Section 1: Description of the Diabetes Prevention Program

The Diabetes Prevention Program (DPP) was implemented according to the DPP Protocol from 1996-2001. The primary objective of DPP was to determine if type 2 diabetes could be prevented or delayed in people with impaired glucose tolerance using three interventions:

- Lifestyle-goals 7% weight loss and 150 minutes activity/week
- Metformin-goal take 850 mg metformin twice daily
- Placebo-goal take two placebo pills daily

In 2001, the study ended early due to the effectiveness of lifestyle and metformin. The lifestyle intervention reduced the risk of diabetes by 58% and the metformin intervention reduced the risk of diabetes by 31%. It was found that treating 7 people with lifestyle prevented one case of diabetes and treating 14 people with metformin prevented one case of diabetes. Weight loss was responsible for the reduction in diabetes and participants in the lifestyle intervention lost an average of 15 pounds the first year and were still maintaining about a 10 pound weight loss after three years. Lifestyle participants exceeded the exercise target averaging 224 minutes/week of activity at one year and 189 minutes/week at year three. Activity was defined as brisk walking. For more in depth information on study results, please access the study publications section of the DPP website at:

http://www.bsc.gwu.edu/dpp

During DPP, the core curriculum of the lifestyle intervention was offered one on one to study participants. Since lifestyle worked best to prevent diabetes, all study participants were offered the lifestyle intervention in a group format in 2002. This NLB manual incorporates participant handouts from group and individual sessions so materials can be used in either setting.

The Diabetes Prevention Program Outcomes Study (DPPOS) began in the fall of 2002. The original DPP participants continue to be followed in DPPOS to determine the long-term effects of active DPP interventions on the development of a) diabetes during a further 5-11 years of follow-up; and b) diabetes complications and cardiovascular disease outcomes. The hypotheses being tested are that both the continued lifestyle intervention and metformin will provide continued separation in the rates of diabetes development, compared with the former placebo group, and that the prevention or delay of diabetes during the DPP and DPPOS will translate into reduced rates of diabetes complications and improved health status.

Section 2: Lifestyle Balance Goals

The Lifestyle Balance goals are:

- To achieve and maintain a weight loss of 7% of participant initial body weight, and
- To achieve and maintain an energy expenditure of 700 kilocalories per week through moderate physical activity (equivalent to approximately 2 ½ hours per week of brisk walking).

2.1. Weight Goal

The weight goal for lifestyle balance is to lose 7% of initial body weight (as measured at Session 1, the first Lifestyle Balance session) and maintain that weight loss. The recommended pace of weight loss is 1 to 2 pounds per week, for a 7% loss within approximately 24 weeks.

Table 2.1. Example Lifestyle Balance Weight Goals*

Example Starting Weight Weight (lb.)	Goal (lb.)	Example Starting Weight Weight (lb.)	Goal (lb.)	Example Starting Weight Weight (lb.)	Goal (lb.)
120	112	185	172	250	233
125	116	190	177	255	237
130	121	195	181	260	242
135	126	200	186	265	246
140	130	205	191	270	251
145	135	210	195	275	256
150	140	215	200	280	260
155	144	220	205	285	265
160	149	225	209	290	270
165	153	230	214	295	274
170	158	235	219	300	279
175	163	240	223		
180	167	245	228		

*Note: The starting weight is the participant's Session 1 weight rounded to the nearest pound. **Calculate weight goals for starting weights that are not included on this table.**

2.1.1. Rationale for the Weight Goal

A 7% weight loss was selected as the DPP Lifestyle Balance weight goal because it is believed to be safe, effective, and feasible. Previous studies have shown that a 10% weight loss lowers glucose and improves cardiovascular risk factors, with an apparent dose-response relationship between magnitude of weight loss and improvement in these

parameters. In addition, standard behavioral weight loss programs produce initial weight losses of approximately 10% of body weight. However, the DPP goal was not only to produce but also to maintain a weight loss for up to 6 years, and maintenance of weight loss has been shown to be difficult, with 10% weight loss at long-term follow-up rarely achieved in weight control programs or clinical trials. Therefore, the goal of a 7% weight loss was selected as more feasible for participants to maintain over the course of the trial.

Participants who wish to lose *more* than 7% of their starting weight may be encouraged to do so, although weight loss below the Lifestyle Balance intervention goal should be encouraged only if the participant continues to have a BMI of greater than 21 (see Table 2.2) after achieving the 7% goal. For example, a participant who weighs 130 pounds at Session 1 would be given a weight goal of 121 pounds (Table 2.1). If the participant reaches that goal and wants to continue losing weight, the Case Manager should refer to Table 2.2. If the participant's height is 65 inches, the participant is already below a BMI of 21 (that is, below 126 pounds), so weight maintenance at 121 pounds should be encouraged rather than further weight loss. On the other hand, if the participant's height is 62 inches, the Case Manager would be able to encourage further weight loss to 115 pounds (a BMI of 21). Coaches may use the handout 'Lifestyle Balance Minimum Weight Goals' (NLB Coach's Manual Session 1, page 22) to determine BMI of 21 in a group setting.

Sustained weight losses of more than 3 pounds per week are not to be advised because of safety issues.

Participants who wish to lose *less* than 7% of their starting weight should be encouraged to reach a 7% loss in a step-wise fashion, but the goal should remain firm.

The weight goal is set at a level that should be challenging but reasonable. It is recognized that not all participants will achieve the goal at all times. However, all participants, with the aid of their Case Managers, should endeavor to achieve and maintain the goal.

Table 2.2 Heights and Weights Equivalent to Body Mass Index (BMI) of 21

Height (in.)	**Weight (lb.)**	**Height (in.)**	**Weight (lb.)**	**Height (in.)**	**Weight (lb.)**
48	69	60	108	71	151
49	72	61	111	72	155
50	75	62	115	73	159
51	78	63	119	74	164
52	81	64	122	75	168
53	84	65	126	76	173
54	87	66	130	77	177
55	90	67	134	78	182
56	94	68	138	79	186
57	97	69	142	80	191
58	100	70	146		
59	104				

2.1.2. Temporary Suspensions of Efforts to Achieve Weight Goal

Efforts to achieve the weight goal will be suspended during pregnancy and lactation. During these periods, women will be instructed to follow the guidelines of their own personal physician.

During 4 to 6 month periods in which a participant is making a serious attempt to stop smoking or has ceased smoking, the participant should be encouraged to continue consuming a healthy diet, to maintain a high level of physical activity, and to try to maintain current weight. Case Managers should recognize that some weight gain may occur during smoking cessation. After 4 to 6 months surrounding smoking cessation, efforts to achieve the original weight loss goal should be resumed.

Likewise, changes in body weight may occur following illness or injury. During these periods it may be necessary to temporarily suspend efforts to achieve the weight loss goal.

The weight goals are always based on weight loss from Session 1. For example, if a participant weighs 180 at Session 1, his/her weight goal is 167 pounds; this remains the weight goal even if the participant at some time gains weight to 200 pounds.

2.2. Physical Activity Goal

The Lifestyle Balance physical activity goal is to reach and maintain an energy expenditure of 700 kilocalories per week. For ease of translation to participants, the goal is described as 2 ½ hours of moderate physical activity (such as brisk walking) per week. This is to be applied to
all participants, regardless of initial level of physical activity. The activity goal is to be achieved gradually over five weeks

2.2.1. Rationale for the Physical Activity Goal

A physical activity goal of 700 kilocalories per week has been selected because previous studies have shown that this level is sufficient to produce improvements in weight, glucose, insulin sensitivity, and overall health. Although a goal of 1000 kilocalories per week has been used in many weight loss and exercise studies, a 700-kilocalorie goal was selected in DPP as more reasonable for participants to maintain over a 6-year clinical trial.

The physical activity goal is a minimum. Participants who wish to be more active may be encouraged to do so. Participants who are already active when they enter the study will need to determine the amount of time they are currently spending in physical activity and then add further activity to reach the 2½-hour goal. For example, a participant who already does aerobic dance for 2 hours per week may continue this and add another ½ hour of aerobic dance or another type of moderate activity to reach the 2½-hour goal. In

addition, participants who are active sporadically (e.g., seasonally) should be encouraged to achieve the goal consistently throughout the year,

It is recognized that not all participants will achieve the activity goal at all times. However, all participants, with the aid of their coaches, should endeavor to achieve and maintain the goal.

2.2.2. Adjustments to the Physical Activity Goal

The physical activity goal will be adjusted during intervals of participant illness or injury. In addition, participants who are classified by the submaximal or maximal exercise tolerance test to have a high risk of cardiovascular complications during exercise should maintain an activity program following the recommendations of their Primary Care Provider.

Section 3: Role and Training of the Lifestyle Balance Staff

3.1. Case Managers (Lifestyle Coaches)

During DPP, each lifestyle participant was assigned a Case Manager (also called a "Lifestyle Coach". The Lifestyle Coach had primary responsibility for conducting the intervention with that participant. The terms lifestyle case manager and lifestyle coach are used interchangeably in this manual. In the main DPP study, the Lifestyle Balance Program was delivered one on one between a participant and coach. When the DPP results showed the lifestyle intervention to be the most effective in delaying the onset of diabetes, all DPP participants were offered a group Lifestyle Balance intervention.

It is anticipated that NLB will most often be delivered in groups. To effectively deliver group NLB it is most desirable to develop a team with expertise in:

- Nutrition
- Exercise
- Recruitment and retention
- Community culture and language
- Behavior modification
- Motivational Interviewing
- Mental Health/Psychology
- Local medical experts

To train coaches before NLB, read the Lifestyle Balance or NLB Manual of Operations, read study publications, attend an NLB training, do supplemental reading on weight loss and exercise and observe and assist experienced Lifestyle Balance coaches.

Tips from communities that have successfully taught NLB include:

- Divide a group of participants among coaches so each participant recognizes their own coach and that coach is responsible for any team chosen follow-up of their caseload of participants
- Share group teaching responsibilities
- Divide tasks among team members
- Hold regular team meetings

3.2 Recommended Location for Conducting Lifestyle Sessions

Each Lifestyle Coach needs adequate space and privacy to conduct lifestyle sessions, phone participants, and store and display lifestyle materials. It is recommended that Coaches have a dedicated office where participants can walk-in for weigh-ins and support. If that is not possible, consider having designated coach office hours as the DPP experience was many participants walk-in when their time permits.

Section 4: Frequency of Contact with Lifestyle Participants

The DPP Lifestyle Balance Program required a **minimum** frequency of contact with each participant. The minimum frequency of contact during DPP is defined below:

- Participants were seen for at least 16 face-to-face sessions in the first 24 weeks after randomization to complete the core curriculum. The first eight of the core curriculum sessions and four of the latter eight were presented by the Case Manager.

- After completing the core curriculum, participants were contacted once a month for the remainder of the years of the trial. A face-to-face contact occurred at least once every two months. The bi-monthly, face-to-face contacts occurred with the Case Manager.

For NLB, it is important to plan your program toward safely achieving the 7% weight loss goal with no greater than a ½-2 pound weight loss/week. For most NLB participants, this safe level of weight loss would require a minimum of a four month program. The 16 Lifestyle Balance Sessions build on information taught at previous sessions. It is highly recommended that session 1-9 occur in the planned order. Coaches can rearrange sessions 10-15 based on common problems being experienced by NLB participants.

Section 5: Overview of Strategies to Achieve the Weight Loss Goal

5.1. Achieving the Weight Loss Goal

Participants in lifestyle balance should try to achieve the 7% weight loss goal within the first six months after joining lifestyle balance and then maintain their weight loss. This recommendation is based on several factors. First, a 7% weight loss equals a weight loss of 7 to 21 pounds (the latter occurring in individuals weighing 300 pounds). These weight losses can be achieved within 24 weeks at a reasonable rate of 1 to 2 pounds lost per week. In addition, in previous weight loss studies and clinical trials of dietary intervention, the maximum weight losses achieved were reached by six months. Finally, the purpose is to achieve the weight loss goal as soon as possible to try to prevent the onset of diabetes; a slower rate of weight loss may increase the risk of diabetes onset.

If participants do not achieve the weight goal within six months, they will be encouraged to achieve it as soon as possible thereafter.

5.2. Self-Monitoring Weight

To help participants achieve and maintain the weight loss goal, all participants will be weighed at every lifestyle balance session. Participants should be weighed in private at the beginning of the session. Weight can be taken with either a balance beam or a digital scale. The type of scale is not important, but an effort should be made to use the same scale throughout the program. Participants should be weighed in light-weight, indoor clothes, without shoes.

The Case Manager will record the weight on the DPP Lifestyle Balance Update (see NLB Coach Manual Session 1, page 12) and on the 'How Am I Doing?' weight graph in the participant's notebook. Participants should be encouraged to complete the weight graph themselves, if possible. The Case Manager and participant should discuss the participant's weight in relation to the 7% weight loss goal, and the Case Manager should continually encourage the participant to achieve the 7% weight loss goal.

In addition to being weighed at every session, all lifestyle participants will be encouraged to weigh themselves at home at least weekly and record their weight on the back of their self-monitoring booklets. Participants should be instructed to weigh themselves on the same day(s) of the week and at the same time of day (for example, on Monday mornings), and the Case Manager should indicate this schedule on the back of the self-monitoring records.

At the beginning of the intervention, Case Managers may want to assign more frequent self-monitoring of weight, for example, daily, and continue to encourage it if the participant finds it helpful. Some participants may respond to frequent fluctuations in their weight by becoming discouraged. However, the Case Manager can use a participant's record of frequent ups and downs in weight to teach the participant to focus

on **trends** rather than on single values and to respond promptly to slips with positive behavior changes until the results are seen consistently on the scales. In this way, frequent self-monitoring of weight can become a source of encouragement to many participants.

5.3. Setting a Fat Intake Goal

To help participants achieve and maintain the weight goal, all lifestyle balance participants will be given a goal for daily total fat intake in grams. The initial focus is on total fat rather than calories for several reasons. A focus on total fat is designed to accomplish a reduction in caloric intake while at the same time emphasizing overall "healthy eating" instead of a restrictive "diet" for weight loss alone. Focusing on total fat also simplifies the message and streamlines self-monitoring requirements. Although the caloric density of fat is stressed from the beginning of the dietary intervention, calorie balance is formally introduced only after 7 weeks into the program. This delay is designed to allow time for the participant and interventionist to determine whether self-monitoring of fat and increasing physical activity is sufficient to achieve weight loss.

At any time during Lifestyle Balance, participants who are interested in monitoring both calories and fat should be given both a fat and calorie goal and encouraged to monitor both aspects of the diet.

The fat goals have been calculated based on 25% of total calories from fat, using a calorie level estimated to produce a weight loss of 1 to 2 pounds per week (described in detail below). The various fat gram levels were then collapsed into one of four goals: 33, 42, 50, or 55 grams of fat.
A level of 25% of calories from fat was selected because it is believed to be effective, safe, and feasible. In the Women's Health Trial, a low-fat dietary-intervention trial, more than 80% of the intervention group had met their fat gram goal, calculated as 20% of baseline calories, within 3 months of randomization and maintained that goal through the end of the trial at 3 years. Although women in this study were not encouraged to decrease energy intake or lose weight, the reduction in fat intake was associated with a 25% reduction in total calories and a weight loss of 3.1 kg after 1 year. Weight loss was more strongly associated with change in percent energy from fat than with change in total energy intake.

All participants are to be given a fat intake goal, but it should be recognized that not all participants will immediately achieve this goal. For example, a participant who eats 40% of their calories from fat may initially find it difficult to achieve the 25% goal and may first reduce to 35% fat and then to 30% fat. However, the participant should be assigned the 25% fat goal, and all progress toward reaching this goal should be praised.

Lowering fat to a specific level is used in Lifestyle Balance as a means to achieving the weight loss goal, rather than as a goal in and of itself. Thus, if a participant is consuming

more than 25% of calories as fat, but is achieving the weight goal, and does not have hyperlipidemia, there is no need to focus on greater reductions in dietary fat.

Table 5.1. NLB Lifestyle Intervention Fat and Calorie Goals*

Starting Wt. (lb.)	FatGoal (g)	Calorie Goal	Starting Wt. (lb.)	Fat Goal (g)	Calorie Goal
120	33	1200	220	50	1800
125			225		
130			230		
135			235		
140			240		
145			245		
150			250	55	2000
155			255		
160			260		
165			265		
170			270		
175	42	1500	275		
180			280		
185			285		
190			290		
195			295		
200			300		
205					
210					
215					

*Note: To determine participants' fat and calorie goals, round their starting weight to the nearest starting weight on this table.

5.4. Setting a Calorie Goal

Some participants will achieve the weight loss goal by self-monitoring fat intake. Others, who may continue to eat large amounts of protein and carbohydrates or inaccurately estimate fat intake, will need to add calorie monitoring to achieve the weight loss goal. Participants who prefer to focus only on fat may do so until the session entitled, Tip the Calorie Balance. At that session a calorie goal will be introduced for participants who have not lost weight as expected.

It is important that the introduction of calorie self-monitoring not be conveyed as "punishment" for "failing" at fat self-monitoring but rather as another learning tool or method for understanding a participant's energy intake patterns.

The calorie goals were calculated by first estimating the daily calories needed to maintain starting weight (starting weight multiplied by 12). Next, between 500 and 1000 calories were subtracted to estimate the calories needed to lose 1 to 2 pounds per week and achieve the weight loss goal within the first 24 weeks. More calories were subtracted for heavier participants with the rationale that they have more weight to lose to reach the 7% weight loss goal (500 calories were subtracted for starting weights less than 150 pounds, 750 calories for starting weights between 150 and 200 pounds, and 1000 calories for starting weights over 200 pounds.) Finally, the ranges of calories estimated for weight loss were collapsed into one of four standard calorie levels: 1200, 1500, 1800 or 2000.

Some participants may report a low fat/calorie intake without losing weight. In this case, the Case Manager should review the quality of the participants' self-monitoring and if lacking, (for example, if portion sizes are being inaccurately reported, if additions such as cream to coffee are routinely forgotten, etc.), the Case Manager should help the participants improve their self-monitoring skills. If after attempts to improve self-monitoring, a participant is still not losing weight, it may be necessary to lower the calorie goal further to help him or her achieve the weight loss goal.

Although the minimum goal has been set at 1200 calories, the goal may be reduced to 1000 calories if a participant is not losing weight and efforts to improve self-monitoring have been made. Because of the possibility of nutritional inadequacy at an intake of 1000 calories, a daily vitamin and mineral supplement at 100% of the Recommended Dietary Allowances should be prescribed for these participants, and the overall nutritional adequacy of the participant's eating pattern should be carefully monitored.

Lowering dietary calories to a specific level is used in Lifestyle Balance as a means to achieving the weight loss goal, rather than as a goal in and of itself. Thus, if a participant is consuming more than the assigned calorie goal, but is achieving the weight goal (and does not have hyperlipidemia), there is no need to focus on greater reductions in calories.

Participants assigned a calorie goal will be asked to either self-monitor calories or follow a study-provided meal plan at the prescribed calorie level. Before being distributed, the sample meal plan should be tailored to suit each participant's food preferences. The meal plan should be presented as a flexible model from which the participant can develop an individualized eating style appropriate for weight loss, rather than as a rigid prescription set in stone.

5.5. Self-monitoring Fat and/or Calorie Intake

All DPP participants were instructed to self-monitor fat intake in grams **daily throughout the first 24 weeks of the study and for one week every month thereafter.** Self-monitoring of daily calorie intake was also assigned in some cases (see above).

All Lifestyle Balance participants are asked to record their intake daily for 24 weeks because of the extensive evidence that self-monitoring is highly correlated with success in reaching dietary change goals. Numerous studies have shown a dose-response relationship between frequency of self-monitoring and level of success in losing weight and/or improving cardiovascular risk factors. **Many experts consider self-monitoring the single most effective approach to changing dietary intake.** Participants in clinical trials and behavioral weight loss studies are typically asked to record their intake daily for the first several months of the intervention.

Participants will be given the following standard self-monitoring tools:

- Tools for weighing and measuring foods (a food scale, metal or plastic measuring cups and spoons, a glass measuring cup, ruler).
- A pocket-sized booklet, entitled "Keeping Track," for recording seven days of food intake with fat and/or calorie values, as well as physical activity.
- "The DPP Fat Counter," a nutrient counter alphabetized by food name, with the fat gram and calorie content of household portions.
- A calculator may be provided to those who would like to use one.

Self-monitoring skills will be taught gradually over the first few weeks of Lifestyle Balance, with self-monitoring of dietary intake and physical activity being introduced sequentially. Participants will be encouraged to be complete and accurate in self-monitoring and at the same time to feel free to use abbreviations and short-cuts that work for them (e.g., write "Breakfast, 200 calories" when they eat their standard 200-calorie breakfast, provided the Case Manager is well aware of the foods in the breakfast from past records). In other words, the **participant is NOT taught to self-monitor with the thoroughness and detail that would be required if the records were to be entered into a computer for nutrient analyses.**

It is recognized that not all participants will self-monitor daily at all times. However, all participants should endeavor to achieve and maintain daily self-monitoring and should receive a strong and clear message that self-monitoring is the key behavior change strategy in the lifestyle intervention.

All self-monitoring records should be collected at the end of a session, reviewed by the Case Manager and given back to the participant at the next session. Summary data, like average fat grams/week, should be recorded on the 'Lifestyle Balance Update' kept for each participant (see NLB Coach's Manual Session 1, page 12). During the class session, the review should be kept brief. After the session, the review should be more thorough, and the Case Manager should write comments on the records and return them by mail or at the next session to the participant. The comments should highlight examples of positive changes the participant has made and help the participant solve any problems encountered, particularly those related to the topics discussed at the previous session. Because the self-monitoring records are intended to help the participant make behavior changes rather than serve as a source of dietary data, the review should *not* be as detailed

or extensive as would be the case when documenting food records to be entered for nutrient analysis.

5.5.1. Guidelines for Individualizing the Frequency or Method of Self-Monitoring

In some cases, a participant may have difficulty self-monitoring daily or using the standard method and tools for self-monitoring. For example, some participants may have very limited reading or math skills. In these cases a simplified form of self-monitoring may be used (see the tool box for weight loss). Likewise, over time some participants may become less adherent to self-monitoring. If weight loss is progressing as expected without self-monitoring, self-monitoring should be encouraged but not required. If weight loss is not occurring, the barriers to self-monitoring should be addressed and an alternate method or frequency of self-monitoring should be assigned, again, with high expectations expressed. See the tool box for weight loss for a description of alternate self-monitoring tools and guidelines for using them.

5.6. Self-Monitoring Fat and/or Calorie Intake After the Core

After the first 24 weeks, if weight loss is maintained at goal, self-monitoring for at least one week every month should be strongly encouraged. For participants who have achieved and maintained their weight goal, the minimum required frequency will be one week of self-monitoring every month. For participants who are not at goal, the Lifestyle Coach should problem solve with the participant. The frequency of self-monitoring should be increased as necessary until the weight goal is achieved and maintained, and/or alternate self-monitoring tools should be recommended to address any barriers to self-monitoring (see tool box for weight loss). Participants who continue frequent self-monitoring may be the ones who will be most successful at long-term behavior change.

Section 6. Overview of Strategies to Achieve the Physical Activity Goal

6.1. Achieving the Physical Activity Goal

Participants are encouraged to achieve the physical activity goal of 700 kilocalories per week (or 2 ½ hours of moderate activity) in a step-wise fashion over a five-week period and then to maintain the goal for the remainder of Lifestyle Balance. The five-week period begins with session 5. During the first week, participants are simply encouraged to do something active on 3 to 4 days per week. On subsequent weeks, the activity level is increased to 60, 90, 120, and finally 150 minutes per week.

If participants do not achieve the physical activity goal within five weeks, they will be encouraged to achieve it as soon as possible thereafter.

6.2. Self-monitoring of Physical Activity

All participants will be instructed to **self-monitor physical activity daily beginning at Session 5 and continue self-monitoring of physical activity throughout the remainder of Lifestyle Balance.** For the first 24 weeks participants will be asked to record physical activity in a pocket-sized booklet, entitled "Keeping Track," in which they will also record food intake. After the first 24 weeks, participants will be given monthly calendars on which to record daily physical activity and will be asked to return the completed calendars in person or by mail every month (see NLB Participant handout Session 16).

Self-monitoring skills will be taught gradually over the first few weeks of Lifestyle Balance, with self-monitoring of dietary intake and physical activity being introduced sequentially.

Achievement of the physical activity goal is based solely on participant self-monitoring records (unlike with weight loss, there is no objective measure to verify self-report of physical activity level). Thus it is extremely important that all participants continue to record their activity daily and that accurate information be obtained. If physical activity is not increasing as expected, alternate methods of self-monitoring should be used. See the tool box for physical activity for a description of alternate self-monitoring tools and guidelines for using them.

All self-monitoring records will be reviewed by the Case Manager. Summary data will be entered on the Lifestyle Balance Update (see NLB Coach's Manual Session 1, page 12). The records will be returned to the participant, with written or verbal comments from the Case Manager. The comments should highlight examples of positive changes the participant has made and help the participant address any barriers to physical activity encountered.

6.3. Definition and Examples of Moderate Physical Activities

The intent NLB is to encourage all types of physical activity. However, depending on the intensity of the activity, more or less than 2 ½ hours of time doing the activity may be required to use 700 kilocalories. We believe that most participants will use walking as their primary type of physical activity. These individuals should be instructed to walk briskly for 2 ½ hours during the week. Other activities that are similar in intensity to brisk walking are shown in Table 6.1; as with brisk walking, participants who do these activities for 2 ½ hours per week will typically expend 700 kilocalories.

Table 6.1. Moderate Physical Activities Usually Equivalent to Brisk Walking

The following physical activities are usually equivalent in intensity to a brisk walk.

- Aerobic dance (high impact, low impact, step aerobics)
- Bicycle riding (outdoors or on an indoor, stationery bike)
- Dancing (square dancing, line dancing) Note: Be careful not to include breaks.
- Hiking
- Jogging (outdoor, indoor, treadmill)
- Karate
- Rope jumping
- Rowing (canoeing)
- Skating (ice skating, roller skating, rollerblading)
- Skiing (cross-country, Nordic Track)
- Soccer
- Stair Master
- Strength Training (free weights, Nautilus, etc.)
- Swimming (laps, snorkeling, scuba diving)
- Tennis
- Volleyball
- Walking (outdoor, indoor at mall or fitness center, treadmill)
- Water Aerobics

Many physical activities may or may not be equivalent to brisk walking, depending on how they are performed by an individual participant. For example, the following activities may be more intense than brisk walking, depending on how they are performed: basketball, squash, handball, and racquetball. On the other hand, the following may be less intense than brisk walking, depending on how they are performed: golf (walking only and carrying or pulling clubs), softball, and baseball. Participants who regularly perform physical activities other than those listed in Table 6.1 should be scheduled for a consultation to determine the minutes per week necessary to expend 700 kilocalories. In addition, the Case Manager should discuss with each participant in detail the physical activities he or she does or plans to do and evaluate each activity on a case-by-case basis in terms of its application toward the study goal. Participants should *not* be given a list,

such as that in Table 6.1., and told that these are "acceptable" activities whereas others are not. Rather, participants should discuss their activities with the Case Manager and/or the exercise physiologist available at the local center to identify a way in which the participants can expend at least 700 kilocalories per week in physical activity.

The following general guidelines are provided to help Case Managers judge whether an activity is equivalent to brisk walking:

- The activity should last at least 10 minutes, not including breaks (although some activities such as tennis or jumping rope may involve short "breaks" in the activity).
- For job-related activities, in addition to the above two criteria, the physical activity should comprise at least 50% of the job.

For example:

Equivalent to brisk walking	**Not equivalent to brisk walking**
Using a gas-powered push mower to mow several acres of lawn with a great deal of exertion.	Using a gas-powered push mower to mow a tiny lawn in five minutes, without much exertion. Using a riding mower to mow several acres of lawn without much exertion.
Delivering the mail if 75% of the day is spent walking.	Delivering the mail if 75% of the day is spent driving a truck.
Going to a dance and dancing most of the evening.	Going to a dance and dancing only a few times during the evening. Spending most of the time socializing and watching others dance.

Some sports and leisure activities are clearly not equivalent in intensity or duration to brisk walking, such as archery, bowling, fishing, light gardening, and pool. These are to be encouraged as part of an active lifestyle but are not to be applied toward the activity goal. Likewise, other activities, such as light yard work and light housework are to be encouraged as part of an active lifestyle but not self-monitored or applied toward the goal because they usually do not represent a **level of activity equivalent to brisk walking**. The criteria of "equivalent to brisk walking " is used with the rationale that such activities will be most likely to help participants lose weight, lower glucose, and improve cardiovascular risk factors.

Some participants may choose to do more vigorous activities, such as running. In these cases it may be unnecessary to do 2 ½ hours of activity to achieve the 700 kilocalorie goal. These cases are expected to occur infrequently and should be discussed with local experts in exercise physiology before making any reductions in the 2 ½ hour goal.

To encourage physical activity, develop informational handouts on physical activity programs available in your community including location, time, place, cost, etc. If possible, partner with local community activity programs with referrals or discounts. Scheduled group walks before or after a session help participants achieve their weekly activity minutes.

Section 7: Guidelines for Implementing Lifestyle Balance

7.1. Key Principles

The key principles underlying Lifestyle Balance are:

It is based on clearly defined goals.

All participants receive a goal for weight loss and physical activity. From the beginning of the intervention, the Case Managers should state these goals without equivocation and set high expectations for participants in terms of achieving and maintaining them for the length of the trial. The rationale is that reaching and maintaining the goals is what will reduce the risk of diabetes onset.

The intervention is based on participant self-management.

Although firm goals are provided, each participant makes personal choices about how to achieve the goals. This allows flexibility and reinforces the ability of the participants to shape and evaluate their own progress by self-monitoring, developing personal goals and action plans, and problem solving. The role of the Case Manager is to guide and support the participants in the process of self-management.

To achieve a balance between firm goals and participant self-management, Case Managers will need to draw on all of their professional skills and experience. Central to the success of the intervention is the relationship between Case Manager and lifestyle participant. Ideally, this relationship might be compared to that between a talented coach and a prized member of an athletic team. As "lifestyle coaches," we recommend that Case Managers practice the following.

- **Express support and acceptance** for participants regardless of their progress toward goals.

- **Look for success and build on it**, no matter how small or gradual.

- At the same time, **maintain the highest of standards and expectations.** A Case Manager should not lessen the goals to match what seems "realistic" or "do-able" for a participant, any more than a health care provider would ask a patient to aim for less than optimal glucose monitoring and regulation. Instead, the Case Manager should express ongoing confidence that the participant will be able to reach and maintain the goals and then provide the utmost support in helping the participant address any barriers to that end. As we all know, expectations are often self-fulfilling. If expected to do poorly, participants are more likely to do poorly; if expected to do well, many participants will rise to the occasion.

- Along the same lines, **do not assume that a barrier to the goals exists until it is evident** (for example, that a participant who has a lower level of education will be unable to calculate fat grams when self-monitoring). Such assumptions are often based on hidden biases that may prove false (for example, many interventionists have reported that it is the participants with less years of education who do the most thorough self-monitoring).

- **When barriers do become evident, involve the participant as much as possible in addressing them, through goal setting and problem solving.** Use and convey an experimental approach--the evidence of a barrier is not a sign of failure on the part of the coach or the participant but rather is a valuable piece of information to be used to design and test a better experiment, together.

- **Be the expert.** Be confident and firm when assigning the strategies for change presented in the intervention (such as self-monitoring of fat gram intake and physical activity). Stress that previous research has shown these strategies to be highly successful for many, many people. However, be flexible about using other strategies as needed. Information and behavioral strategies have been included in the intervention because of their likelihood of enhancing achievement and maintenance of the lifestyle balance goals, not as ends in themselves.

The intervention is to be tailored to participant lifestyle, learning style, and culture.

The lifestyle balance program should be tailored to each participant's lifestyle, learning style, and culture. Many, many factors (such as ethnic heritage, socioeconomic status, marital status, and roles at work and at home) will have an impact on the eating and activity behaviors of participants. Such factors will also be at work in the lives of the Lifestyle Coaches themselves and will influence the way they interact with participants.

Lifestyle Coaches should therefore remain open and sensitive to whatever factors may be important to each individual participant and at the same time, avoid stereotyping or making assumptions. The goal is to implement the lifestyle balance intervention with awareness, consideration, and careful communication so that differences can be used to enhance the intervention rather than get in its way.

Some points to keep in mind regardless of a participant's lifestyle or cultural heritage:
- Be careful to avoid interpreting a behavior within your own cultural context without asking.
- Low-literacy English is not a sign of intelligence or a predictor of success.

7.2. Core Curriculum

The first sixteen sessions of the lifestyle balance program, called the "core curriculum," is the most structured phase. In the core curriculum, all participants are taught the same basic information about weight loss and physical activity and are given the opportunity to

practice related behavioral skills both during the intervention sessions and at home. Also it is during the core curriculum that the Lifestyle Coaches and lifestyle participants get to know each other and learn how best to work together to achieve the study goals. Each NLB team needs to determine the level of weight maintenance activities that will be offered once the Core Curriculum of Lifestyle Balance is completed.

7.2.1. Type and Frequency of Contact During the Core Curriculum during DPP

DPP required participants to be seen a **minimum of 16 times during the core curriculum**, and the **entire curriculum was to be presented within 24 weeks**. Although the exact schedule of visits varied depending on holidays, illnesses, travel, and so on, it was strongly recommended that participants were seen weekly for at least 20 of the 24 weeks. If this was not possible, another option was to meet with the participant weekly for the first eight or 12 sessions and then every other week for the remainder of the 24 weeks. More frequent contact schedules have been shown to produce greater weight losses, so the maximum frequency of contact should be maintained as long as possible, given participant willingness and staff and budget constraints. The tool box for attendance specifies procedures to be tried if participants are not attending sessions. Phone calls to participants between visits may be helpful and can be used to reinforce and encourage behavior change.

Participants were seen on an individual basis during the core curriculum. Only a few participants per clinical center were randomized to the intervention program each month, making group sessions impractical. Also, individual contacts were ideal for tailoring the presentation of the intervention to the educational needs of each participant. Individual sessions were scheduled at times most convenient to the participant, for example, in the evening for participants who worked during the day and prefer evening appointments.

A family member or other support person was invited to attend any or all sessions. Decisions about whether to include another family member or support person should be based on the participant's wishes.

When scheduling groups, care must be taken that the time is convenient to all participants, that the arrangement is agreeable to all, and that "make-up" individual sessions are conducted as needed. Remember to plan the length of your Lifestyle Balance Program so that it allows a long enough time for participants to safely lose weight.

7.2.2. Role of the Lifestyle Balance Team

The leader for a particular session may be determined by the expertise of your team members. The intended role of the Case Manager, or other staff member who presents the core curriculum sessions, is one of educator, facilitator, and "coach." The participant is responsible for implementing and evaluating strategies to reach the study goals, with the support and guidance of the Case Manager or other staff. Self-monitoring, goal

setting, and home activities are included in each session to reinforce the participant's sense of personal responsibility for the success of the intervention.

7.2.3. Location of Lifestyle Balance Sessions

Most Lifestyle Balance sessions should be held in a private room. A scale (balance beam or digital electric) must be available so that the participant can be weighed at each session. On some occasions, the Case Manager may wish to conduct a session while taking a walk with the participant, at the participant's home, or at another location selected for an educational goal, such as at a restaurant. However, the location should enhance rather than distract from the basic content of the session. Because the sessions are dense with fundamental information and skills, it may be best to reserve most alternate locations for sessions held during the maintenance period, for example, holding a group supermarket tour at a grocery store.

7.2.4. Maintaining the Basic Content and Sequence of Lifestyle Balance Sessions

We anticipate that for most groups, one session will be presented at each meeting. However, if a participant is having trouble with a particular topic, it may be desirable to stay on that topic for an extra meeting. For example, the session "Be a Fat Detective" is particularly dense with information and skills and could be divided into two meetings, especially if a participant has difficulty learning to use the self-monitoring tools. A good goal is to at a minimum, present one new session every two weeks, and the entire 16 sessions of Lifestyle Balance should be completed in 24 weeks.

If a participant is having trouble in an area and the session on that topic does not occur until later in the core curriculum, the Case Manager should briefly address the issue and problem solve with the participant as appropriate. At the same time, the Case Manager should keep the focus on the topic for the current session and delay the formal presentation of the other material until it appears in the standard curriculum. For example, during the session "Be a Fat Detective" (Session 2), a participant might say, "I eat out for lunch all the time. How can I find low-fat foods when I eat out?" The Case Manager might suggest that the participant:

a. Use the Fat Counter to self-monitor when he eats out just as he would at other times, and if a food isn't in the Counter, find one that is the most similar,
b. Ask the waiter for any nutrient information, if available, and
c. For the next session, bring in any nutrient information he collects plus menus from the restaurants he eats at during the week and together the participant and Case Manager will estimate the fat grams for various choices on the menus.

This response keeps the focus of the session on self-monitoring, rather than shifting it to a lengthy discussion of various strategies for healthy eating when eating out, which is formally presented in Session 10, "Four Keys to Healthy Eating Out." Indeed, many participants will be faced with challenges related to eating out before Session 10, but the topic formally appears this late in the curriculum because the session builds on previous sessions that address self-monitoring, cues, and problem solving. Similarly, if a

participant says he will be unable to lower his fat intake or increase his physical activity because of family pressures, lack of motivation, and so on, the problems raised by the participant should be discussed and strategies suggested to deal with the problem. However, the formal presentation of social support, problem solving, lapses, and so on, would be held until the appropriate session.

7.2.5. Guidelines for Tailoring the Presentation of the Lifestyle Balance Sessions

The Case Manager should tailor the presentation of the sessions to each participant's learning style, stage of change, and progress toward the study goals. For instance, the Case Manager should explain concepts in the sessions by using examples that are relevant to a participant's ethnicity, financial means, and preferences. The Case Manager should feel free to replace any of the examples given on participant work sheets with other, more relevant, examples. Similarly, the Case Manager should feel free to use supplementary educational aides if it is clear that this approach will enhance learning for a participant and not draw attention or time away from the basic concepts presented.

Some examples of appropriate ways to tailor a session: Displaying test tubes filled with shortening to varying levels to illustrate the fat content of different foods, providing individual samples of low-fat food products to taste.

Some examples of inappropriate ways to tailor a session: Having a hypnotist come to the session on motivation; dropping the session on slips because the participant has not had any lapses; presenting a cooking demonstration on low-fat vegetarian cooking at the session entitled, "Healthy Eating." (This last example is considered inappropriate because it would take time away from the many basic concepts to be presented at this session and would not be relevant to all participants. However, this topic *may be appropriate for a group session during maintenance* if a number of participants express a need for or interest in this topic.)

7.2.6. Guidelines for Using the Participant Notebook

Each Lifestyle Balance participant will be given a three-ring binder, the Participant Notebook, a**nd at each session will receive a copy of the materials for that session.** Participants are *not* to be given the entire set of materials at one time. Participants should take the binder home with them at the end of each session and bring it to the next session.

The Case Manager should use the participant handouts during the session to present the main points while the participant follows along. The Case Manager and participant should feel free to write or draw on the handouts, indicating points of emphasis, adding examples, and so on. The participant should fill in any blanks or complete any practice activities in his or her own words whenever possible.

The participant handouts are to be inserted into the participant's study notebook during or at the end of the session.

7.2.7. Use of Supplemental Materials and Tools of Presentation

The core curriculum is the most structured part of the Lifestyle Balance Program. A great deal of information is presented to participants during this phase, and there is concern that participants not be overloaded with additional information and related materials. For this reason, **limit supplemental materials**. The key concepts of the intervention may be lost if participants are given too much information or too many handouts.

If a participant asks for more detailed information on a topic or asks for information on a topic not presented in the curriculum (for example, the cholesterol content of foods), we caution Case Managers to evaluate the request carefully before proceeding. For example, at first glance, it may seem that more highly educated participants who ask for additional information should be given as much information as possible to encourage their sustained interest and adherence. However, the opposite may be the case if a participant is "intellectualizing" rather than dealing with the behavioral issues that need to be addressed if change is to occur.

To evaluate when and whether to provide additional information, consider the following:

- Did the participant ask technical questions indicating the desire for additional information or seem interested in knowing more?
- If yes, would additional information address the questions or interests **and** increase the likelihood of the participant reaching the goals for lifestyle change?
- If yes, provide the information. If no, determine how to move the focus back to the lifestyle change issue at hand.

In most cases, it may be best to hold additional information until after the core curriculum. Case Managers and participants may find it helpful to remember and use requested information during weight maintenance. It is best to present new skills and information slowly and have participants practice these new skills before adding others.

7.2.8. General Guidelines for Conducting a Lifestyle Balance Session

Specific guidelines for conducting each core curriculum session are given in the NLB Coach's Manual. General guidelines are given below.

Before the participant arrives for each session, the Case Manager should:

- Review the participant's chart and the session script in the NLB Coach's Manual for the previous session, noting the home activities assigned, action plans made, and any other pertinent issues.
- If applicable, review and comment in writing on any Keeping Track books returned at the previous session.

- Review the script for the upcoming session in the NLB Coach's Manual.
- Prepare all materials required for the session, including supplementary materials and any small motivational items (such as mugs, key chains, and so on) to be distributed.

During every session, the Case Manager should perform the following unless otherwise indicated in the NLB Coach's Manual. The entire session should last from 45 to 60 minutes, with the exception of Session 1 which is likely to last more than 1 hour.

1. Weigh the participant.

Participants should be weighed in private at the beginning of each session. Weight can be taken with either a balance beam or a digital scale. The type of scale is not important, but an effort should be made to use the same scale throughout the study. Participants should be weighed in street clothes, without shoes.

Record the weight on the Lifestyle Balance Update form and/or the Group Session Update Log (found in NLB Coach's Manual Session 1), and have the participant graph the weight in the participant's notebook.

2. **Receive and review any Keeping Track records** completed since the last session. Record summary data for both weight and physical activity on the Lifestyle Balance Update Form, as instructed on the form. Give the participant feedback and helpful suggestions and enter the weight and physical activity on the graphs in the participant's study notebook. Participants should be encouraged to complete the graphs themselves, if possible.

The NLB Coach's Manual Session 2, provides detailed guidelines for reviewing Keeping Track records with participants. At later sessions, a briefer review will be sufficient in most cases, and comments will most likely focus less on the process of self-monitoring and more on the specific behavioral or other goals emphasized at that point in the intervention. At any time, however, the Case Manager should be alert to any lapse in basic self-monitoring skills that may have an impact on achievement of the lifestyle balance goals and should review the skills as necessary.

Throughout the trial, the Case Manager should praise some aspect of the records returned, no matter how small (for example, the Case Manager should not overlook the very fact that the records were returned, regardless of whether goals were reached or the quality of the record keeping). In addition, Case Managers should be careful not to discourage participants by providing too many suggestions for improvement.

3. **Discuss successes and difficulties in meeting goals** since the last session.

4. **Review the last session.** Briefly summarize the main points of the previous session, and discuss any related thoughts and experiences the participant has had, including any home activities, goals, or action plans that were assigned.

5. **Present the new topic.** The Case Manager should follow the NLB Coach's scripts in terms of what to present and in what sequence, while tailoring exactly *how* the topic is presented (such as the language and examples used) to the participant's learning style. In no instance should the Case Manager "read" the script to the participant. The script is provided only as a model to guide and help the Case Manager.

   Using the participant work sheets for the session, present the main points while the participant follows along on the handouts. Indicate on the handouts anything you want to emphasize or clarify (for example, feel free to add examples, underline main points, and so on). Have the participant fill in any blanks or complete any practice activities directly on the handouts. The handouts are to be inserted into the participant's notebook during or at the end of the session.

6. **Set goals, develop action plan(s), and assign home activities** for the coming week(s). Complete any related work sheets with the participant. Instruct the participant to put a check mark in the boxes (☐) on the "To do next week" handouts as home activities are completed.

After each session, telephone calls may be made to participants as needed to support the achievement of study goals. Phone calls after the early sessions will be particularly important to reinforce the basic skills taught in those sessions and to support the participant in applying those skills. All telephone calls to participants should be documented. For best success, develop a system for following up no shows as soon as possible.

7.3. Maintenance

See the DPP Lifestyle Manual for Contacts After Core.