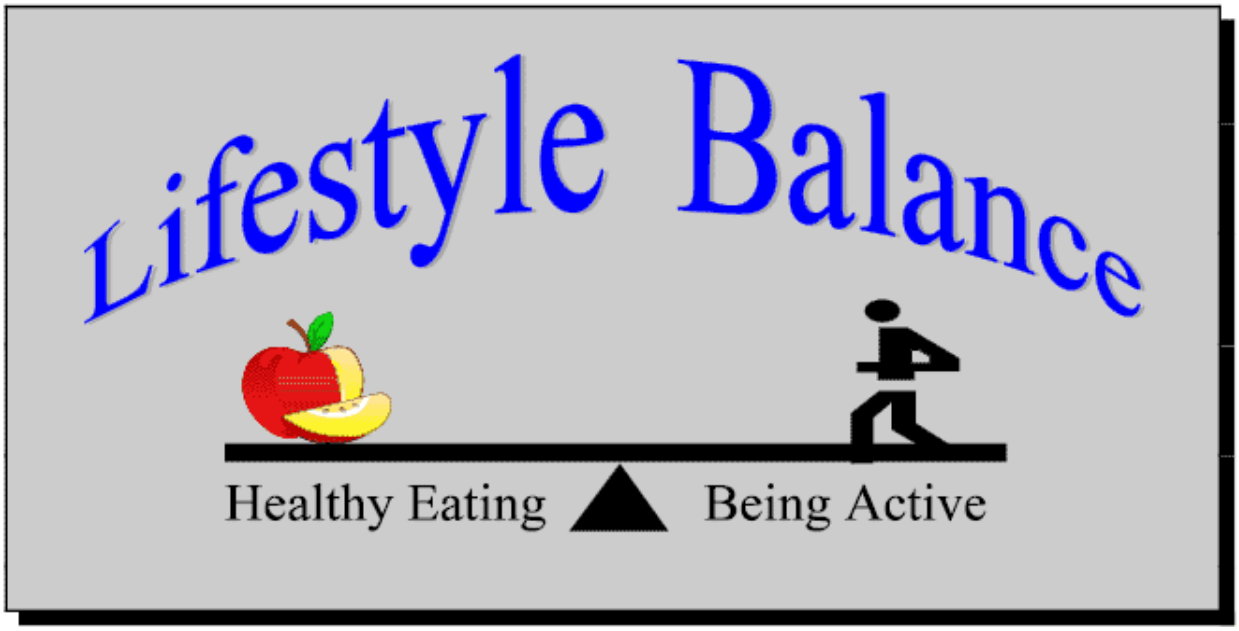

The Diabetes Prevention Program's
Lifestyle Change Program

Section 7: Guidelines for Implementing the DPP Lifestyle Intervention

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Section 7: Guidelines for Implementing the DPP Lifestyle Intervention

7.1. Key Principles

The key principles underlying the DPP lifestyle intervention are:

It is based on clearly defined study goals.

All participants receive a study 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 study 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 study 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 study 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 study 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 study 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 study 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 less educated participants 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 study goals, not as ends in themselves.

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

The DPP lifestyle intervention 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 DPP lifestyle 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 in the DPP.

See Appendix C for additional information on tailoring the intervention to diverse populations.

7.2. Core Curriculum

The first part of the DPP lifestyle intervention program, called the "core curriculum," is the most structured phase of the intervention. 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. In the remaining 3 to 6 years of the intervention, Case Managers are given much more flexibility to focus on issues of particular relevance to the individual participant.

7.2.1. Type and Frequency of Contact During the Core Curriculum

Participants must be seen a **minimum of 16 times during the core curriculum**, and the **entire curriculum must be presented within 24 weeks**. Although the exact schedule of visits will vary depending on holidays, illnesses, travel, and so on, we strongly recommend that participants are seen weekly for at least 20 of the 24 weeks. If this is not possible, another option would be 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 and when calls to the LRC are to be made. Phone calls to participants between visits may be helpful and can be used to reinforce and encourage behavior change.

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

A family member or other support person may be 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.

In some cases, several participants may be randomized to the lifestyle intervention at approximately the same time. In these situations the intervention sessions may be conducted with a small group of participants. However, 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. In addition, no participant should wait more than two months between randomization and the start of the core curriculum.

7.2.2. Role of the DPP Staff

The first eight and any four of the second eight sessions must be presented by the Case Manager. The remaining four of the second eight sessions may be presented by a peer or home health aide who has received appropriate training and supervision or by a local expert in behavioral psychology, nutrition, or physical activity (see Section 3).

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 Core Curriculum Sessions

Most core curriculum sessions should be held in a private room in a clinic or similar setting. 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 core curriculum 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 Core Curriculum Sessions

The basic content and sequence of the core curriculum sessions must be consistent across clinical centers and from participant to participant within each center. Otherwise, at the end of the trial we will not be able to describe the intervention program as implemented or draw conclusions about its efficacy. Specific instructions for conducting each core curriculum session are given in Appendix A.

DPP lifestyle participants are given a choice as to which intervention goal to focus on first, either weight loss or physical activity. This choice determines the sequence of the first eight sessions, and the scripts in Appendix A include guidelines for conducting both sequences. The scripts for Sessions 2-8 are numbered as follows: the first number indicates the sequence for participants who focus on the physical activity goal first, or do not express a preference; the second number indicates the sequence for participants who focus on the weight loss goal first.

After the participant decides whether to start with activity or weight loss, the Case Manager should select the appropriate sequence of materials and then **proceed through the 16 sessions in the order prescribed**. This will ensure that all participants receive the same intervention

program, that sessions on physical activity, nutrition, and behavioral topics are interspersed, and that topics that build on those presented earlier come in the correct sequence.

We anticipate that for most participants, 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. At a minimum, one new session should be presented every two weeks, and the entire 16 sessions of the core curriculum 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" (either Session 4 or 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 Core Curriculum Sessions

While maintaining a standard curriculum in terms of the basic content and sequence of the 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 in Appendix A and 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 Work Sheets

Each DPP lifestyle participant will be given a three-ring binder **and 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 work sheets 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 work sheets, 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 work sheets 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 During the Core Curriculum

The core curriculum is the most structured part of the intervention. 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, **no supplemental materials should be given to participants without prior approval from the LRC**. Similarly, any tools of presentation that an individual clinical center or Case Manager would like to use should be sent to the LRC for review beforehand. This process is designed to help the Case Managers maintain the needed focus of each session, and it will also allow the LRC to bring supplemental materials and tools of presentation to the attention of the other clinical centers so

that all can benefit. It is important that Case Managers realize that more information is not always better. In fact, 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 that the intervention extends over several years. It is best to present new skills and information slowly and have participants practice these new skills before adding others.

Finally, Case Managers are to present **only** the strategies described in the protocol and approved for use in the tool boxes or by the LRC. Strategies that have worked for a friend who has tried to lose weight (e.g., a nutrient bar or shake or an unusual exercise machine) should not be recommended to participants without prior approval from the LRC.

7.2.8. General Guidelines for Conducting a Core Curriculum Session

Specific guidelines for conducting each core curriculum session are given in Appendix A. General guidelines are given below.

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

- Review the participant's chart and the script in Appendix A 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 Appendix A.

- Prepare all materials required for the session, including supplementary materials suggested in the tool boxes or Appendix A, if appropriate, and any small motivational items (such as mugs, key chains, and so on) to be distributed.

During every core curriculum session, the Case Manager should perform the following, in the sequence given here, unless otherwise indicated in Appendix A. The entire session should last from 30 to 45 minutes, with the exception of Session 1 which is likely to last 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 DPP Lifestyle Intervention Data Form, 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 Intervention Data 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.

For the first few core curriculum sessions, Appendix A 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 study 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 the study 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 script inAppendix A 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 work sheets. Indicate on the work sheets 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 work sheets. The work sheets 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" work sheets 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 core curriculum 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.

7.3. Maintenance

See the DPP Lifestyle Manual for Contacts After Core.