



## 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. The Recruitment and Retention subcommittee will suggest topics that the sites can utilize for these meetings. Finally, participants will 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. A member of the research team with background in diabetes education (physician, PhD, nurse, or dietician) will provide the participant the opportunity to ask questions and discuss the content of the written information.
3. 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.
2. Engage participants in the study by providing stress free, 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.

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.

The meetings will be scheduled in advance at times convenient for participants. Participants will 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).

During a SEP meeting, a topic related to healthy living (diet/nutrition or physical activity) will be presented by an individual trained in the content area. 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 (e.g. insulated lunch bag when the topic is meal planning), or be eligible to win a door prize (e.g. grocery or fitness/sports store gift card). The site investigator or co-investigator will introduce the speaker and welcome the attendees.

### **12.3.2 Documentation of Meeting Attendance**

Prior to each meeting, the site Research Coordinator will generate a report, via the EDC, of all active participants at the site. The report will serve as a participant Attendee report and will be used to monitor attendance by putting a check box next to the attendees' names. As participants enter the meeting room, the Research Staff can ask for their names and check the box signifying they attended the session. The report will then be used to record the participant's attendance in the EDC system.

### **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 ideas and recommendations for possible meeting formats as well as guidelines on the degree of latitude for sites to emphasize certain aspects of a topic that may be more relevant to their geographic area than to others.

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**