

The Diabetes Prevention Program's *Lifestyle Change Program*

Section 2: The DPP Lifestyle Intervention Goals

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Section 2: The DPP Lifestyle Intervention Goals

All DPP participants randomized to the lifestyle intervention are to try to achieve two study goals:

• To achieve and maintain a weight loss of 7% of their 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 the DPP lifestyle intervention is to lose 7% of initial body weight (as measured at Session 1, the first Lifestyle Balance session) and maintain that weight loss throughout the trial (see Table 2.1.). The recommended pace of weight loss is 1 to 2 pounds per week, for a 7% loss within approximately 24 weeks. Further information on achieving the weight loss goal is found in Section 5.

Example Starting Weight (lb.)	Example Weight Goal (lb.)	Example Starting Weight (lb.)	Example Weight Goal (lb.)	Example Starting Weight (lb.)	Example Weight 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		

Table 2.1. Example DPP Lifestyle Intervention Weight Goals*

*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 has been selected as the study 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 is 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 has been 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 DPP 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 DPP 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).

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 study 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 throughout the study. However, all participants, with the aid of their Case Managers, should endeavor to achieve and maintain the goal.

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				

Table 2.2. Heights and Weights Equivalent to a Body Mass Index of 21

2.1.2. Temporary Suspensions of Efforts to Achieve Weight Goal

Efforts to achieve the weight goal will be suspended during pregnancy and lactation (see Protocol). 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. These events should be documented and brought to the attention of the LRC.

The weight goals, however, remain in effect for all participants throughout the study. The goals are always based on weight loss from Session 1. For example, if a participant weighs 180 at Session 1, his/her DPP 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 DPP 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 (see Section 6).

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 has been selected 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 $2\frac{1}{2}$ -hour goal. For example, a participant who already does aerobic dance for 2 hours per week may continue this and add another $\frac{1}{2}$ hour of aerobic dance or another type of moderate activity to reach the $2\frac{1}{2}$ -hour goal. In addition, participants who are active sporadically (e.g., seasonally) should be encouraged to achieve the goal consistently throughout every month of the study.

It is recognized that not all participants will achieve the activity goal at all times throughout the study. However, all participants, with the aid of their Case Managers, 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 (see Protocol) will not be allowed to participate in physical activity until receiving definitive therapy. Those who have symptoms or signs of cardiovascular disease during the exercise test are eligible to participate in the physical activity goals will need to be individually adjusted.