



Manual of Procedures (MOP)

Section 12. Support and Education Program

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12.1 SUPPORT AND EDUCATION PROGRAM

D2d participants are at increased risk for diabetes. In accordance with the latest American Diabetes Association (ADA) Standards of Care, at baseline the study will: (1) provide participants with written information on the current recommendations for prevention of type 2 diabetes (emphasizing lifestyle intervention aiming to achieve and maintain at least a 5% weight loss and increased physical activity to at least 150 min/week of moderate activity). The content of these recommendations was developed by the U.S. Department of Health and Human Services National Diabetes and Education Program; and (2) send a letter to participants' primary care providers indicating that participants are at risk for diabetes and to advocate efforts at weight loss and increasing physical activity. This approach is consistent with the lifestyle advice that was provided to participants in other diabetes prevention trials that have compared medications with placebo.

Importantly, during the study, all participants will be invited to join the D2d Support and Education Program (SEP). As part of this program, participants will attend group meetings, held twice yearly at each site, to discuss specific topics in nutrition, exercise, and diabetes (e.g. healthy eating strategies for the holidays). These meetings will allow the opportunity to meet other participants and will also serve as a way to enhance retention. In addition, educational handouts will be provided to participants during their regularly scheduled study visits. Participants will also receive a D2d study newsletter at regular intervals, which will include a section on healthy nutrition and exercise.

12.2 BASELINE VISIT

The study will provide education on prevention of type 2 diabetes as follows:

1. Participants will be given written information on the current recommendations for prevention of type 2 diabetes. Specifically, participants will receive the booklet: *Small Steps Big Rewards, Your Game Plan to Prevent Type 2 Diabetes*, (NIH Publication No. 06-5334, Revised October 2006) which includes a Food and Activity Tracker (see Appendix). This booklet is available in both English and Spanish. The booklet is intended to help individuals assess their risk for type 2 diabetes and provide information on how to implement a program to prevent or delay its onset.
2. Staff will send a letter to participants' primary care providers indicating that participants are at risk for diabetes and to advocate efforts at weight loss and increasing physical activity.

12.3 INTRA-STUDY SUPPORT AND EDUCATION PROGRAM

During the study, there will be a support and education program to:

1. Ensure all participants (regardless of their randomization assignment) receive the standard of care education on the prevention of type 2 diabetes by distributing educational handouts at each regular study visit.
2. Engage participants in the study by providing stress free and socially interactive group meetings twice per year to learn about healthy living strategies.

12.3.1 Support and Education Program (SEP) Meetings

Collaborating clinical sites will host two SEP meetings per year. Participants will be encouraged to attend, but it will not be a protocol requirement. However, attendance will be tracked and recorded in each participant's e-CRFs.

12.3.1.1 Overview and Goals

The goals of the SEP meetings are the following:

1. To provide participants with up-to-date information on the lifestyle recommendations for the prevention of type 2 diabetes.
2. To promote participant retention.

During a SEP meeting, a topic related to healthy living (e.g. diet/nutrition or physical activity) will be presented by an individual trained in the content area. This individual may be a member of the D2d study team or an invited guest speaker. The site investigator, co-investigator, or research coordinator will introduce the speaker and welcome the attendees. The investigators are encouraged to take part in group discussions with participants.

Since retention is one of the primary goals, meetings should be as interactive and engaging for participants as possible; therefore presentations should not be overly didactic, and activities that are more social in nature should also be incorporated. Sites are encouraged to be creative and to customize these meetings to suit their facilities, expertise, geographic location, and study population. Webinars may be used by the site as a means to include participants who wish to take part but are unable to attend in person.

12.3.1.2 Topics, Materials, and Activities

The overall schedule of topics will be determined by the Support and Education Subcommittee (SES) and may be found in Appendix 12.4.4. For each topic, a PowerPoint slide set, moderator outline, and optional supplementary handouts will be made available (see Appendix 12.4.7). The slides may be modified by individual sites as needed (i.e. additions or substitutions may be made) to be better suited to the speaker or more appropriate to the audience.

Participants will be offered healthy snacks during the meetings, an opportunity to socialize with other participants, and, at some meetings, be given appreciation tokens for attending or be eligible to win a door prize (e.g. grocery or fitness/sports store gift card). Cooking demonstrations, games, raffles, and various types of activities may be included and should relate in some way to the day's topic. A list of optional ideas for enhancing the group session experience for participants may be found within the General Guidelines in Appendix 12.4.6.

12.3.1.3 Scheduling the Meetings

The meetings will be scheduled in advance at times convenient for participants. Participants may be invited to the SEP meeting during a scheduled contact (e.g. study visit, phone contact, visit reminder phone calls) or outside a scheduled contact (e.g. via e-mail invitations or postal mail). However, carefully crafted, mailed invitations requesting an RSVP are recommended as these will help to distinguish the group sessions from routine study visits, and communicate to the participant that they are intended to be special, fun events.

Meeting dates will be decided by each individual site; while sites will not be required hold them within a specific month, the twice-yearly meetings should be separated by at least 4 months and no more than 8 months. For each meeting, sites should consider offering more than one session at different times and/or different days to accommodate the availability of all (or at least most) participants.

12.3.1.4 Documentation of Meeting Attendance

Prior to each meeting, the site Research Coordinator should generate a list of all active randomized participants at the site. As participants enter the meeting room, the Research Staff can ask for their names and check that they attended the session.

12.3.1.5 Feedback

Site staff will be asked to complete a brief questionnaire after each group session, and to submit it to the Coordinating Center. The purpose of the questionnaire is to provide feedback to the SES on specific components of the meeting or on approaches taken by the facilitators that were particularly successful; these experiences will be shared with all sites to aid them in planning future events.

12.3.2 Educational Handouts

A series of educational handouts, adapted from the National Diabetes Prevention Program, will be provided to all participants at their regularly scheduled study visits in a pre-set order. The purpose of these handouts is to ensure that all participants receive the same standard of care information regardless of when they are enrolled in D2d or whether or not they are able to attend the group meetings. The order that corresponds to the study visits is outlined in the Support and Education Program Schedule (Appendix 12.4.4). The handouts may be found in Appendix 12.4.5 and should be printed by sites as needed.

12.3.3 Support and Education Program Planning Group

The D2d Support and Education Subcommittee (SES) will review and modify the standard of care education on the prevention of type 2 diabetes as needed and plan / develop the themes and content of the twice-yearly meetings so they are standard and consistent across sites.

Possible topics and content materials may be suggested by any SES member and these will be posted to the D2d website portal for consideration by all committee members prior to their monthly committee meetings, where they will be discussed and decisions on whether to incorporate them will be made.

In addition to content, the SES will provide general guidelines to sites on running group sessions (see Appendix 12.4.6) and will be available to provide advice or recommendations to individual sites upon request.

The SES will also provide recommendations regarding modes of dissemination of materials and newsletters to participants, such as the use of both print and electronic versions, in order to reach all participants as effectively as possible.

12.4 APPENDICES

12.4.1 NDEP-60: Small Steps Big Rewards, Your Game Plan to Prevent Type 2 Diabetes

12.4.2 NDEP-60: Fat and Calorie Counter

12.4.3 NDEP-60: Food and Activity Tracker

12.4.4 Support and Education Program Schedule

12.4.5 Educational Handouts for Regular Study Visits

12.4.6 General Guidelines for Hosting Group Sessions

12.4.7 Slide Sets, Moderator Outlines, and Optional Handouts for Group Sessions

12.4.8 Site Feedback Questionnaire