- **Don't leave things in a pile around the house.** They remind you to keep leaving more things there, rather than putting them away. Take separate trips to put them away instead.

In summary, it takes time to break old habits and build new, healthier ones, but it can be done. One of the most important steps you can take is to get rid of problem cues and add new ones that will help you lead a healthier life. **You can make food and activity cues work FOR you, not against you.**

Assign home activity.

Here is what I want you to do next week. First, get rid of one problem food cue in your life. Let's make a plan for that. *(Ask the participant the questions on the work sheet and fill in the blanks).* Also, add one positive cue for being more active. *(Ask the participant the questions on the work sheet and fill in the blanks).* What problems do you think you might have in trying to make these changes? How will you deal with them?

As always, keep track of your weight, eating and activity and do your best to reach your goals (specify goals on cover of Keeping Track books).

Finally, answer these questions before you come in to the next meeting ("Did you follow your plan?" and so on). We'll talk about how you did when you come in next week.

Any questions?

Session 9:
Problem Solving

Objectives:

In this session, the participant will:

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

To Do Before the Session

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.

Weigh the participant.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Review Graph activity.

> Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

Graph physical activity.

> Were you able to get rid of the problem food cue and add the positive cue for being more active? What problems did you have? What could you do differently next week?
>
> Were you able to make the active lifestyle choices you had planned? Keep track of calories and stay under your calorie goal and/or follow the meal plan *(if applicable)*?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the upcoming sessions and the problem solving process.

> In the first eight sessions of the Lifestyle Balance program, you learned *how* to eat healthy and be more active. Healthy eating and being active will help you lose weight and be healthier in general. We also hope it will reduce your chance of developing diabetes.

But healthy eating and being more active means changing your habits, and making the changes a permanent part of your lifestyle. Many things can get in the way of changing habits. That's what we'll focus on in the next several sessions. We will discuss:

- Negative thoughts,
- Slips and your reactions to slips (a slip is when you don't follow your eating or activity plan),
- Stress, and
- What people say and do (or "social cues").

All of these things can get in the way of healthy eating and being more active.

What are some examples of things that get in the way for you?

Name several problems that the participant has already discussed at earlier meetings, if possible. E.g., You wanted to go out for exercise, but it was too cold. You wanted to eat less fat, but your children wanted you to buy potato chips.

It's inevitable that problems like these will come up.

But problems can be solved. Today we're going to talk about the *process* of problem solving. This is the process that you and I will be working on together throughout the study.

Explain the five steps to problem solving.

In general, there are five steps to solving problems.

1. The first step is to **describe the problem in detail. Be specific.**

For example, instead of defining the problem as "I eat more fat than I should," be specific about the kinds of foods you eat that are high in fat--maybe high-fat desserts or red meats. Be specific about when you eat them, and describe these situations in detail. For example, you may eat high-fat desserts when you go to your mother's house and she offers them to you.

Also, **look at what led up to the problem**. Many problems involve a chain of actions: one action leads to another and then another and eventually this leads to inactivity or overeating. This is called an "**action (or behavior) chain.**"

Try to see the steps (or "links") in the action chain, including:

- **Things around you that cue (or prompt) you to eat or to be inactive.**
  We've talked about food and activity cues before. Examples are a bakery near where you work, television watching, or a carton of ice cream in your freezer.

- **People in your life who don't support your efforts** to lose weight and be more active. Examples are a co-worker who offers you doughnuts every morning, children who insist that you deep-fry chicken rather than baking it, or a spouse who wants you to watch TV in the evening rather than exercise.
- **Thoughts or feelings that get in your way.** Examples are defeating thoughts like, "I'll never be disciplined enough to exercise every night." Or feelings of boredom, stress, loneliness, or anger that lead to overeating.

Here is an example of an action chain *[refer to the diagram*]:

Sarah is a busy woman with a job and a family. Yesterday she was extremely busy at work and she **didn't eat lunch** because she didn't have time to go out. In the afternoon, her **boss was very critical** and demanding, and **Sarah felt stressed and anxious.** At the end of the day, Sarah **came home tired, upset, and hungry.** She **went right to the kitchen.** She immediately **saw a package of cookies on the kitchen counter**, and before she knew it, she **ate a fair number of the cookies.**

It may seem complicated to look at a problem in this much detail. But actually, it makes problem solving much, much simpler.

- You see that the real problem may not be the last step (eating the cookies)but rather all of **the things that led up to it** (like not eating lunch and soon).
- Uncovering the action chain will help you to **find the "weakest links" in the chain to break.** There's a saying that a chain is only as strong as its weakest link. By naming all of the links in the chain, you will be able to find the weakest ones, the places where you can make a change most easily.

2. Step 2 is to **brainstorm your options**. What are all of the possible solutions to the problem? "Brainstorming" means to create a storm of ideas in your brain. Let the ideas pour out, no matter how crazy they may seem. Anything goes. The more ideas the better. And it's actually helpful to include some crazy, extreme ideas because it helps open your mind and stir up your creative juices.

   By brainstorming, **you'll see that you aren't at all powerless to change your situation.** You have many options. Here are some possible ones for Sarah *[refer to work sheet].*
3. Third, **pick an option to try.** Weigh the pros and cons of each option, and choose one (or it might be a combination of several) that is **very likely to work** and that **you can do**. In other words, be realistic. You should be confident that you will succeed.

   It's also helpful to try to **break as many links as you can, as *early* as you can** in the chain.
   For example, it will be much easier for Sarah to control her eating in the evening if she eats some lunch and doesn't arrive home hungry. It will be easier for Sarah to avoid eating too many cookies if she doesn't buy the cookies in the first place. Another reason to try to break an action chain as early as possible is that **you will have more links to work with.**

If eating lunch doesn't help Sarah and she still arrives home tired, upset, and hungry, she can still choose low-calorie snacks like fruit when she gets home.

Let's say that Sarah chooses the option of packing a quick bag lunch.

4. Fourth, **make a positive action plan.** This is where you spell out exactly:

- What you will do,
- When you will do it, and
- What you need to do first.
- Also, make a plan for any roadblocks that might come up,
- And build in steps that will make success more likely. For example:

Will it help you to involve someone else?

Can you do anything to make it more fun and enjoyable?

Will it help if you:

Write your plan down and post it on your refrigerator or calendar?

Tell your plan to someone else, so you're committed to following it?

Join an exercise class or club so you're more committed?

Make a date with someone to exercise?

Sometimes if you build in a step to get yourself over the first "hump," then everything begins to snowball and the rest is much easier. For example, here is Sarah's action plan *[review work sheet]*.

5. The fifth step of problem-solving is to **try it and see how it goes.** Did it work? If not, what went wrong? Use what you have learned to problem solve again and make a new action plan. Remember, **problem solving is a process. Don't give up.** It often takes many tries to find a solution.

Review another example if you think it would be helpful. Use one that is tailored to the individual (for instance, an example of the food preferences of the family getting in the way of the participant's goals).

Now let's apply this process to you.

Have the participant practice the steps using a problem he or she is experiencing now.

For next week, I want you to work on solving a particular problem. Think of a problem that you're having now with eating less fat/calories or being more active.

Complete the **Lifestyle Balance Problem Solver** work sheet with the participant.

For next week:

- Keep track of your weight, eating, and activity.
- Follow your action plan. And answer the questions on the work sheet.

Session 10:
Four Keys to Healthy Eating Out

Objectives:

In this session, the participant 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 the participant frequents.
- Practice making a meal selection from an appropriate menu.
- Practice out loud how to ask for a menu substitution.

To Do Before the Session:

- If possible, have the participant bring in menus from the restaurants he or she frequents.
- Get materials ready:
- Sample menus from local restaurants.
- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, booklets on the nutrient content of fast foods).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

> Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Try your action plan? What did you learn from the problem solving process?

Graph physical activity.

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the four keys to healthy eating out.

Today we're going to talk about eating out. **What kinds of places do you eat out at?**

Tailor the rest of the session to one or two of the places where the participant eats out most often. If the participant doesn't name several places or is not specific enough, prompt for a few of the following examples: fast-food restaurants, other restaurants, church or community centers, cafeterias, friend's homes, snack bars or vending machines, in an airplane.

Do you find it difficult to stay under your fat gram goal when you eat out at these places?
What is difficult for you?

There are four basic keys to healthy eating out. *[First, indicate each of the major headings on the work sheet, as scripted below. Later you will come back to the specific points under each heading.]*

1. First, **plan ahead.** Having a plan will help you to anticipate difficult situations and handle them more easily. You won't run into so many surprises.
2. Second, **ask for what you want.** Be firm and friendly. We'll talk in a minute about how to do this so you won't offend anyone.
3. Third, **take charge of what's around you**. Take steps to make what's around you **support** you in your efforts to eat healthy. Get rid of the things that get in the way, if you can.
4. And finally, **choose foods carefully.**

Help the participant identify specific examples of how to apply the four principles.

Let's use **one of the places where you eat out as an example**.

What are some ways you can **plan ahead** for eating out at ....?

Follow along on the work sheet as you **discuss each of the four keys to healthy eating out *as they apply to that type of restaurant*.** Use some of the examples given below, but don't try to be exhaustive. Rather, choose those examples that relate to the specific difficulties faced by the participant. You may want to jot down on the work sheet a few strategies that are particularly relevant.

When you review **how to ask for what you want**, use the following script:

Many people find it hard at first to ask a waiter or waitress for something special. With practice, it gets easier. Here are some tips:

- **Begin with "I", not "You."**
  "I would like," "I need," "I will have." Using "I" statements shows that you take responsibility for your own feelings and desires. "I would like my chicken broiled with lemon juice instead of gravy," or "I would like tossed salad instead of coleslaw, please."
  "You should have," "you said," "you don't understand." Using "you" often puts others on the defensive. "You didn't put the salad dressing on the side!" Better:" I asked to have the salad dressing on the side, please."

- **Use a firm and friendly tone of voice that can be heard.**
- **Look the person in the eye.**
  Eye contact says a lot. Avoiding eye contact often means you don't believe what you are saying.
- **Repeat your needs until you are heard. Keep your voice calm.**
  Sometimes it may take several tries before you are understood. If you need to repeat yourself, keep your voice low but firm. A loud voice can be threatening to others.

Wishy-washy	"Oh, well. I guess they couldn't broil the fish."
Threatening	"You said you would broil my fish!"
Firm & friendly	"This looks very nice. But I asked for my fish to be broiled, not fried. Would you have some broiled for me, please?"

When you review the fourth principle, **choose foods carefully,** have the participant:

- **Practice making a meal selection from an appropriate local menu.**
- **Practice out loud how they would ask for a menu substitution.**

Refer to menus from local restaurants and the “What’s on the menu?” and “Fast food can be lower in fat” handouts for examples. It’s important to role play aloud at this point to give the participant practice actually choosing words that are comfortable for him or her. At some point you may want to go to a restaurant with the participant and by ordering first, you can model how to make healthy meal selections and ask for menu substitutions. Participants may also need encouragement to ask family members to support them when they are at a restaurant, for example, to ask a spouse to say, “I’m glad you ordered milk for your coffee,” instead of, “Are you sure you don’t want cream?”

At fast-food restaurants

1. **Plan ahead.**
   - Pick a restaurant carefully. Most fast-food restaurants now serve some low-fat foods, such as grilled chicken and salads with low-fat dressing.
   - Plan what you will order without looking up at the menu. Menus can tempt you to order what you don't want.

2. **Ask for what you want. Be firm and friendly.**
   - For example, "May I have my coffee with a little low-fat milk rather than cream, please?" "Please leave the mayo off my burger."
   - Ask how much is usually served. For example, "How many ounces is the hamburger, please?"

3. **Take charge of what's around you.**
   - Be the first in your group to order. You won't be tempted by what or how much others order and they may follow your good example.

4. **Choose foods carefully.**

   - Try grilled chicken sandwiches without special sauces or a salad with low-calorie dressing.
   - Stay away from French fries. If you must have them, order a regular size (not a double) and Don’t finish them all.
   - If you must have a hamburger, order a regular size, without cheese, not a double or a cheeseburger.

At other restaurants (not fast-food)

1. **Plan ahead.**

   - Pick the restaurant carefully. Go to one with low-fat choices. Call ahead to see what is on the menu. Stay away from "all you can eat" buffets, brunches, and happy hours.
   - Eat less calories and fat during other meals that day or for a few days in advance.
   - Have a little something to eat before you go to the restaurant so you're not too hungry when you get there. Eat fruit, some low-fat crackers, or drink water before you go out.
   - Plan what to order without looking at the menu. Looking at the menu can tempt you to order more than you want.
   - Don't drink alcohol before the meal. It may make it harder for you to follow your good intentions. Try tomato juice, club soda, or mineral water, instead.

2. **Ask for what you want. Be firm and friendly. Remember, you are paying for the meal. You have the right to ask for special services. And most restaurants want to make you happy.**

   Ask for the foods you want:

   - Ask for food substitutions. For example, catsup or mustard instead of mayonnaise on a sandwich. A tossed salad instead of coleslaw. Baked potato instead of French fries.
   - Can foods be prepared in a different way? For example, ask that the fish be broiled and seasoned with lemon juice, not butter; ask that butter, margarine, and sauces be left off the vegetables.
   - Don't be afraid to ask for foods that aren't on the menu. Many restaurants will prepare grilled meats, fish, and chicken without added fat or sauces, fresh fruit salads, and steamed vegetable platters with rice, even if they're not on the menu. Or look for foods on a different part of the menu (for example, if fresh fruit is on the breakfast menu, it may well be available as a dessert for dinner).

   Ask for the amounts you want:

   - Ask how much is usually served. For example, "How many ounces is the hamburger, please?"
   - Ask for salad dressings, gravy, sauces, or spreads "on the side." For example, ask for dry toast with margarine on the side. Then use only a small amount. Or order salad dressing on the side, then limit the amount you use. (One idea is to dip your fork into the dressing before each bite.)
   - Ask for less cheese or no cheese.

- Split a main dish or dessert with someone. Or order an appetizer as a main dish.
- Order a smaller size (appetizer, senior citizen's or children's portion, cup of soup).
- Before or after the meal, have the amount you don't want to eat put in a container or "doggie bag" to take home.

3. **Take charge of what's around you.**

- Be the first to order. You won't be tempted by what others order, and they may follow your good example.
- Keep foods off the table that you don't want to eat.
  a. When a waiter or waitress brings rolls, chips, or other complimentary foods, say "No, thank you," and hand the food back right away.
  b. When you order something, ask that half of it be put in a doggie bag **before** it's brought to the table. Then have it brought to you with the check.
- Ask that your plate be removed as soon as you are finished. You won't be tempted to eat more than you want while others finish their meals.
- Remove table tents from the table that advertise high-fat/calorie foods such as desserts.

4. **Choose foods carefully.**

- You can tell a lot from the words on a menu. Watch out for these high-fat words; look for these low-fat words, instead. [Refer to handout.]
- Watch out for sauces on meats, vegetables, and so on. Ask that these foods be served without the sauce.
- Think about how much food you really need. Do you need an appetizer? Bread? Make some compromises. "I'd rather have dessert so I'll skip the appetizer."
- Trim visible fat off meat.
- Take skin off chicken.

At another person's home or community center/potluck dinners

1. **Plan ahead.**
   - Bring something from home for yourself and others. Examples: fruit salad, vegetable salad with low-calorie dressing.
   - Talk to the host or hostess before you go, if you are comfortable doing so(particularly if you eat at their home often). Ask for their support in your efforts to lose weight.
   - Eat a little something before you go, so you aren't too hungry when you arrive.

2. **Ask for what you want. Be firm and friendly.**
   - Say "No, thank you. That looks lovely, though," when offered a food you'd rather not eat.

3. **Take charge of what's around you.**
   - At buffets or cocktail parties, stay away from the buffet or appetizer table. Choose a small plate, and after serving yourself, sit at a table far away.

4. **Choose foods carefully.**
   - Take only a small amount of high-fat/calorie foods, just enough to taste.
   - Look at everything on the buffet before serving yourself. Then choose only 3 or 4of your favorite foods, instead of trying a little of everything.

Airplanes

1. **Plan ahead.**

   - Order a special menu ahead. Call 24 hours before departure. Many airlines have low-fat and vegetarian menus available.

2. **Take charge of what's around you.**
   - Say "No, thank you," smile, and hand the peanuts right back to the flight attendant.

Banquets, Conferences

1. **Plan ahead.**

   - Ask what is on the menu. Is anything prepared without fat?
   - Order a special menu ahead. Even if the choices are limited, many caterers will prepare a steamed vegetable plate with rice and fruit salad upon request.

Assign home activity.

Describe a problem you have when you eat out. *[Record on the work sheet.]* Choose one of the four keys to healthy eating out that is likely to help you solve the problem and that you can do. Make a positive action plan. *[Complete the work sheet with the participant.]*

For next week:

- **Keep track** of your weight, eating and activity.
- **Try your action plan.** And before you come to the next session, answer the two questions on the bottom of the work sheet (Did it work? If not, what went wrong?).
- For participants who eat out often, ask the participant to collect menus for restaurants the participant frequents and bring them in to the next session.

Any questions?

Session 11:
Talk Back to Negative Thoughts

Objectives:

In this session, the participant 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.

To Do Before the Session:

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, a Stop! Sign prop to hold up when you hear the participant expressing a negative thought).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Try your action plan? What did you learn last week about healthy eating out?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

If the participant has brought in restaurant menus, help the participant practice ordering from the menus.

Help the participant identify examples of negative thoughts.

Today we're going to talk about stopping negative thoughts.

Everyone has negative thoughts at times. These negative thoughts can lead you to overeat or be inactive. Then afterwards you may feel even worse about yourself. A vicious cycle of self-defeat can result.

For example, suppose you came home after a hard day at work. You think to yourself, "I'm tired of working so hard. I'm sick of being in this study. I can never eat what I want." This negative thought might lead you to eat some potato chips. And then you think, "I did it again. I'll never lose weight." Next, you're discouraged and go on to eat more of them.

Sometimes we aren't aware we are having negative thoughts. Negative thinking becomes such a habit for most of us that we tend to believe and act on our negative thoughts without even hearing them.

The goal of this session is to help you hear your negative thoughts and teach you to talk back to them.

Here are some common examples of negative thoughts.

Review each category and the example(s) on the work sheet, then ask a question or two to get the participant thinking about his or her own experience with negative thoughts.

1. **Good or Bad Thoughts.**
   These thoughts divide the world into:

   - Good and bad foods;
   - Seeing yourself as a success or failure;
   - Being on or off the program.

   Sometimes this is called "all or nothing" or "light bulb" thinking (either on or off) with nothing in between.

   Example: "Look at what I did. I ate that cake. I'll never be able to succeed."

   - Do you have some foods you consider "good," and some foods you consider "bad?"
   - What happens when you eat a little of what you consider to be a "bad" food?
   - Can you think of some problems with considering a food "bad?"

2. **Excuses (or Rationalizations)**
   These thoughts **blame something or someone else for our problems.** We act as if they have so much power that we have no choice but to overeat or be inactive.

   We don't mean to go off the program, but we "can't help it."
   Example: "I don't have the will power."
   "I have to buy these cookies just in case company drops in."

   - Can you think of a time when you bought some high-fat/calorie food "for someone else"? Did they really need the food, or do you think you used them as an excuse to buy the food for yourself?

3. **Should Thoughts.**
   These thoughts **expect perfection.** Of course, no one is perfect, so SHOULD thoughts are a **set-up for disappointment**. They also **lead to anger and resentment** because "should" assumes that someone is standing over us, forcing us to do what we don't want to do.

   Example: "I should have eaten less of that dessert."

   - What kind of things do you think you "should" or "should not" do to lose weight and be more active?
   - What do you expect yourself to do perfectly (for example, self-monitoring)? What happens when you expect perfection of yourself? How do you feel? How does it affect your future decisions and choices?

4. **Not As Good As Thoughts.**
   These thoughts **compare us to someone else** and then **blame ourselves for not measuring up.**

   Example: "Mary lost two pounds this week, and I only lose one."

   - Do you compare yourself to someone else? Who?
   - How does comparing yourself to that person affect you? How does it make you feel? How does it affect your decisions and choices about eating and being active?

5. **Give Up Thoughts.**
   These thoughts **defeat us.** They **often follow the other kinds of negative thoughts.**

   Example: "This program is too hard. I might as well give up."

   - Do you ever want something good to eat and think, "I'm sick of this Lifestyle Balance program"?

Explain how to talk back to a negative thought.

Once you are aware of a negative thought, you can "talk back to it." Here's how:

1. First, **catch yourself** having the negative thought. Ask yourself, "Is this thought moving me forward or bringing me down?" As soon as you're aware of a negative thought, say to yourself, **"I'm doing it to myself."**

2. Then **imagine shouting "STOP!" to yourself.** Picture a **huge, red stop sign.** *[You may want to hold up the STOP! sign prop at this point.]* The stop sign is so big that it takes up all the room in your mind. This should startle you and get rid of the negative thought.

3. **Talk back with a positive thought.** No matter how effectively you've stopped a negative thought, it will probably return again in a similar situation because it has become a habit for you. So it's important to **begin to build a new habit: positive thinking.** After you stop a negative thought, talk back to it with a positive one.

Review the categories and the examples on the work sheet, making the following points.

- **Good or Bad:** Talk back with **Work Toward Balance.**
  Don't expect perfection of yourself, but don't indulge yourself either. Work toward an **overall balance.**

- **Excuses:** Talk back with **It's Worth a Try.**
  Instead of looking for something or someone else to blame, why not give yourself a chance? Try something. You just might succeed.

- **Should:** Talk back with **It's My Choice.**
  You are in charge of your eating and activity. No one else is responsible for your choices or standing over you with unrealistic expectations.

- **Not As Good As:** Talk back with **Everyone's Different.**

- **Give Up:** Talk back with **One Step at a Time.**
  Problem solving is a process. It takes time to make life-long changes. Learn from what doesn't work and try another option. Learning is always a success.

Now let's **practice** stopping negative thoughts and talking back with positive thoughts.
Look back over the kinds of negative thoughts we've discussed. What kind are most familiar to you? For example, do you tend to make excuses or are you more likely to compare yourself to someone else? What are some examples?

Write examples of negative thoughts on the work sheet. If the participant doesn't name examples, use several from the previous pages.

Now let's take them one at a time. First, say the negative thought out loud. Then say "Stop!" And then talk back to it out loud with a positive thought.

Use the remaining time in the session to actually role-play this with the participant. Use a stop sign prop if you find it helpful. Record the positive thoughts on the work sheet.

This session may be an appropriate time to review with participants the work sheet “Remember Your Purpose” (Session 1) on which they recorded their personal reasons for joining the study and so on. Details from this work sheet may provide images and words for the participant to use in talking back to negative thoughts with positive ones. Any imagery that is significant to the participant may help make the process of “talking back” more meaningful and fun; for example, a participant might find it enjoyable to imagine a devil on one shoulder and an angel on the other, and to see the task of positive thinking as, “letting the angel talk.”

Assign home activity.

For next week:

- Keep track of your eating and activity.
- Catch yourself thinking negative thoughts. Write them in your Keeping Track books.
- Practice stopping them and talking back to them with positive thoughts.

Next week we'll talk about how you did.

Any questions?

During this session, some participants may raise problems outside the expertise of the Lifestyle Coach, such as a significant clinical depression, anxiety, or a clinical eating disorder.

Session 12:
The Slippery Slope of Lifestyle Change

Objectives:

In this session, the participant will:

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

To Do Before the Session

Review the participant's progress. Note any plans that were made to improve weight loss and activity level, which strategies were used, and which were successful or unsuccessful. If the participant is not currently at goal for weight loss and/or activity, refer to the Tool Box for ideas of additional strategies required or optional for particular problems.

If you have copies of some of the participant's past Keeping Track records, review them as well. Note some of the positive changes the participant has made.

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Have materials ready:

- Keeping Track book.
- Pages for the participant notebook.
- Meal plans appropriate for the participant's calorie goal. Tailor to the participant's food preferences as much as possible before the session.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? What negative thoughts did you catch yourself thinking? Were you able to stop them and talk back with positive thoughts?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Review the participant's progress since Session 7 or 8, and if not at goal, develop an action plan to improve progress in reaching weight loss and activity goals.

Today we're going to talk about what are called "slips," or times when you don't follow your plans for healthy eating or being active.

> Let's use skiing as an example. Everyone who learns to ski knows that they will "slip" and fall down. It's a natural part of learning to ski. What a skiing instructor does is to help beginning skiers anticipate when they might fall down and show them how to get up again. That's what we'll do today--talk about when you might "slip" from your eating and activity plans, and how you can get back on track again after you slip.

Note: Throughout this session, try to use analogies in addition to skiing that are meaningful to the participant. (For example, one analogy is how we handle fires. First, we try to identify high-risk situations in which fires are likely to occur. Second, we try to take steps to avoid these situations if we can. Third, in case a fire does occur, we plan ahead for a way to put out the fire and/or escape.

We make a plan that is as simple and easy to remember as possible so that we are more likely to follow it while under stress.) You will also want to use a meaningful analogy for how the participant has developed other skills by making mistakes and learning from them, such as learning to drive a car, bake a cake, and so on.

> Before we talk about slips, we'll take some time to review your progress

- **What are some of the major changes you've made to be more active?** Include both what you do to reach your goal (that is, those activities you record) and what you do to be more active in general **What changes have you made to eat less fat (and fewer calories)?** Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these change**s.**

Have you reached your weight goal? Your activity goal?

Refer to the How Am I Doing? graphs for weight and activity, and check yes or no on the worksheet.

If the participant is **at goal** for weight loss and activity, praise the progress made.

If the participant is **not at goal** for weight loss or activity, praise whatever progress has been made. Encourage the participant to improve, and develop a related plan using the work sheet. **Follow the guidelines in the Tool Box as to which strategies are required to address particular problems identified.** For example, some participants may need to be given meal plans at a lower calorie level.

Define slips.

Now let's move on to the topic for today, **"slips."**

Slips are times when you don't follow your plans for healthy eating or being active.

Slips are:

- **A normal part of lifestyle change.** Just like falling down is a normal part of skiing. If you are going to ski, you are going to fall. All skiers will fall. And everyone who sets out to lose weight and be more active will have slips.
- **To be expected.** If you haven't already had some slips, you most certainly will have them in the future. Slips are **inevitable.**

Does this sound discouraging? Well, it doesn't have to be. Because **slips don't hurt your progress. What hurts your progress is the way you *react* to slips.** So today we'll talk about the best way to react to slips when they happen.

Identify some things that cause the participant to slip from healthy eating or being active.

Different people have different things that cause them to slip. For example, **moods or feelings** cause many people to slip from healthy eating.

Some of us tend to overeat when we're **happy**. Imagine that:

Your **family is celebrating.** Maybe it's a holiday, a birthday, or a vacation. There is plenty of everyone's favorite foods, from appetizers to desserts. And for years, your family's custom has been to "take it easy," have fun and just relax during these times. **What would this situation be like for you? Would you tend to slip in this kind of situation?**

Some of us are more vulnerable to overeating when we're **bored**. Imagine that:

You're **at home alone, watching a favorite TV program.** You're feeling okay, pretty relaxed, but a little bored. A commercial comes on at the end of the program, and you find yourself wandering into the kitchen. **What would this be like for you?**

Other people overeat when **upset**. Imagine that:

You are settling down for a relaxing evening at home. Someone in your family starts to talk about something that's been part of an **ongoing argument** between the two of you. You both get angry and he or she stomps out of the house, slamming the door. You head for the kitchen. **What would this situation be like for you?**

Or here's another example:
You're **behind on a project at work.** The boss has been looking in on you every10 minutes and glaring at you impatiently. You feel pressured and very tense. You go get yourself a cup of coffee and see a delicious snack that someone brought in that morning. **What would this be like for you?**

Which is the *most* difficult for you in terms of slipping from healthy eating: feeling happy, bored, or upset? *[Record on the work sheet.]* **Are there other things that cause you to slip from healthy eating?**

Give the participant time to name a few examples. Record on the work sheet.

What things cause you to slip from being active?

Have the participant name several examples, such as vacations, holidays, feelings or moods, cold or hot weather.

The situations that lead to slips differ from person to person. For example, you may tend to eat when you're bored, whereas someone else may get involved in a hobby. Or when you are at a party, you may be so busy talking and laughing that you forget to eat, whereas someone else may find the goodies are just too tempting. **What causes you to slip is learned. It is a habit.**

The way you react to slips is also a habit. You can learn a new way to react to slips that will get you back on your feet again.

Discuss what to do after a slip to get back on your feet again.

First, **remember two things:**

- **Slips are normal and to be expected.**99.99% of all people who are on their way to losing weight and being more active have slips. But a slip doesn't need to lead to giving up completely. Slips can and should be useful learning experiences.
- **No one time of overeating or not being active, no matter how extreme, will ruin everything.** You won't gain more than a few pounds of weight even after the biggest eating binge imaginable--unless you *stay* off track and keep overeating time and time again. **The slip is not the problem. The problem occurs if you don't get back on your feet again and keep going toward your goals.**

So after you have a slip:

1. **Talk back to negative thoughts with positive thoughts.**
   The negative thoughts that come after a slip can be your worst enemy. They can lead to feeling discouraged, guilty and angry and undermine your ability to handle the slip effectively. Talk back to the negative thoughts with positive ones. "I am not a failure because I have slipped. I can get back on my feet again."

2. Next, **ask yourself what happened.**
   Use the opportunity to look closely at the situation and ask yourself what happened. Was it a special occasion? If so, is it likely to happen again soon? Did you overeat because you were lonely, bored, or depressed? Did you eat because of social pressure? Did you skip activity because you were too busy with other things, or because of work and family pressures? Use these questions to review the situation and think about it objectively. **Learn from the slip.**

Then you can plan a strategy for handling the situation better next time. **Can you avoid this situation in the future** (for example, by not sitting near the food or by not wheeling/walking past the candy machine)? If you can't avoid it, **can you manage it in a better way** (for example, by making sure you have low-calorie foods available at home)?

3. **Regain control the very next time you can.**
   Do **not** tell yourself, "Well, I blew it for the day," and wait until the next day to start following your eating plan. **Make your very next meal a healthy one. Get back on schedule with your activity plan right away**. You will not have set yourself back very much if you follow this suggestion.

4. **Talk to someone supportive.** ("Talk it through, don't eat it through.")
   Call your lifestyle coach or someone else on staff. Call another participant or another friend. Discuss your new strategy for handling slips. Commit yourself to renewed effort.

5. Finally, **focus on all of the positive changes you have made** and realize that you can get back on track. The same person who "blew it" today is the same person who has been successful during many previous weeks. Slips do not reveal the "real you" (hopeless, lacking willpower, etc.). They are simply another occasion of behavior. **Remember, you are making life-long changes. Slips are just one part of the process.**

Assign home activity.

Describe one thing that has caused you to slip from healthy eating.
Could you **avoid it** in the future? If so, how? *[Record on the work sheet.]*

If not, make a plan for **how to get back on your feet** the next time you slip. *[Record.]*

Describe one thing that has caused you to slip from being active.
Could you **avoid it** in the future? If so, how? *[Record on the work sheet.]*
If not, make a plan for **how to get back on your feet** the next time you slip. *[Record.]*

For next week: a) Keep track of your eating and activity. b) Try your two action plans.
c) Answer the questions on the work sheet.

Any questions?

Session 13:
Jump Start Your Activity Plan

Objectives:

In this session, the participant will:

- Discuss ways to add interest and variety to the participant's 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.

To Do Before the Session:

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, on various barriers to physical activity).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

> Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?
>
> Did you try your two action plans to get back on your feet after slipping? How did it go?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Discuss ways to add interest and variety to the participant's activity routine.

> So far in the Lifestyle Balance program, our focus in terms of physical activity has been on increasing the amount of time you are active. We've moved gradually from 30minutes per week to 2 ½ hours per week of new physical activity. By this time in the program, many participants find that their activity routine has become a little stale and boring. **Boredom is a problem because it may cause you to slip back into old habits of not being active.** So it's important to be aware of

any boredom you're feeling about your activity plan, and do something to keep it fresh and interesting.

That's what we'll talk about today--**ways to "jump start" your activity routine** (or give it new energy when it's becoming a little too "routine").

First, **add variety**.

- **Do something new and different** now and then. Don't expect yourself to do the same activity, day in and day out, every season of the year, any more than you would expect yourself to eat the same food, day in and day out, all year long. Remember, you are making life-long changes, and being active is something you will be doing for the rest of your life. So build in some variety. For example, if you usually do aerobic conditioning during the week, strength (resistance) training on the weekend.

Can you think of some ways to vary what you do for activity?

Record on the work sheet. Include lifestyle activity but be sure the participant understands to self-monitor only the physical activities that are similar (or higher in) intensity (refer to Manual of Operations).

If the participant expresses interest in learning more about a particular activity, such as strength(resistance) training, consider making an appointment for the participant to meet with the exercise specialist on staff for instruction.

Do the same activity in a new place. For example:

- Wheel/walk on a different path through the park.
- Wheel/walk in a different neighborhood after work.

What are some ways you can vary where you do your activity? *(Record.)*

Be active as a way to be social.

- Instead of going out for a cup of coffee, go out for a "wheel or walk and talk" with a friend or family member.
- Plan a weekend hike with a group of friends.
- Go wheeling/walking with a club.
- Join a basketball team.
- Sign up with a group of friends for a wheel or walk for charity.

What are some activities you could do with a friend, family member, or group as a way to socialize? *(Record.)*

It also helps if you **make being active fun.**

- Some people enjoy listening to a radio, music tapes or books on tape while they exercise
- Plan tours of cities when you travel.

What would be fun for you? *(Record.)*

Another way to prevent boredom is to **challenge yourself**.

- Prepare yourself for a race.
- Set up a friendly competition with a friend (whoever wheels or walks the most miles before a certain date gets taken out to lunch by the other).

What would make activity more challenging for you? *(Record.)*
Have you been bored at times with your activity in the past?
Have you found anything to be particularly helpful for you at those times?

If you're not bored now, please be sure to bring it up whenever you do feel bored in the future. Use me and our activity specialist as resources to help you. For example, we can talk about some community programs that might add interest to your activity routine, and so on.

Define "aerobic fitness."

One way to add something new to your activity routine is to begin to focus on **improving your "aerobic fitness.**"

"Aerobic fitness" refers to **how well your heart can pump oxygen ("aer-")**through your blood to your muscles in your body.

Your heart is a muscle, too. If you exercise your heart (make it beat faster), it will become stronger over time. This is just like the muscles in your arm becoming stronger if you lift weights every day.

As your heart becomes stronger, you'll notice that it's easier for you to do things like wheeling or walking up inclines and carrying groceries.

Explain the F.I.T.T. Principles.

Not all ways of being active will help strengthen your heart--only those that are "F.I.T.T."
This is what "F.I.T.T." stands for:

"F" stands for **frequency**, or **how often you are active.**

Aerobic fitness levels go down within 48 hours of no activity, so it's important to be active often.

- Try to be active on most days of the week (at least 3 days per week is recommended; 5 to 7 days are even better).
- To avoid soreness and injury, it's best to **increase the frequency slowly.**

"I" stands for **intensity,** or **how hard you are working while being active.**

This is usually measured by **how fast your heart beats.** We want your heart to beat faster than it usually does, so that it will become stronger, but we don't want it to beat so fast that you could injure yourself.

- The goal is to stay within what's call your "target heart rate", about 50-70 % of the maximum number of times your heart can beat in a minute for someone your age.

  Here is how to **figure your target heart rate.**

  Review the formula on the work sheet and calculate the participant's own target heart rate.

  Have you ever taken your heart rate or pulse?

Review with the participant the steps for taking your heart rate as described on the work sheet. Use a pen or marker to mark on the participant's wrist exactly where he or she is able to find the pulse. This will help the participant find it quickly when exercising.

- Another way to get a rough idea of how hard you should be working is to **breathe fast enough that you can talk but not sing.** You should be able to have a conversation with a friend while exercising, but **if you can break into song, speed it up!**

  On the other hand, **if you have trouble breathing and talking while you exercise, slow down.**

- **As you do regular physical activity over time, your heart doesn't beat as fast** as it used to. For example, you'll notice that your heart doesn't beat as fast when you wheel or walk up an incline, and you don't get as out of breath.

  This means that you are becoming more fit, that your heart is doing the same amount of work with less effort. It also means that to continue strengthening your heart, **you will need gradually to do more challenging activity to reach your target heart rate.** For example, you'll need to exercise more intensely than you used to get the same benefit in terms of aerobic fitness.

"T" stands for **time,** or **how long you are active.**

- To improve your aerobic fitness, you should **stay active continuously for at least 10 minutes.** That's why we don't ask you to record in your Keeping Track any activity that doesn't last at least 10 minutes.
- We recommend that you **slowly increase the time you are active to 20 to 60 minutes.**
- The **total number of minutes per week should at least equal your Lifestyle Balance activity goal for that week.**

The final **"T"** stands for **type of activity.**

- To improve your fitness, you should do **"aerobic"** activities. As we said before, these are activities that **challenge your heart.** Brisk exercise will result in aerobic activities.
- These activities **use large muscle groups** and
- **Last 10 minutes or longer.** Brief activities that don't require your heart to work harder, such as bowling, pitching a softball, or washing a window, will not improve your aerobic fitness.

Introduce another way to measure exercise intensity.

Measuring your heart rate is one way to keep track of your intensity (or how hard you are working) when you're active. But even without measuring their heart rate, most people have a good sense of how hard they're working when they're active, just by listening to their body.

Rate yourself on this scale while you're being active. How hard are you working?

Review the work sheet with the participant. For your own background information as a Lifestyle Coach, the scale is based on Borg's original Rating of Perceived Exertion (RPE) Scale which is a numerical scale from 6 to 19, with 7 corresponding to very, very light, 9 to very light, 11 to fairly light, 13 to somewhat hard, 15 to hard, 17 to very hard, and 19 to very, very hard. The original scale was designed to approximate what one would estimate the corresponding heart rate to be, by adding a zero to the end of the RPE. For example, an RPE of 13 (somewhat hard) would approximate a heart rate of 130. So if a participant calculated her upper heart rate limit to be 130, her upper RPE limit would be around 13.

Assign home activity.

For next week:

- Keep track of your weight, eating and activity.
- Do your best to reach your activity goal for the week. *[Record.]*
- Take your heart rate or pulse every time you're doing physical activity.
- Adjust how hard you are working during an activity so that you stay within your target heart rate *[specify]* or keep how hard you are working at this level *[specify].*

Any questions?

You may want to ask the participant to invite a family member to the next session, Make Social Cues Work for You, if you and the participant think that would be helpful in planning strategies for handling social cues.

Session 14:
Make Social Cues Work *for* You

Objectives:

In this session, the participant 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, having visitors, and holidays.
- Make an action plan to change a problem social cue and add a helpful one.

To Do Before the Session:

Ask the participant to invite a family member to this session if you and the participant think that would be helpful in planning strategies for handling social cues.

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, with tips for handling parties, holidays, vacations, and other social events; low-fat/calorie recipes for entertaining; helpful ideas for low-fat eating and staying active while traveling).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

> Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?
>
> What was it like taking your pulse or **heart rate**? Were you able to stay within your target heart rate?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Review the concept of food and activity "cues" and define social cues.

In an earlier session we talked about **how to "take charge of what's around you."** We took an imaginary video camera through your house and where you work, and we looked for problem food or activity "cues," things that would prompt you to think about eating or to be inactive, like a TV set or a bag of cookies on a kitchen counter. We planned some ways to get rid of problem cues and add positive cues (for example, watch less TV, keep high-fat foods out of the house).

In that session we focused on the sight and smell of food or certain activities that make you think about food. Today we're going to talk about **social cues**, or **what other people say or do that affects your eating and activity.** Again, we will plan some ways to **reduce problem social cues** and some ways to **add positive ones.**

Give examples of problem social cues and positive social cues.

Problem Social Cues

One of the most powerful **problem social cues** is:

- **The sight of other people eating problem foods or being inactive** (for example, you go to a bar where you see other people eating potato chips and watching TV).Can you think of an example in your own life? Is it difficult for you when you see someone in your family or a friend eat certain foods? (Record examples briefly on the work sheet.)
- **Being offered (or pressured to eat) problem foods** or **being invited to do something inactive** are also negative cues (for example, your spouse buys you candy for your birthday or a friend asks you to come over to watch football).What are some examples in your own life?
- **Being nagged** is a negative cue (for example, your spouse says, "You shouldn't be eating that bacon. It's too high in fat."). Some people may think that nagging is helpful, but actually it tends to cause the behavior it's designed to stop. Does anyone nag you about your eating or activity?
- **Hearing complaints** is a negative cue, too (for example, your daughter says, "I hate this frozen yogurt. Real ice cream is better," or your spouse says, "You're always outside exercising. You don't have any time for your family any more.").

  Do you hear complaints from anyone about your eating or activity?

Now let's compare problem social cues with **positive social cues.**

Positive social cues include:

- The **sight of other people eating healthy foods or being active** (for example, you go out to dinner with another participant who orders low-fat foods or you go to an aerobics class). Can you think of any people who are good examples for you? In what way? (Record on the work sheet.)

- **Being offered healthy foods** or **being invited to do something active** (for example, your mother offers you fruit salad for dessert or asks you to go for a wheel or walk). Does anyone do this for you?

- **Being praised** (for example, your spouse says, “The oatmeal was delicious this morning, honey.”). Who praises you for your efforts and accomplishments?

- **Hearing compliments** (for example, your daughter says, “Thanks for buying frozen yogurt, Mom. It’s a lot healthier than ice cream,” or your spouse says, “You’re really committed to exercising every day. I’m proud of you.”). Does anyone compliment you?

When you respond to a social cue in the same way over and over again, you build a habit. The cue becomes paired with the way you respond, and your response becomes more and more automatic. In an earlier session, we used the example of eating popcorn whenever you go to the movies as a food cue that over time becomes a habit for many people. It works the same way with social cues.

Let’s say that since childhood, your mother has offered you second helpings of food at the dinner table. You developed a habit of accepting her offer. Now when you return home as an adult and your mother offers you second helpings, it is hard for you to refuse.

It’s important to understand that with social cues, the **other person has also learned a habit.** So in the example we’ve just used, your mother has learned to offer you second helpings and expects that you will accept the offer. **This makes social cues even harder to change than other cues.**

Discuss ways to change problem social cues.

How can you change problem social cues?

1. As with problem food cues, one of the best things you can do is to **stay away from the cue, if you can**. For example:

- Move to a different room if a family member eats problem foods in front of you.
- Skip certain parties that are just too tempting for you.
- Socialize with people by going bowling, dancing, or to the movies. Don’t go out to eat as a way to socialize.
- Change the subject when someone starts talking about food or your weight or activity.

2. **Change the cue, if you can.** This means trying to influence the other person’s habit, if you can. For example, when someone nags, complains, eats problem foods in front of you, or pressures you to eat:

- **Discuss the problem. Brainstorm options.** For example, "It's hard for me when you eat ice cream in front of me. It really tempting. Is there away we could get together and have fun, but not eat ice cream?" **Be willing to compromise** to find a solution that will work for everyone.
- **Tell people about the study, your efforts to lose weight and be more active, and why this is important to you.** Many people will be willing to help if they understand that you are trying to change your eating and activity and why.
- **Ask others to praise you for your efforts and ignore your slips. This is KEY to your success.** Explain to your friends and family that this is what would be most helpful to you. In turn, be sure to thank them when they notice your efforts and overlook your slips.

  (Role play this with the participant, using an example that is meaningful to him or her.)

3. If you can't stay away from the problem social cue or change it, **practice responding in a more healthy way**. Over time you will **build a new, healthier habit** and **the other person will learn a new habit, too,** because of your new response. For example:

- **Say "No" to food offers.** If you are consistent and continue to say "No," others will eventually stop offering.
- One of the most important things you can do is to **show others you know they mean well, and suggest something they can do to help you. Be specific.** Most people mean well when they nag, offer food or pressure someone to eat (for example, many people think that being a good hostess means insisting that guests have second helpings). If you recognize that they mean well and give them a specific, positive alternative, they can still feel helpful and you are more likely to reach your goals, too. For example, when a hostess offers you second helpings, say, "Thanks so much for offering. You know what I'd really enjoy is some coffee." **If you can, give them specific ideas of how to help ahead of time,** before you are confronted by a challenging situation.

Role play saying "No" to food offers, using an example that is meaningful to the participant.
Illustrate that the participant should be prepared to say "No" several times to someone who continues to offer, e.g., "Are you sure you don't want a piece of cake?"

Remember that **it takes time to break an old habit or build a new one.** Change doesn't happen overnight. And with social cues, there are at least two people involved in making a change: yourself and someone else. **Don't expect other people to adjust instantly** to a new way of relating, any more than you expect yourself to change instantly.

Discuss ways to add positive social cues.

Not all social cues are problems. You can use social cues to *help* you eat healthier and be more active. For example:

- **Spend time with people who are active and make healthy food choices.** For example, at parties stand next to people who spend most of their time talking and dancing instead of eating.

- **Put yourself in places where people are active**. For example, join an exercise club or sports league. Come to the study activity sessions.

- **Set up a regular "date" with others to be active**. You will be more likely to be active because you won't want to disappoint them by cancelling.

- **Ask your friends to call you to remind you to be active or to set up dates to be active.**

- **Bring a low-fat/calorie food to share.** For example, bring a fruit salad to a potluck dinner.

- **Be the first to order when you eat out at a restaurant** and order healthy foods.
  This is much easier than waiting until after others order high-fat foods and then trying to make a healthier choice. In addition, you will provide a positive social cue for other people.

- **Be social by doing something active.** For example, exercise and talk. Go out dancing instead of going out to dinner. Start a family tradition of going for exercise after dinner instead of watching TV.

  An important way to change negative social cues and add positive ones is to **ask people who want to support you for help.**

  What people in your life want to support you? *[Record a few names.]*

  What could they do to help you? Here are some ideas. Would any of these be helpful to you?

Review the ideas on the work sheet. Check a few that the participant thinks would be helpful.
Add other ideas at the bottom of the chart. Some participants may want to copy the work sheet to give to a supportive friend or family member.

Discuss ways to handle social events such as parties, having visitors, or holidays.

Social cues are especially powerful at social events such as parties, holidays, vacations, and when you have guests in your home or are a guest in someone else's home. These events:

- **Upset our routine** (for example, you usually exercise after dinner, so how do you fit exercising in on a day when you're going to a party after dinner?),

- **Challenge us with unique food and social cues** (for example, your family serves appetizers whenever there are guests in the house but not at other times; you go on vacation to a place you've never been before and you're not familiar with any of the restaurants),

- **May involve habits that have developed over many years and so can be very powerful** (for example, for the past 30 years on Thanksgiving, your family has watched the parade on TV and had pumpkin pie with whipped cream for dessert).

What are some social events that are difficult for you?

Get an idea of the kind of social events the participant attends. If it is near a holiday or vacation, you may want to focus during the remainder of the session on brainstorming options and making an action plan for that specific event. Optional participant handouts (see Appendix) are available that provide guidelines for holidays, parties, vacations, and so on.

To handle social events well, try to anticipate the problems that will occur. What exactly might be difficult for you? Then brainstorm your options ahead of time. Here are some ideas: *[review the examples on the work sheet]*:

- **Plan ahead.**
- **Stay away from problem cues when you can.**
- **Change problem cues.**
- **Respond to problem cues in a more healthy way.**
- **Add helpful social cues.**

Stay positive. Think of every social event as an opportunity to learn what works well for you and what doesn't. Remember, you are building healthy habits for a lifetime.

For participants that entertain, you may want to distribute some low-fat/calorie ideas and/or recipes (for example, recipes for low-fat dips and a list of low-fat crackers). Participants who travel often may appreciate the optional handout on helpful ideas for low-fat eating and staying active while traveling.

Assign home activity.

With the participant, develop and record on the work sheet two action plans to:

- Change a problem social cue.
- Add a helpful social cue.

If it is near a holiday, vacation, or particular social event, include an action plan for that event.

Assign home activity.

This week:

- Keep track of your weight, eating and activity.
- Try your two action plans for making social cues work for you.

And before the next session, answer the questions (Did it work? If not, what went wrong?) for both action plans

Session 15:
You Can Manage Stress

Objectives:

In this session, the participant will:

- Discuss how to prevent stress and cope with unavoidable stress.
- Discuss how study participation can be a source of stress and how to manage that stress.

To Do Before the Session:

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

> Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?
>
> Were you able to follow your action plans (change the problem social cue and add the helpful one)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Define stress and its relevance to the study.

> **Stress is tension or pressure. Stress is a natural part of living our life**.
>
> **Any change, good or bad, big or small, can cause stress.** Big changes or events in our life--like getting married, a serious illness, changing jobs--can cause stress. Small events- like losing your keys, having a birthday, having a flat tire, or needing to get your errands done before picking up your children--can also cause stress.

What kinds of things make you feel stressed?

Why are we talking about stress in the Lifestyle Balance program? Because **many people react to stress by changing their eating and activity habits.** Some people eat and drink too much as a way to deal with stress. Others may stop eating. Some people become very inactive and withdrawn.

What is it like for you when you get stressed?

If the participant does not provide examples, mention one or two situations that are typically stressful (such as being under a deadline at work, illness, being faced with unexpected responsibilities such as a sick child or car repair). Ask how the participant feels or reacts. Based on the response, point out any physical and emotional symptoms (headache or muscle tension) and behavioral changes that might affect eating and activity.

- Do you get any physical symptoms like a headache or stomach ache or muscle tension?
- Do you change your behaviors when you feel stressed?
- Do you eat more when you are stressed?
- Do you change the kinds of food you eat?
- Do you change how active you are or the kind of physical activities you do?

Discuss ways to prevent stress.

An ounce of prevention is worth a pound of cure, and this is certainly true when it comes to stress. The best approach is to **prevent stress whenever you can**. Here are some ideas:

1. **Practice saying, "No."**
   Practice saying "No" when someone else asks you to do something you don't want to do. Say "Yes" only when it is important to **you.**

   Saying "No" can be hard. It causes some tension or stress. But that stress is usually short-lived. If you say "Yes," you may have hours, weeks, or months of stress as you do whatever you agreed to do.

2. **Share some of your work with others, both at home and at work.**
   Delegate what you can to someone else. For example, your spouse and children might be able to help clean the house, cut the lawn, shop for food, prepare meals, and do laundry. A co-worker might be able to help you with an overwhelming project at work.

   Sharing work doesn't mean you're being irresponsible. Giving responsibility to others, even if they aren't as experienced as you, gives them a chance to learn, participate, and gain experience. One warning: Don't expect them to be perfect. Criticizing the efforts of others who are trying to help can be another source of stress. Instead, support them for their efforts and be patient as they gain skills.

3. **Set goals you can reach.**
   Sometimes we create our own stress by trying to be perfect. If you set reasonable goals, you are more likely to succeed. When you succeed, you are less likely to feel stressed. Remember, we talked about this when we discussed negative thoughts—if you try to be perfect, you probably won't succeed!

   Periodically, take a good look at the demands you are placing on yourself. Ask yourself, "Am I expecting myself to do more than anyone could possibly do?"

4. **Take charge of your time.**

   Make schedules with the real world in mind. Don't try to accomplish in 30minutes what realistically will take an hour. Take a good look at your to-do list, eliminate what isn't essential, and give yourself a realistic amount of time to accomplish the rest.

   Get organized. Chaos is very stressful. It's also inefficient. Devote some time every day to getting organized, and you will save time and stress in the long run.

5. **Use the steps for solving problems.**
   If changing your eating and activity habits is causing stress, take action. Use the steps to solving a problem that we discussed in an earlier session:

   - Describe the problem in detail. Discuss it with your family or friends if they are involved.
   - Brainstorm your options.
   - Pick one option that is very likely to work and that you can do.
   - Make an action plan.
   - Then try it and see how it works.

   Continue the process until you find a solution. Sitting on problems can cause even more stress. Solve them instead and move on.

6. **Plan ahead.**
   Think about what kind of situations are stressful for you. These are times when you are at high risk, so plan ahead for how to handle them or work around them. For example, are holidays especially stressful for you? If so, plan some ways to make your life easier during the holidays. Examples: Buy frozen meals to have on hand for busy days. Decide what parts of decorating the house are not essential to you and spend that time relaxing instead.

7. **Keep things in perspective. Remember your purpose.**

Maintain a positive attitude. Think of all the good things in your life. And remember why you joined the study.

8. **Reach out to people.**
   Think about who you can turn to for support. **Ask supportive people to help** when you are overwhelmed or need someone to encourage you. We talked about this last week.

9. **Be physically active.**
   Many people find that being active helps them cope with stress and feel more relaxed and able to manage stressful situations more smoothly.

Discuss ways to cope with unavoidable stress.

What about the times when you can't avoid stress?

- **First, catch yourself feeling stressed as early as you can.**
  We talked before about action or behavior chains and that it's important to try to break them as early as possible. The same is true of stress. If you learn to recognize the signs of stress and catch yourself early in the process, you may have a chance to avoid some of the harmful consequences such as overeating or being inactive.

Do you have any signs when you are getting stressed?

- **Take a 10-minute "time out."**
  Develop a new habit of responding to stress with a "time out"--stop what you are doing and take a few minutes for **yourself.** Do whatever you find helpful that doesn't involve food. Examples:

  a. **Move those muscles.** Research has shown that being active relieves tension, reduces anxiety, and counters depression. So when you notice yourself feeling stressed, make yourself go out for 10 or 15-minute of exercise. The distraction and breathing can do a lot to make you feel better.

  b. **Pamper yourself.** Take a bath. Manicure your nails. Massage your feet. Read a magazine. Read the funnies. **Just take out 10 minutes for YOURSELF.**

  c. **Breathe.** Most of us tend to hold our breath when we are under stress, which creates more tension in the body and mind. So when you catch yourself feeling stressed, try this: Take a full, deep breath. Count to five. Then let go of your breath slowly. Let the muscles in your face, arms, legs, and body go completely loose.

Discuss how study may be a source of stress and ways to manage that stress.

We understand that **the study itself and the lifestyle changes we recommend may cause stress.** Changing your behaviors and helping your family to make related changes can create pressure and tension.

Here are some possible ways that the study may cause stress and some examples of how to manage that stress.

Review the work sheet with the participant. Note that some of the possible sources of stress may not apply to the participant--for example, the participant's family may enjoy low-fat foods. Be careful that the review of the work sheet does not create a negative perspective, and help the participant feel able to cope should such stresses arise.

Assign home activity.

How does the study cause you stress? *[Record on work sheet.]* What are some other major sources of stress in your life? *[Record on work sheet.]* Pick one of the examples you've given, and let's make an action plan for either preventing that stress or coping with it.*[Complete the work sheet.]*

For next week:

- Keep track of your weight, eating and activity.
- Follow your action plan.

Then answer the questions on the work sheet (Did it work? If not, what went wrong?) before we meet next time.

Session 16:
Ways to Stay Motivated

Objectives:

In this session, the participant will:

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

To Do Before the Session:

Review the participant's progress notes since Session 1. Note any plans that were made to improve weight loss and activity level, which strategies were used, and which were successful or not successful. If the participant is not currently at goal for weight loss and/or activity, refer to the Tool Box for ideas of additional strategies required or optional for particular problems.

If you have copies of some of the participant's past Keeping Track records, review them as well.
Note some of the positive changes the participant has made.

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Get materials ready:

- Keeping Track book(s).
- Optional forms for self-monitoring during maintenance, such as the Lifestyle Balance Calendar, if applicable.
- Pages for participant's notebook.
- Lifestyle Balance certificate of participation. There are several versions; choose the version that is appropriate for the participant's level of progress. You may want to print the certificate on special paper and add the participant's name in calligraphy if possible (by computer or by hand). Have the principal investigator at your center sign the certificate before the session.
- Meal plans appropriate for the participant's calorie goal, if applicable.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Were you able to follow your action plan (to prevent or cope with one source of stress)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant. Graph physical activity.

Give the participant a certificate of participation and introduce the upcoming calendar of sessions.

This is the last of the 16 core sessions of the Lifestyle Balance program.

Congratulations! This certificate is to let you know how very important your participation in the study has been during this time.

Sign the Lifestyle Balance certificate of participation and give it to the participant. Personalize it by mentioning briefly some of the particular contributions and efforts that the participant has made.

It's very important to keep in mind that, even though you have finished the first 16 sessions, the **weight loss and physical activity goals remain in place for the rest of the study**. So at our next visit, we'll talk about how we'll work together in the future to help you...

If the participant hasn't reached the goals, emphasize reaching them and then maintaining them for the rest of the study. If the participant *has* reached both goals, emphasize maintaining them and surpassing them if possible because they are *minimum* goals.

Let's set up an appointment for the next visit ....

If at all possible, make the appointment for one or two weeks from now. Do **not** go to monthly or bimonthly visits at this point (for a detailed discussion of this issue, see the Manual for Contacts After Core, Session 1). Also, do **not** design a general schedule for the after-core period at this point; wait until the first after-core session when you will discuss the frequency of contact in the context of the goals for the after-core.

Review the participant's progress since Session 1, and if not at goal, develop a plan to improve progress.

Today we're going to talk about ways to stay motivated for the long term, to make healthy eating and being active last for a lifetime. But first, let's review your progress since the beginning of the program.

- **What are some of the major changes you've made to be more active?** Include both what you do to reach your goal (that is, those activities you record) and what you do to be more active in general (the lifestyle activity that you don't record, like taking the stairs instead of an elevator).

- **What changes have you made to eat fewer calories and less fat?**

Briefly record on the work sheet some of the changes made by the participant. Be as specific as possible. Praise and encourage the maintenance of these changes.

Have you reached your weight goal? Your activity goal?

Refer to the How Am I Doing? graphs for weight and activity, and check yes or no on the worksheet.

If the participant is **at goal** for weight loss and activity, praise the progress made.

If the participant is **not at goal** for weight loss or activity, praise whatever progress has been made. Encourage the participant to improve, and develop a plan using the work sheet. **Follow the guidelines in the Tool Box as to which strategies are required to address particular problems identified.** For example, some participants may need to be given meal plans at a lower calorie level.

Discuss the importance of motivation.

In programs like Lifestyle Balance, **motivation is crucial to maintaining healthy eating and physical activity for the long term.** But how to stay motivated is **one of the biggest problems people face.**

One reason it's difficult to stay motivated is the fact that many people do well. This sounds ironic--your progress itself makes it hard to *maintain* that progress. But think back to when you first joined the study. *[Tailor the following examples to the individual participant's experience thus far in the program.]* You may have felt tired when you went up stairs and that motivated you to become more active. Now that you're more active, you can climb stairs without difficulty. So that source of motivation (feeling tired when you climbed stairs) is gone.

It's the same for weight. When you first came into the study, your clothes may have been tight and that motivated you to lose weight. If your clothes are looser on you now, you no longer have tight-fitting clothes as a source of motivation.

Discuss ways to stay motivated.

However, it *is* possible to stay motivated for the long term and, as I said, it is very important to maintaining healthy eating and staying active. Here are some things that other people have found helpful.

1. **Stay aware of the benefits you've achieved and hope to achieve.**
   Again, think back to when you first joined the study. What did you hope to achieve?

   Record on the work sheet. Refer the participant back to the work sheet from Session 1A, Remember Your Purpose, and review. Also **acknowledge any costs** that the participant articulates at this point (or that the participant has discussed with you before). Be aware that, throughout the study, participants will continue to weigh the costs versus the benefits of the program as they perceive them.

Have you reached these goals?

Have you received any benefits that you didn't expect?

What would you like to achieve during the next six months of the study? Let's make a list and then you can review these when you need motivation. *[Record.]*

2. **Recognize your successes.**

   What changes in your eating and activity habits do you feel proudest of? What has been easier than you thought it would be? What has been harder than you thought it would be?

   When you are feeling low on motivation, think about all of these positive changes and give yourself credit for them. Try not to lose the momentum you have reached so far.

3. **Keep visible signs of your progress so you can see how far you've come.**

   - **Post a graph of your weight loss and activity on your refrigerator door.** Not only will it keep you aware of your progress, but loved ones will take note and congratulate you for your movement in the right direction.

   - **Mark your activity milestones on a map toward a particular goal.** For example, create a simple map of the number of miles it would take to wheel or walk to a favorite vacation spot or tour a favorite city. Mark milestones along the way (the halfway point, a fun museum to stop at along the way, and so on). You might even want to go on an actual vacation at that place when you reach your goal.

   - **Measure yourself at monthly intervals.** Keep track of your progress in terms of specific measurements (for example, waist circumference or the number of belt loops).

4. **Keep track of your weight, eating and activity.**
   It's common to "drift" away from new habits. You may gradually make small changes in your eating and activity over a long period of time, and not even be aware that you are slowly going back to your old habits. The best way to prevent this and stay in control is to continue to keep track. Keeping track will help you catch changes before they sneak up on you.

   Give the participant optional forms for self-monitoring during maintenance, such as the Lifestyle

Balance Calendar, if applicable.

- **Record your activity daily.**
- **Record what you eat this often:** . *[Fill in the blank. The minimum should be one week per month, but some participants may want to or be willing to continue daily self-monitoring.]*
- **Record your weight on**. *[Fill in the blank, for example, "on Monday mornings."*]

  If you gain weight, you will need to keep track more often.

5. **Add variety to your routine.**

   We've talked before about how to "jump start" your activity plan. Have you added some variety to keep yourself from being bored with staying active? Have you noticed any difference in how you feel about being active?

   The same thing is true with eating. You don't need to use the same low fat salad dressing every night. Experiment with new low fat products. Try new recipes and restaurants. Don't approach healthy eating as a chore. It is an art.

   What meals, snacks, or particular foods are you most bored with? Can you think of some ways to vary this part of your eating?

   Record the participant's ideas on the work sheet. Examples:

   - Use seasonings and flavorings to add flavor to lower-fat dishes. (Review the handout on adding flavor without fat.)
   - Try a wide range of fruits, vegetables, and grains.
   - Include a variety of colors, textures, and tastes on your plate.
   - Make one night a week an "ethnic night," "soup night," or "vegetarian night." Experiment with preparing various recipes for these foods.
   - If you eat out often, plan more meals at home.
   - If you eat at home often, plan more meals out. (Have you stopped eating out because you're trying to lose weight? Has this left you feeling restricted and deprived? Have you stopped inviting friends over to eat or accepting invitations to eat at their homes? Don't deny yourself the pleasure of social eating. Instead, make a plan for how to handle these times, then try your plan, and see how it works. You may make a few mistakes at first, but it's important to know that you **can** eat out and still eat healthy.)
   - Share food preparation and dining with others as a way to relax. Invite people over to prepare dinner together. Cook with your children and spouse.
   - Plan potluck dinners around a certain theme and share the best recipes you discover as a group.
   - You may want to subscribe to a magazine that includes healthy recipes and food ideas, such as Weight Watchers, Eating Well, or Cooking Light.
   - Or take a class to learn how to cook, at least the basics.

If the participant expresses interest in learning more about a specific topic such as ethnic cooking or vegetarian eating, address it briefly here and plan to provide more detail at a future meeting or group session.

6. **Set new goals for yourself, and develop ways to reward yourself when you meet each goal.**

   The **goal** should be **specific and short-term** ("I will not use butter or margarine on my vegetables this week"). It should also be something that's not too easy or too hard(something that will present **"just enough" of a challenge** for you that you will be able to do it and will also feel that you've accomplished something).

   The **reward** should be **something that you will do or buy if and only if you reach your goal**. The reward doesn't need to be fancy or cost a lot of money. It can be something that you normally enjoy doing (like reading the paper or taking a hot bath) with the difference being that you will do it *only if* you reach your goal. For example," After I finish exercising, I'll call my friend and chat." Then, if you need a boost to keep you going during your exercise, you can think about what you'll talk about on the phone with your friend.

   What are some non-food ways you can reward yourself for reaching a goal?

   Record ideas on the worksheet, such as:

   - Buy myself fresh flowers,
   - Treat myself to a manicure,
   - Go to a movie,
   - Set some money aside for something you want to buy or do,
   - Take a bubble bath,
   - Buy a favorite magazine, or
   - Take some time for myself. (Specify.)

7. **Create some friendly competition.**

   Get a friend or relative to enter into a friendly competition with you. This should be the **kind of competition in which you both win.** For example:

   - If you and your friend are both active every day for a month, at the end of the month what will you do?
   - If you are active every day for a month and your daughter does her homework every day, at the end of the month what will you treat yourselves to?
   - See how many days in a row you can be active for at least 30 minutes. Try to beat yourself. For example, if last month you were active for seven days in a row, see if you can do better this month.

8. **Use me and others to help you stay motivated.**
   If you notice that your motivation is dropping, call me. Or call someone else on the Lifestyle Balance staff. Or call a friend or another participant. Everyone has trouble staying motivated sometimes, so we all understand. And we can help each other through the tough times.

Assign home activity.

Pick one way to stay motivated that you think would be most helpful to you right now. Choose something that is very likely to work and that you can do. Be realistic. Be specific. *(Record on work sheet.)* Let's **make an action plan** related to that. *(Complete the work sheet.)*For next week, keep track of your eating and activity. Follow your action plan. And answer the questions on the work sheet before you come in for your next session.

D. WEIGHT MIRROR

A. General Principles:

- As a component of the Behavioral Intervention, the Internet based freeware, Weight Mirror, will be used to create a 'virtual image' of the participant that is 7% lighter than their measured weight at the onset of the study.
- Visualization of weight loss, in this manner, will be used as a motivational tool.
- A photograph of the participant will be taken at the onset of the study, and uploaded to the Weight Mirror program for virtual image creation. The area of interest on the website will include eyes to knees inclusive of right/left body dimension.
- Original photograph will be used as a reference along with the virtual image, and included in the Lifestyle Manual to be given to each participant
- Photographs will be updated at 6 and 12 months
- **http://makeovr.com/weightmirror/**

Figure 4. A woman with paraplegia before (left) and after (right) a 7% 'virtual' weight loss.

CAREGIVER STANDARD CARE: GENERAL PHYSICAL ACTIVITY GUIDELINES FOR HEALTHY LIVING

- Guidelines are outlined by the Center for Disease Control and Prevention and can be located at www.cdc.gov Division of Nutrition, Physical Activity and Obesity
- Physical activity is anything that gets your body moving. According to the *2008 Physical Activity Guidelines for Americans*, you need to do two types of physical activity each week to improve your health–aerobic and muscle-strengthening.

For Important Health Benefits

Adults need at least:

2 hours and 30 minutes (150 minutes) of moderate-intensity aerobic activity (i.e., brisk walking) every week **and**

muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders, and arms).

OR

1 hour and 15 minutes (75 minutes) of vigorous-intensity aerobic activity (i.e., jogging or running) every week **and**

muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders, and arms).

OR

An equivalent mix of moderate- and vigorous-intensity aerobic activity **and**

muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders, and arms).

10 minutes at a time is fine

We know 150 minutes each week sounds like a lot of time, but it's not. That's 2 hours and 30 minutes, about the same amount of time you might spend watching a movie. The good news is that you can spread your activity out during the week, so you don't have to do it all at once. You can even break it up into smaller chunks of time during the day. It's about what works best for you, as long as you're doing physical activity at a moderate or vigorous effort for at least 10 minutes at a time.

For Even *Greater* Health Benefits

Older adults should increase their activity to:

5 hours (300 minutes) each week of moderate-intensity aerobic activity **and**

muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders, and arms).

OR

2 hours and 30 minutes (150 minutes) each week of vigrous-intensity aerobic activity **and**

muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders, and arms).

OR

An equivalent mix of moderate- and vigorous-intensity aerobic activity **and** muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders, and arms).

Aerobic activity – what counts?

Aerobic activity or "cardio" gets you breathing harder and your heart beating faster. From pushing a lawn mower, to taking a dance class, to biking to the store – all types of activities count. As long as you're doing them at a moderate or vigorous intensity for at least 10 minutes at a time.

Intensity is how hard your body is working during aerobic activity.

How do you know if you're doing light, moderate, or vigorous intensity aerobic activities?

For most people, light daily activities such as shopping, cooking, or doing the laundry doesn't count toward the guidelines. Why? Your body isn't working hard enough to get your heart rate up.
Moderate-intensity aerobic activity means you're working hard enough to raise your heart rate and break a sweat. One way to tell is that you'll be able to talk, but not sing the words to your favorite song. Here are some examples of activities that require moderate effort:

- Walking fast
- Doing water aerobics
- Riding a bike on level ground or with few hills
- Playing doubles tennis
- Pushing a lawn mower

Vigorous-intensity aerobic activity means you're breathing hard and fast, and your heart rate has gone up quite a bit. If you're working at this level, you won't be able to say more than a few words without pausing for a breath. Here are some examples of activities that require vigorous effort:

- Jogging or running
- Swimming laps
- Riding a bike fast or on hills
- Playing singles tennis
- Playing basketball

You can do moderate- or vigorous-intensity aerobic activity, or a mix of the two each week. A rule of thumb is that 1 minute of vigorous-intensity activity is about the same as 2 minutes of moderate-intensity activity.
Some people like to do vigorous types of activity because it gives them about the same health benefits in half the time. If you haven't been very active lately, increase your activity level slowly. You need to feel comfortable doing moderate-intensity activities before you move on to more vigorous ones. The guidelines are about doing physical activity that is right for you.

Muscle-strengthening activities – what counts?
Besides aerobic activity, you need to do things to strengthen your muscles at least 2 days a week. These activities should work all the major muscle groups of your body (legs, hips, back, chest, abdomen, shoulders, and arms).
To gain health benefits, muscle-strengthening activities need to be done to the point where it's hard for you to do another repetition without help. A repetition is one complete movement of an activity, like lifting a weight or doing a sit-up. Try to do 8—12 repetitions per activity that count as 1 set. Try to do at least 1 set of muscle-strengthening activities, but to gain even more benefits, do 2 or 3 sets.

You can do activities that strengthen your muscles on the same or different days that you do aerobic activity, whatever works best. Just keep in mind that muscle-strengthening activities don't count toward your aerobic activity total.
There are many ways you can strengthen your muscles, whether it's at home or the gym. You may want to try the following:

- Lifting weights
- Working with resistance bands
- Doing exercises that use your body weight for resistance (i.e., push ups, sit ups)
- Heavy gardening (i.e., digging, shoveling)
- Yoga

We have included a guide for adults based on the “2008 Physical Activity Guidelines for Americans”.

CAREGIVER STANDARD CARE:
GENERAL DIETARY GUIDELINES FOR HEALTHY LIVING

- Dietary guidelines for Americans are outlined by the Office of Disease Prevention and Health Promotion and can be found at www.health.gov/dietaryguidelines/

The 2010 Dietary Guidelines was designed to help people choose a healthy diet. It emphasizes 3 major goals for Americans:

- Balance calories with physical activity to manage weight
- Consume more of certain foods and nutrients such as fruits, vegetables, whole grains, fat-free and low-fat dairy products, and seafood
- Consume fewer foods with sodium (salt), saturated fats, trans fats, cholesterol, added sugars, and refined grains

Key Recommendations

BALANCING CALORIES TO MANAGE WEIGHT

- Prevent and/or reduce overweight and obesity through improved eating and physical activity behaviors.
- Control total calorie intake to manage body weight. For people who are overweight or obese, this will mean consuming fewer calories from foods and beverages.
- Increase physical activity and reduce time spent in sedentary behaviors.
- Maintain appropriate calorie balance during each stage of life—childhood, adolescence, adulthood, pregnancy and breastfeeding, and older age.

FOODS AND FOOD COMPONENTS TO REDUCE

- Reduce daily sodium intake to less than 2,300 milligrams (mg) and further reduce intake to 1,500 mg among persons who are 51 and older and those of any age who are African American or have hypertension, diabetes, or chronic kidney disease. The 1,500 mg recommendation applies to about half of the U.S. population, including children, and the majority of adults.
- Consume less than 10 percent of calories from saturated fatty acids by replacing them with monounsaturated and polyunsaturated fatty acids.
- Consume less than 300 mg per day of dietary cholesterol.
- Keep *trans* fatty acid consumption as low as possible by limiting foods that contain synthetic sources of *trans* fats, such as partially hydrogenated oils, and by limiting other solid fats.
- Reduce the intake of calories from solid fats and added sugars.
- Limit the consumption of foods that contain refined grains, especially refined grain foods that contain solid fats, added sugars, and sodium.
- If alcohol is consumed, it should be consumed in moderation—up to one drink per day for women and two drinks per day for men—and only by adults of legal drinking age.[5]

FOODS AND NUTRIENTS TO INCREASE

Individuals should meet the following recommendations as part of a healthy eating pattern while staying within their calorie needs.

- Increase vegetable and fruit intake.
- Eat a variety of vegetables, especially dark-green and red and orange vegetables and beans and peas.
- Consume at least half of all grains as whole grains. Increase whole-grain intake by replacing refined grains with whole grains.
- Increase intake of fat-free or low-fat milk and milk products, such as milk, yogurt, cheese, or fortified soy beverages.[6]
- Choose a variety of protein foods, which include seafood, lean meat and poultry, eggs, beans and peas, soy products, and unsalted nuts and seeds.
- Increase the amount and variety of seafood consumed by choosing seafood in place of some meat and poultry.
- Replace protein foods that are higher in solid fats with choices that are lower in solid fats and calories and/or are sources of oils.
- Use oils to replace solid fats where possible.
- Choose foods that provide more potassium, dietary fiber, calcium, and vitamin D, which are nutrients of concern in American diets. These foods include vegetables, fruits, whole grains, and milk and milk products.

Recommendations for specific population groups

Women capable of becoming pregnant[7]

- Choose foods that supply heme iron, which is more readily absorbed by the body, additional iron sources, and enhancers of iron absorption such as vitamin C-rich foods.
- Consume 400 micrograms (mcg) per day of synthetic folic acid (from fortified foods and/or supplements) in addition to food forms of folate from a varied diet.[8]

Women who are pregnant or breastfeeding[7]

- Consume 8 to 12 ounces of seafood per week from a variety of seafood types.
- Due to their high methyl mercury content, limit white (albacore) tuna to 6 ounces per week and do not eat the following four types of fish: tilefish, shark, swordfish, and king mackerel.
- If pregnant, take an iron supplement, as recommended by an obstetrician or other health care provider.

Individuals ages 50 years and older

- Consume foods fortified with vitamin B_{12}, such as fortified cereals, or dietary supplements.

BUILDING HEALTHY EATING PATTERNS

- Select an eating pattern that meets nutrient needs over time at an appropriate calorie level.
- Account for all foods and beverages consumed and assess how they fit within a total healthy eating pattern.
- Follow food safety recommendations when preparing and eating foods to reduce the risk of foodborne illnesses.

STUDY DOCUMENTATION: RANDOMIZATION, DATA COLLECTION & REPOSITORY.

A. Overview

Methods of documentation and data collection

Paper forms

Paper forms will be used to document that certain study procedures were completed.

General guidelines:

- Please use blue or black ink.
- Make sure all items are filled out.

To correct mistakes:

- Draw a single line through the incorrect information and initial and date the correction.

Electronic spreadsheets and Database

Electronic spreadsheets will be used to store information about the study participants.

General guidelines:

- These files should be stored securely at your local facility with access limited to the research staff involved with the study.
- If possible, the files should be stored on a network or server that is backed up regularly.
- Study participant information and data will be entered into a secured web-based data repository supported by the primary study site (see "Velos" and "Assessment Center" section below).

Participant research file

All original paper documents associated with each participant should be kept in a participant research file at the center in which they were enrolled. See Appendices for a list of all documents to be stored in the participant research file. All original paper documents, except the signed informed consent, W9, and payment form should have the Subject ID recorded on the top of each page of the document.

Recruitment

Each center will be responsible for identifying and recruiting participants into the study in accordance with the local ethics board approved methods.

Study Visit

Informed consent

For the protection of human subjects, informed consent must be obtained before asking an individual to initiate any research activities. It is the responsibility of each PI to ensure that informed consent is obtained prior to collecting data.

The IRB at each center must approve the informed consent forms and procedures. Additional information may be added based on individual IRB requirements, but required information may not be excluded from the forms.

The following items must be considered when administering informed consent.

1) Informed consent procedures should only be conducted by authorized study investigators.
2) Informed consent procedures should be conducted in a quiet area, affording privacy to the potential participant.
3) In seeking consent, be sure to provide potential participants with the 8 essential elements of informed consent:
    - Advise them that the study involves research, why the potential participant is being asked to participate, the expected duration of study participation, and a description of the procedures.
    - A description of the risks associated with participating.
    - A description of the benefits to participating.

Note: Subject payment is **not** considered to be a benefit of this study.

- The alternatives to participating in the study.
- How confidentiality of records will be maintained.
- Availability or non-availability of medical treatment or compensation for physical injuries incurred as a result of participation in the study.
- Inform them that participation is voluntary.
- Provide information of whom to contact for answers to questions.

4) Once all pertinent information is provided to the potential participant, give the potential participant the opportunity to read the consent form and answer any questions raised.
5) Have the participant initial each page of the consent form and sign/date where appropriate.
6) Have the investigator sign, date, and <u>time</u> the appropriate page.
7) Provide the participant with a copy of the original consent document.
8) Store the signed original consent and documentation forms in a secure and designated file for consent forms.

Randomization

Randomization code lists will be generated prior to start of participant recruitment by the biostatistician at the coordinating center. The coordinating center will maintain a list of randomization codes for each site. The research team member who will conduct the informed consent process will contact the coordinating center by phone when the potential participant arrives for their initial visit to obtain the group assignment. The research staff member should call the first name on the contact list below. If that person cannot be reached, they should leave a voicemail message and contact the second person, until someone is reached. Someone at the coordinating center will be available during the normal business hours of 8:00 am – 5:00 pm (Eastern time). If you are planning on conducting testing during non-business hours, please let the coordinating center know so that we can make arrangements to have someone available to provide you with the group assignment.

Name	Phone number	Secondary phone number
Luisa Betancourt	305-243-6320	786-488-1661
Patricia Burns	305-243-6320	786-991-8186

Assigning Subject ID

Upon enrollment and verification of eligibility, each participant must be assigned a Subject ID**.** This is essential for tracking participants and ensuring accuracy in participant files. This code must be included at the top of each page of each document associated with the participant.

To safeguard participant confidentiality, the Subject ID should not be included on the participant's signed informed consent document and documentation of informed consent form.

The Subject ID is a code that links individual participants to all of their research materials. This code is a 4 digit number. The first digit is the location where the participant enrolled and the last three digits are the number of subjects enrolled in the study at each site. Below are the codes to be used for assigning Subject IDs.

First digit should be assigned as follows:

1 = MIA (Miami)
2 = CH (Craig Hospital)

Second, digits should be assigned as follows:

1= SCI/D subject enrolled in study
2= Caregiver subject enrolled in study

Third and forth Continue assigning these digits sequentially as each new subject is enrolled in the study, regardless of group assignment.

01= first subject enrolled in study
02= second subject enrolled in study

Continue assigning these digits sequentially as each new subject is enrolled in the study, regardless of group assignment.

i.e. The first SCI/D participant in the study at The Miami Project ID would be :

- DRPP – 1101

His/her caregiver would be

- DRPP- 1201

Data collection

Below is a summary of the forms that will be use to collect some of the data during the study visit and the method of collection. Instructions for collection of each measure are included in Appendix XXXX

Form #	SCI – CRF Forms
00	DRPP- Visit Checklist
01	Inclusion-Exclusion Documentation SCI
02	Medical and Surgical History Eval SCI
03	1RM SCI
04	GXT- VO_2 test

05	Anthropometric Measures
06	Dietary-Food Record
Caregiver – CRF Forms	
00 b	DRPP- Visit Checklist
01 b	Inclusion-Exclusion Documentation SCI
02 b	Medical and Surgical History Eval SCI
03 b	1RM SCI
04 b	GXT- VO_2 test
05 b	Anthropometric Measures
06 b	Dietary-Food Record

Study Activities (methods of data collection)

SCI

Study Activity/Test	**Collected with**
Medical and Surgical History (to be approved by Study Physician)	Paper form-Velos
Blood Draw / Eat	Paper form (result- data excel file) – Velos
ASIA (if not within 2 years)	Paper form – Velos
Strength test	Paper CRF – Excel/Velos
Body Mass	Paper CRF – Excel/Velos
Graded Exercise Test	Paper CRF – Excel/Velos
SCI Functional Index (SCI-FI) – 6 domains	Assessment Center
Craig Handicap Assessment and Reporting Technique (CHART)	Assessment Center
Spinal Cord Independence Measure-II (SCIM-III)	Assessment Center
The International SCI Basic Pain Data Set (ISCIBPDS)	Paper Form – Excel/Velos
The Neuropathic Pain Symptom Inventory (NPSI)	Paper form – Velos
The West Haven-Yale Multi-dimensional Pain Inventory (MPI-***SCI***)	Paper form – Velos
LSQ-9	Assessment Center
SCI Exercise Self-Efficacy Scale (SCI-ESES).	Assessment Center
Credibility and Expectancy Questionnaire (CEQ)	Assessment Center

CAREGIVER

Study Activity/Test	**Collected with**
Medical and Surgical History (to be approved by Study Physician)	Paper Form – Excel/Velos
Blood Draw / Eat	Paper form (result- data excel file) – Velos
Strength test	Paper CRF – Excel/Velos
Body Mass	Paper CRF – Excel/Velos
GXT	Paper CRF – Excel/Velos
PROMIS – physical function – all domains	Assessment Center
PROMIS – Social Satisfaction Short Form	Assessment Center
Pain Interview for Care Givers	Paper form – Velos
The West Haven-Yale Multi-dimensional Pain Inventory (MPI)	Paper form – Velos
Hospital Anxiety and Depression Scale (HADS-A) Anxiety Subscale,	Assessment Center
Credibility and Expectancy Questionnaire (CEQ)	Assessment Center

B. APPENDICES: SAMPLE CLINICAL RESEARCH FORMS

Subject ID: ______________ Date_______________________________

A Lifestyle Intervention Targeting Enhanced Health and Function for Persons with Chronic SCI in Caregiver/Care-Receiver Relationships: Effects of Caregiver Co-Treatment. ***This header should be affixed as an identifier for all CRF's.***

Form 00 – Visit Checklist SCI participants Period of Testing:

Assessment	Date Completed	Time Completed	Study Personnel Initials
Informed Consent			
Inclusion/Exclusion Criteria Form & Checklist			
W-9 Form & Payment Form			
Health History Questionnaire			
Body Mass Measures (Weight-Height)			
VO2 test			
1RM test			
Fasting Blood- Glucose, lipid Profile -Inflammatory markers			
Personal characteristics (Demographics)			
ASIA EXAM *If not performed within 2 years			
Basic Pain an Classification (ISCIBPDS)			
Neuropathic pain (NPSI)			
Multidimensional Pain (MPI-SCI)			
Craig Handicap Assessment and Reporting Technique (CHART) (computer based)			

SCIM-III (computer based)			
SCI-FI (computer based)			
SCI Exercise Self Efficacy (SCI-ESES) (computer based)			
Credibility and Expectancy Questionnaire (CEQ) (computer based)			
Life Satisfaction Questionnaire-9 (LSQ-9) (computer based)			
Payment Form Submitted For Processing			

Comments:____
____
____
____
____

Study Staff Signature/Initials: ____

*This footer should be affixed as an identifier for all CRF's.

Study Personnel should complete these questions (verbal administration).

Form 01 -Inclusion – Exclusion Documentation Form SCI Participant

Inclusion/Exclusion Criteria must be documented and eligibility must be determined before any other assessments can be completed. Please transfer the results of the IC/EC assessment from their respective forms to this document before proceeding

Height: __________________ Weight: ___________________

Inclusion Criteria **(must all be YES)**	**Criteria Met (Y/N)**	**Document Criteria (comments; lab values)**
1. Is the SCI/D AIS A-D C5-L1 and > 1 Year- post injury?		
2. Is the person age 18-70?		
3. WC >94 cm? plus one of:		
• BMI ≥ 21		
• Dyslipidemia (either; HDL-C≤ 40mg/dL (**men**) and ≤50 mg/dL (**women**), or TG ≤ 150 mg/dL).		

Exclusion Criteria **Participant excluded if any of the following is YES**	**Criteria Met (Y/N)**	**Document Criteria (comments; lab values)**
1. Exercise conditioning for recreation or competition within 3 months of study entry or diet involving caloric restriction for 6 months.		
2. weight loss/gain of 10% within the preceding 6 months		
3. Surgery within 3 months		
4. Grade 3-4 pressure ulcer within 3 months;		
5. upper limb pain that limits exercise		
6. recurrent acute infection or illness		
7. pregnancy		
8. previous myocardial infarction (MI) or cardiac surgery		
9. Type I or II diabetes (by World Health Organization [WHO] criteria		
10. Conditions that affect safety or influence the ability to follow instructions: Traumatic Brain injury (moderate/severe), substance		

abuse/dependence, major psychiatric condition or participation in another trial where exercise/diet/behavior therapy would be confounded		
11. anti-hypertensive medication (excluding drugs for acute autonomic hyperreflexia), anti-hyperglycemic agents, and lipid-altering agents		

Eligible to Participate (circle one): **Yes** **No**

Comments:____

Form 02- Medical & Surgical History

Name (Last, First, Middle)	**Age**	**Sex**

1. CARDIOVASCULAR	Diagnosed Condition?	Onset Date or Year	Current Problem?
Myocardial Infarct	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Angina - Coronary Artery Disease	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Congestive Heart Failure (CHF)	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Arrhythmias	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Hypertension	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Venous Disease	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Peripheral Arterial Disease	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	__ / __ / ____ mm dd yyyy	☐ Yes ☐ No
2. RESPIRATORY	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**

Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No

3. GASTROINTESTINAL	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Hepatic	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Stomach - Intestine	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Pancreas	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
4. ENDOCRINE	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Diabetes Mellitus	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Other, specify	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
5. PSYCHIATRIC/MENTAL HEALTH	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**

Specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
6. RHEUMATOLOGICAL	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No

7. NEUROLOGICAL	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Stroke	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
Paralysis	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
Brain Injury:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
Other, specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No
8. GENITOURINARY	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Specify:	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No

Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
9. ALLERGY	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
10. MUSCULOSKELETAL	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No

11. BLOOD/LYMPHATIC	**Diagnosed Condition?**	**Onset Date or Year**	**Current Problem?**
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	__ / __ / ____ *mm dd yyyy*	☐ Yes ☐ No
12. DERMATOLOGICAL	**Diagnosed**	**Onset Date or Year**	**Current**

	Condition?		Problem?
Specify:	☐ Yes ☐ No	___ / ___ / ______ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	___ / ___ / ______ *mm dd yyyy*	☐ Yes ☐ No
Specify:	☐ Yes ☐ No	___ / ___ / ______ *mm dd yyyy*	☐ Yes ☐ No

Spinal Cord Injury Related Health History

Injury etiology:

☐ Vehicular crash (car, truck, ATV, motorcycle, bicycle, boat, aircraft, etc.)

☐ Violence (gunshot, stab wound, hit with blunt object, explosion, etc.)

☐ Fall (from height or level ground, trip over an object, slipping on wet surface, etc.)

☐ Sports

☐ Other: ____

Surgeries performed directly related to spinal cord injury (choose all that apply and include date):

☐ Anterior fusion____

☐ Posterior fusion____

☐ Internal fixation/instrumentation____

☐ Decompression____

☐ External Fixation/Traction____

☐ None

☐ Unsure

Current medical complications, related to SCI:

☐ Pressure ulcers (location, stage)____

☐ Urinary tract infections, ____

☐ Bone fractures (date, location, cause, treatment)__________________________________

☐ Autonomic dysreflexia (frequency, primary stimulus, treatment) _______________________

☐ Other____

Surgical history, aside from spinal cord injury (Include date):

☐ Tonsillectomy_____ ☐ Head/neck cancer_____ ☐ Brain surgery_____ ☐ Gallbladder_____

☐ Cardiac/heart_____ ☐ Lung cancer_____ ☐ Ulcer_____ ☐ Abdominal Cancer_______

☐ Kidney_____ ☐ Bladder_____ ☐ Gynecological_____ ☐ Colostomy___________

☐ Prostate_____ ☐ Hernia_____ ☐ Knee_____ ☐ Infection______

☐ Shoulder_____ ☐ Peripheral vasculature_____ ☐ C-Section_____ ☐ Ankle_____

☐ Elbow_____ ☐ Wrist_____ ☐ Hip fracture_____ ☐ Melanoma_____

☐ Hand_____ ☐ Foot_____ ☐ Appendectomy_____ ☐Other,_____

☐ Hip/knee replacement_____ ☐ Tendon transfer____ ☐Nerve transfer_____

Current Medical Symptoms

☐ Fever ☐ Chills ☐ Sore throat ☐ Bloody urine

☐ Night sweats ☐ Headaches ☐ Blurred vision ☐ Double vision

☐ Coordination loss ☐ Fainting ☐ Shortness of breath ☐ Chest pain

☐ Palpitations ☐ Dizziness ☐ Loss of consciousness ☐ Pale stools

☐ Stomach pain ☐ Diarrhea ☐ Tarry stools ☐ Stiffness

☐ Joint pain ☐ Joint swelling ☐ Bloody stools ☐ Weight loss

☐ Other, _________

Current Medications: (List name, dose, frequency)

☐ Spasticity: ____

☐ Bladder: ____

☐ Pain: ____

☐ Depression: ____

☐ Heart/blood pressure: ____

☐ Cholesterol/lipids: ____

☐ Diabetes: ____

☐ Recreational drugs: ____

☐ Other: ____

Other General Health Items

Do you currently smoke cigarettes, or have you smoked in the past? ☐ YES ☐ NO

If yes, how long have you smoked cigarettes (years)? ________________

If yes, how many cigarettes do you smoke-have you smoked per day (packs/day)? ______________

If smoked in the past, when did you stop smoking (years)? ________________

Do you drink alcohol? ☐ YES ☐ NO

If yes, how many drinks do you have each day? ____

Biological Interventions

Have you ever participated in any biological intervention previously? ☐ YES ☐ NO

If yes, select type below and include description and year of intervention:

☐ Cells ____

☐ Medication____

☐ Implanted Device____

☐ Hypothermia treatment____

Form 03 - 1RM Test

Period of Assessment: ________________

Study Personnel should complete this assessment

Horizontal Row	**Dips**
____ X 5 _____	____ X 5 _____
____ X 3 _____	____ X 3 _____
____ X ? _____	____ X ? _____
Overhead Press	**Lat Pulldown**
____ X 5 _____	____ X 5 _____
____ X 3 _____	____ X 3 _____
____ X ? _____	____ X ? _____
Pulley Curls	**Butterfly**
____ X 5 _____	____ X 5 _____
____ X 3 _____	____ X 3 _____
____ X ? _____	____ X ? _____

Study Staff initials: ________________

Form 04 – SCI Participant: Graded Exercise Test

Stage	**Time**	**Watts**	**HR** (last 15s of stage)	**RPE** (last 15s of stage)
1	0:00-1:00			
2	1:01-2:00			
3	2:01-3:00			
4	3:01-4:00			
5	4:01-5:00			
6	5:01-6:00			
7	6:01-7:00			
8	7:01-8:00			
9	8:01-9:00			
10	9:01-10:00			
11	10:01-11:00			
12	11:01-12:00			
13	12:01-13:00			
14	13:01-14:00			
15	14:01-15:00			

Test end time: __________

Reason for test termination:

____

Does subject think he/she could have gone any longer?

____

Form 05 – SCI Participant: Anthropometric Measures

Measure	Screening(-2)	0	6	12
Date:				
Time:				
Weight:				
W/C:				
BMI:				

Form 06 – SCI Participant: Dietary Food Record

FOOD INTAKE DATES (DD/MM/YY) ______/______/________

GENERAL INSTRUCTIONS FOR DIETARY RECORD KEEPING

1. Print in ink.
2. Record each meal **IMMEDIATELY** after it is eaten, if possible.
3. Start each **NEW DAY** on a **NEW PAGE**.
4. Record **BRAND NAMES** where applicable.
5. Record **NAMES OF RESTAURANTS** at which food was consumed.

KEEPING A DIET RECORD

1. Recording of accurate diet information is essential during this study to assess dietary intake. This record should include all food and liquids (except for water) eaten any time of the day or night. Try to write down your food record immediately after each meal or snack.
2. Keep a record of EVERYTHING you eat & drink on four consecutive days including two weekend days.
3. To the best of your ability describe in detail the food you ate. Use this checklist as guide:
    - <u>Specifically how food was prepared</u>. Was it boiled, steamed, broiled or fried?
    - <u>Were any ingredients added</u> (i.e. butter, margarine, fat oil, salad dressing, sugar, syrup, etc?)
4. The following items will help you give more accurate measurements and descriptions of foods and beverages eaten.
    - Record in fluid ounces (fl. oz.): All beverages, including alcohol.
    - Record by number & size (small, medium, large): Breads, rolls, crackers, fruits & vegetables, snacks.
    - Record weight in ounces (oz.) & after cooked. Length x width x thickness: Meat, poultry, shellfish, and cheese.
    - Record by serving (sv.) and size. Pie, cake (i.e. apple pie: 1/6 of 8" pie).
    - Record in cups (c.). Rice, potatoes, cereal, soups, fruits, vegetables, casseroles.

- Record in teaspoon (tsp.) or tablespoon (tbsp.) (3 tsp. = 1 tbsp.). Jelly, jam sugar, sauces, gravies, syrup, salad, dressing, butter, margarine, nuts, seeds, oil

To the best of your ability, give a detailed description of the food you eat and the beverages you drink. Use this checklist as a guide.

- Were fats and oils used in cooking or baking? If yes, what brands?
- Was salad dressing or mayonnaise used in salads or sandwiches?
- Was fat added or used in cooking vegetables? If yes, what kind?
- What kind of milk did you drink or use in cooking?
- What brand of margarine was used on bread or in cooking?
- Were gravies or sauces added to any of your meals?
- What cuts of meat were eaten?
- Was the meat fried, broiled or baked?
- Was the fat cut off?
- Was skin removed from poultry?
- What type of cheese was used?
- Were whole eggs, egg whites, or egg substitutes used as ingredients?

Please answer the following questions:

What brand name of margarine did you use last week?

What brand of oil did you use last week?

Do you add salt to your cooking or at the table? YES____ NO ____

FOOD RECORD

Day 1 ____ Day 2 ____ Day 3 ____ Day 4 ____

Day of the Week: S M T W TH F S

Date ___________________________

Time	Place (Home/Restaurant)	Food Eaten	Amount (Weight or Volume)	How Prepared

Comments:____

____

____

______

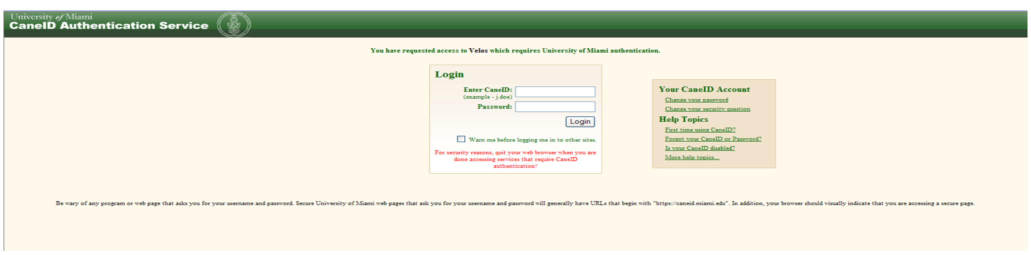
C. Velos: Patient Data Collection Repository

General Principles:

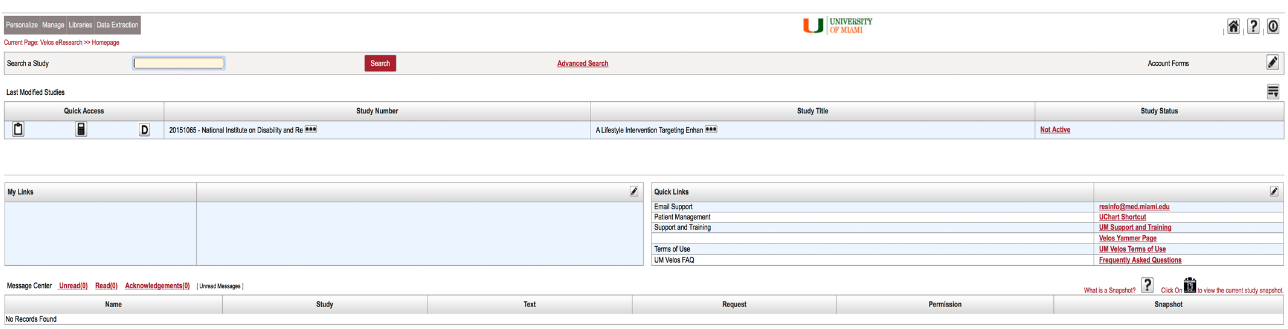
- Velos eResearch is a secured web-based application, backed-up and supported on site at UM
- The Velos eResearch clinical trials management system provides study teams with a tool to track study patients and their status histories, individual study calendars and progress in completing a protocol, adverse events, and any associated data collection.
- Department administrators can track the financial aspects of performing a protocol and generate invoices to collect reimbursement from sponsors.
- Data Safety and Monitory Boards/Committees can run reports to track compliance with protocol standards
- Facilitates compliance with University processes and policies.
- Ensures strict and controlled access to protected health information (PHI), allowing for patient identifiable information to be stored safely in an electronic format
- Velos eResearch has electronic CRF's that will be used to collect data.
- Source data in 'hard copy' will be forwarded to the lead center for data entry and filing

Directions for accessing and utilizing Velos eResearch:

- ***Complete Instruction and training will be given prior to study enrolment**
- Using your web browser, you will navigate to: http://velos.miami.edu where study participant information can be entered in to the data repository
- This will load the login homepage:



- This will load your credentialed homepage where you can access the study:



- Treatment Arms, study calendars, and data entry forms for the study will be built in to the Velos database (sample below):

Personalize | Manage | Libraries | Data Extraction

UNIVERSITY OF MIAMI

Current Page: Study >> Setup

You are working on study:

Summary | Versions | Admin Schedule | Study Setup | Budget | Milestones | Notifications | Study Status | Reports | Study Team | Broadcast | Forms

Study Dictionaries/Settings

If no modifications have been specified, the default settings will be applied.

VIEW/EDIT DICTIONARIES AND SETTINGS

Type	Use
Adverse Event Dictionary	Free Text Entry
Patient Study ID Generation	auto

Study Treatment Arm

Treatment Arms currently associated with this study are:

ADD NEW

Treatment Arm	Description	Delete
	-	
	-	

Associated Calendars

Calendars currently associated with this study are:

UPDATE MULTIPLE SCHEDULES | COPY AN EXISTING CALENDAR | SELECT A CALENDAR FROM YOUR LIBRARY

Calendar Name	Refresh Notifications	Description	Status	Status Details	Reports	Delete	Save to Library
		Calendar for patients on the exercise arm. It tracks measured variables along with exercise regimen	Active	Status Details	Schedule		
		Calendar for patients on the exercise arm. It tracks measured variables along with exercise regimen	Active	Status Details	Schedule		

Associated Forms

Forms currently associated with this study are:

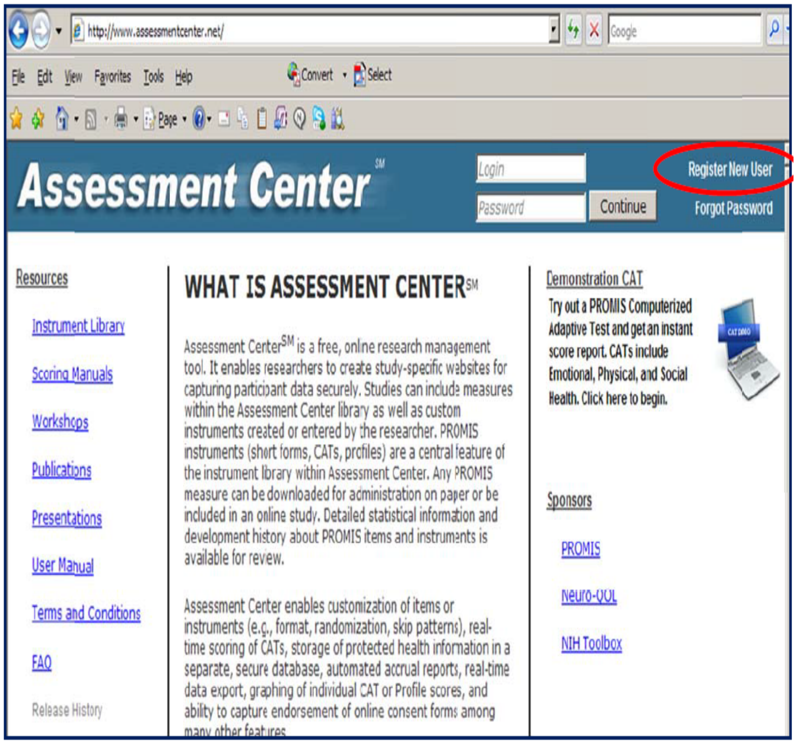
COPY AN EXISTING FORM | DISPLAY AND SEQUENCING OPTIONS | SELECT A FORM FROM YOUR LIBRARY

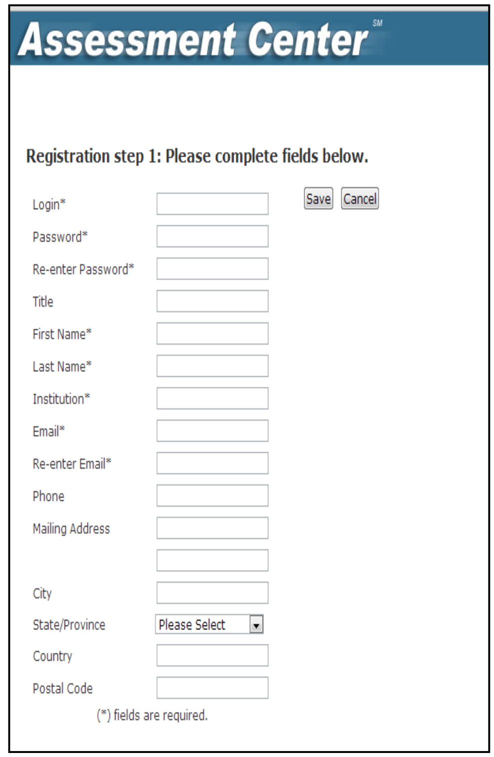
Form Name	Description	Linked To	Status	Preview	Delete	Info	Save to Library
Anthropometric Data (Nash Study)	Visit	Patient	Active				
Anthropometric Data II (Nash Study)	Visit	Patient	Active				
Blood Testing (Nash Study)	-	Patient	Active				
Fitness Attributes (Nash Study)	-	Patient	Active				
Screening Form (Nash Study)	-	Patient	Active				
SF-36 Your Health and Well-Being v2	-	Patient	Active				

D. **Assessment Center: Patient Data Collection Repository.**

To access Assessment Center, go to the following website: www.assessmentcenter.net

Step 1: Click 'Register New User' in upper right corner of the home page→





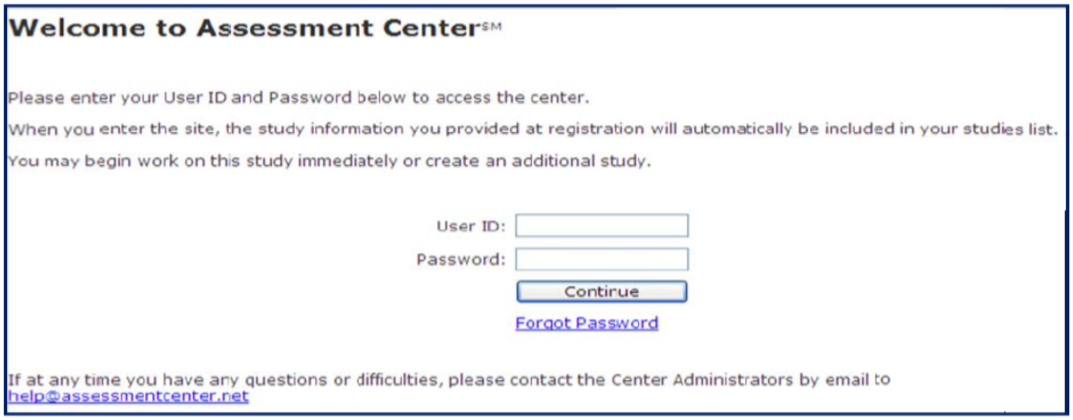
Step 2: Complete the required fields, click 'Save' & Accept the Terms and Conditions

It is important to note that several registration elements are required to be unique across AC.

- User ID must be unique (i.e. it cannot already exist in Assessment Center)
- User ID must be at least six characters (any combination of letters and numbers)
- Last Name, First Name, and Institution must also be unique in AC
- A password does not have to be unique across the system, but must be at least six characters (letters, numbers or special characters).

Other functions available on the Login page are forgotten password retrieval and contact information for AC administrators.

Step 3: First Login – a must!



Once you have been registered successfully, you will be directed to a page which contains instruments from the AC library in PDF format. You should then click on the 'Go to AC login Page' hyperlink and enter your User ID and password to begin working in AC.

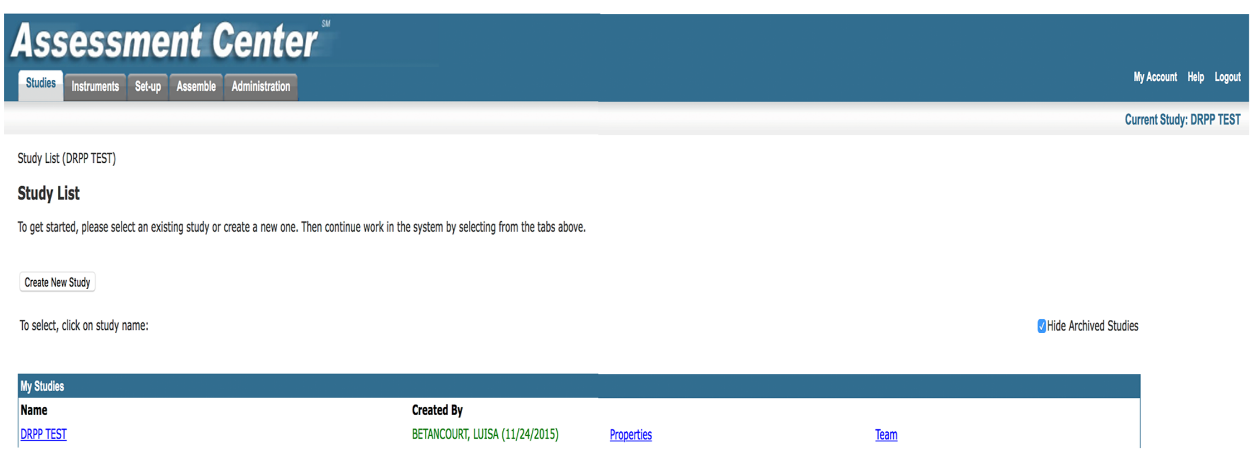
NOTE: You must login at least once to complete registration.

Accessing the DRPP Study on Assessment Center

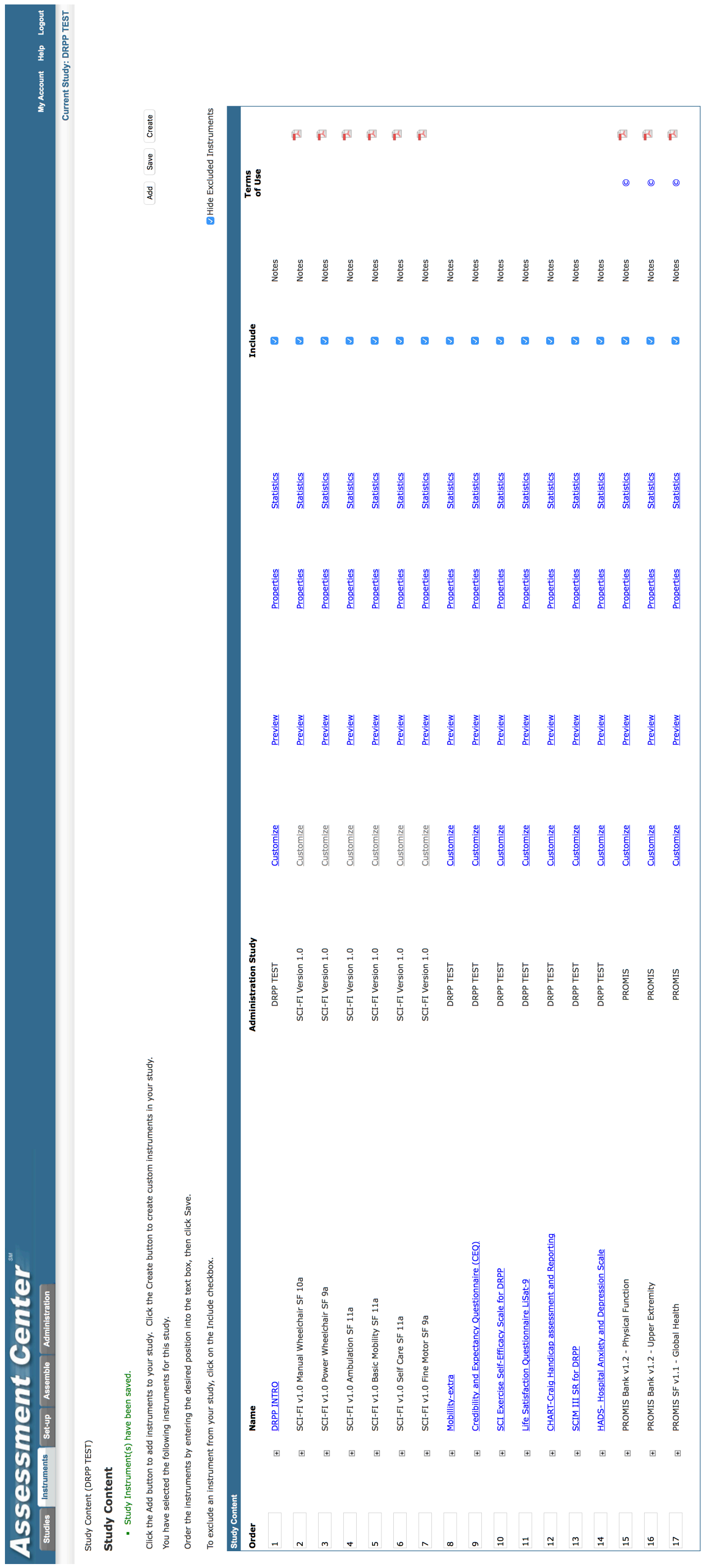
Once you have registered in AC and logged in at least once, you MUST send your name and email address to Luisa Betancourt (lbetancourt@med.miami.edu) to be added to the study. Luisa will send an email to inform you that you have been successfully added. The next time you Login to AC you will see this study name listed on the "Studies" tab in AC.

The first screen accessed upon logging into AC is the Studies tab. All work within AC is organized within studies.***When you log in**, if <u>you do not see</u> the DRPP study name in your list of studies**, please contact Luisa Betancourt at Lbetancourt @med.miami.edu.

- After login, you can access your credentialed homepage for the study:



- Data entry forms for the study will be built in to Assessment Center (sample below):



- A welcome/introductory form is included for study participants to orient them to upcoming tasks:

Welcome to the DRPP Study! We thank you for your participation. If you have any questions, please ask a DRPP staff member for help.

You will be answering a series of questionnaires to see how you are feeling about life, pain level and your overall health. Please answer the questions as honestly as you can.

Previous Next Exit

SAFETY REPORTING

The following section details the requirements for reporting serious adverse events and unanticipated problems to the CC. Each IRB may have different rules and regulations, so please check with your local IRB to see if there are any additional requirements that pertain to your site.

Reporting requirements

All sites are required to report serious adverse events and unanticipated problems involving risk by emailing the appropriate paper form to the CC within 10 working days of learning of the event. This e-mail will then be forwarded to the University of Miami IRB and other participating sites to notify them of the event within 10 working days of the receipt by the CC.

IRB Reporting Guidelines for Internal Adverse Events:

- An Internal Adverse Event must meet all of the following:
    - Unexpected
    - Related or possibly related to the research intervention
    - Serious or otherwise suggest that the research places the subject or others at a greater risk of harm than was previously known or recognized
- Internal adverse events that are fatal or life threatening and related or possibly related to the research intervention must be reported to the IRB **within 24 hours**.

All other internal unexpected, serious adverse events related or possibly related to the research intervention must be reported to the IRB within ten working days

IRB Reporting Guidelines for External Adverse Events

- An External Adverse Event must meet all of the following:
    - Unexpected
    - Related to the research intervention
    - Serious and suggests that the research places subjects or others at greater risk than was previously recognized
- The local investigators must make the determinations of relatedness and expectedness based on the available information.

All unexpected, serious adverse events related to the research intervention must be reported to the CC within 10 working days of learning of the event.

IRB Reporting Guidelines for Unanticipated Problems (UAP) and Non-Compliance

- Investigators shall email the CC within 10 working days of any unanticipated problems or non-compliance that occurred during the course of conducting the study. The site should provide the following information:
    - Describe the unanticipated problem which occurred during the conduct of the research (include subject ID, chronology of events, persons involved, etc.)
    - Explain the reason(s) this unanticipated problem occurred
    - Indicate whether the described unanticipated problem involves risk to human subjects or other (for each described problem, indicate the risk to each individual subject or to the study population in general)
    - Describe steps which have been taken to resolve the problem and procedures implemented to avoid future occurrences.
    - REPORTABLE EVENT FORM FROM IRB

Definitions

Unanticipated Problem involving Risk to Human Subjects or Others: Any accident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency
- Related, or possibly related, to a subject's participation in the research
- Place subjects or others at a greater risk of harm (including physical psychological, economic or social harm) than was previously known or recognized.

Adverse Event (AE): Any unfavorable medical occurrence, which may include abnormal signs (e.g., abnormal physical exam or laboratory findings), symptoms, or disease temporally associated with, but not necessarily considered related to, the subject's participation in research.

Unexpected Adverse Event (UAE): An occurrence not identified by nature, severity or frequency in the investigator's brochure, sponsor protocol or current University IRB-approved research protocol or informed consent document, taking into account the characteristics of the subject population being studied.

Serious Adverse Event: An occurrence which results in a life-threatening or fatal outcome, requires or prolongs inpatient hospitalization, produces a persistent or significant disability/incapacity, results in a congenital anomaly/birth defect, or based on appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above.

Non-Compliance: Failure on the part of the investigator or any member of the study team to follow the terms of the approved protocol or to abide by applicable laws or regulations or the IRB policies (includes protocol deviations). This includes protocol deviations. The IRB will determine whether reports meet the definition of serious or continuing non-compliance.

CONSUMER ADVISORY BOARD (CAB)

- We will convene a CAB composed of persons with SCI and caregivers of persons with SCI. The panel will be selected and chaired by Jennifer French, MBA, a woman living with C6-7 tetraplegia, Executive Director of the Neurotech Network, author of 'On My Feet Again', and a 2012 medaled paralympian.
- Ms. French will empanel the CAB from a list of persons living within the catchment area who have an interest in issues of health maintenance and caregiver well-being after SCI.
- Ms. French will convene annual CAB meetings following receipt from Dr. Nash of a progress report outlining the following evaluation elements:
  1. Study recruitment
  2. Compliance
  3. Retention
  4. Safety
  5. Interim scientific outcomes
  6. Scientific/'lay' outputs
  7. Ethical issues
- The CAB progress evaluation will be generated by Ms. French, and forwarded to the Independent Medical Monitor (IMM; see below) and Dr. Nash.
- Dr. Nash will reply to the CAB evaluation with a written action plan, forwarding copies to the CAB (via Ms. French) and the IMM.
- The evaluation will be included in the IRB continuing reports, and NIDILRR quarterly APRs.

INDEPENDENT MEDICAL MONITOR (IMM)

- As 'the probability and magnitude of harm or discomfort anticipated in the proposed research may exceed risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests' [45 CFR 46.102], we have elected to incorporate an IMM in the medical oversight and project evaluation plans.

Trevor Dyson-Hudson, M.D., (IMM, uncompensated) is Director of SCI Research and Outcomes and Assessment Research at Kessler Foundation Research Center (West Orange, NJ) and an Associate Professor, Department of Physical Medicine and Rehabilitation, Rutgers New Jersey Medical School, Newark, NJ. He received his medical degree from the Albert Einstein College of Medicine in 1995. In 1992, while he was a third-year medical student, Dr. Dyson- Hudson sustained an SCI (C6/C7 tetraplegia, complete) while playing rugby football. He returned to medical school in 1993 and graduated in 1995. He completed a one-year transitional internship at the Albert Einstein College of Medicine in 1996 and completed a Rehabilitation Research Fellowship with the Department of Physical Medicine and Rehabilitation, University for Medicine & Dentistry – New Jersey Medical Center and the NIH Center for Complementary and Alternative Medicine for Stroke and Neurological Disorders at Kessler.

Dr. Dyson-Hudson conducts clinical SCI research and is PI/Co-investigator on a number of SCI grants. He is Project Director of the NIDRR-funded Northern New Jersey Model SCI System. His research interests include prevention and treatment of common secondary medical complications affecting persons with SCI, including cardiometabolic disease and its component risks. Dr. Dyson-Hudson is a licensed physician in New Jersey and New York. He is on the Professional Standards Board for the Rehabilitation Engineering Society of North America and is a member of the American Paraplegia Society (APS) and ASIA, as well as SCI-consumer organizations, the National SCI Association (NSCIA) and the United Spinal Association (USA). He also serves on the Cardiometabolic Clinical Practice Guideline Panel for the Consortium for SCI Medicine sponsored by the PVA. Dr. Dyson-Hudson's biosketch and letter of commitment are contained in the proposal appendices. He is uniquely qualified to participate in project evaluation, and will serve without financial compensation (beyond expenses), which is standard for IMMs and required to maintain 'independent' MM status. Dr. Dyson Hudson will assure that study participants are safe and that the study is being conducted in accordance with high scientific and ethical standards. He will also:

- Assess study performance for recruitment, retention and follow-up, protocol adherence, and data quality and completeness; all to assist in successful and timely study completion.
- Review, consider, and approve (if indicated) protocol modifications.
- Receive quarterly grant progress reports (and APR's) to advise the sponsor and the study investigators on necessary modification of study practices and procedures.
- Review study data, analyses, and findings in advance of publication or presentation.

IMM Authorities: Should Dr. Dyson-Hudson determine that this study: a) has answered the primary study question, b) is futile or will not reach a firm conclusion, c) is not being conducted according to high scientific or ethical standards, or d) poses an unreasonable or unnecessary risk to participants, he has the authority to recommend to the sponsor that the study be terminated, temporarily suspended, or amended, as appropriate. IMM reports will be included in the IRB mandated continuing and final reports as part of project evaluation. As noted, his programmatic reviews are part of the program evaluation process, and will be shared with the CAB.