D2d ANCILLARY STUDY PROTOCOL

AS13-06

Assessment of the (NDEP) GAME PLAN Toolkit in the D2d Study

Version 1.0

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Introduction

The D2d study is providing all participants with the National Diabetes Education Program (NDEP) "Small Steps Big Rewards. Your GAME PLAN to prevent Type 2 Diabetes" (referred to as the GAME PLAN tool kit) written education materials. The three-booklet package is comprised of an educational booklet, food and activity tracker, and fat and calorie counter. It is one of NDEP's most popular diabetes prevention publications. The kit is consistently among the top ten downloaded resources from the NDEP website and nearly 17,000 print copies were ordered in 2012. The GAME PLAN tool kit was last revised in 2006, however the effectiveness and usefulness to individuals has yet to be assessed. The IRB approved D2d study Protocol version 1.4 stated that D2d study participants would be given the option to complete a pre-test questionnaire at the D2d study baseline visit, prior to being provided with the tool kit (pre), and a post-test questionnaire after reading the materials at the month 3 study visit.

This protocol provides additional information and detail for the Institutional Review Board to review this minimal risk study.

Ancillary Study Objective:

The objective of this ancillary study is to obtain data on the usability and effectiveness of the GAME PLAN toolkit (Appendix A) as an educational tool for adults at risk for type 2 diabetes. The effectiveness has not yet been investigated. The hypothesis is that providing participants with the GAME PLAN toolkit will improve their understanding of techniques to prevent type 2 diabetes.

Specific objectives are to determine:

1. What information participants learn from reading the materials.

2. If the contents and tools are appropriate, comprehensive, and easy to use.

3. What updates might improve the toolkit's relevance and usability.

The information collected by this study will be used to revise the toolkit contents.

Methods:

The English-language and Spanish-language materials will be assessed.

At the baseline D2d study visit the Research Coordinator (or designee) will ask participants to participate in the ancillary study (see Appendix 2, Research Coordinator Instructions). The D2d study participants will be provided with the pre-test (Appendix 3). The pre-test introduction states that completion of the pre-test is voluntary. Completion of the pre-test is expected to take approximately 10 minutes. It is expected that it will be done during the wait time between D2d study glucose tolerance test blood sample collections, therefore not increasing the study visit duration. After completing the pre-test, participants will be provided with GAME PLAN toolkit and encouraged to read the materials. The post-test (Appendix 4) will be provided to participants during their month 3 D2d study visit before any

additional diabetes education is delivered. Completion of the post-test is expected to add no more than 20 minutes to the study visit. The pre- and post-tests use existing, validated items to the extent possible.

All D2d study clinical sites are expected to participate and all D2d study participants will be asked at the baseline visit to participate in this ancillary study, until the sample size is reached. Once the pre-test sample size is reached the D2d Coordinating Centers will notify the clinical sites that the sample size has been reached and that no additional pre-tests need to be administered. Each participant who completed a pre-test will be asked to complete the post-test at the 3-month visit.

Completed tests will be faxed or scanned and email to NDEP utilizing the attached Fax Coversheet (Appendix 5). The completed test will include only the participant D2d study enrollment ID, which at the site can be linked to the participant. No participant identifiers will be submitted to NDEP.

Sample size/ Data Analysis

Sample size was determined based on the principle of saturation, which is highly affected by the heterogeneity of the population, the number of selection criteria, and the budget and resources available. Sample size and power were calculated for paired-sample t-tests using G*Power 3.1.5. A total sample size of 272 people completing both pre- and post-tests will provide a confidence interval of 5.522 and allow detection of small effects ($d > 0.20$) at alpha = 0.95 and power = 0.95. Distributing 600 pre-test questionnaires (English and Spanish) should allow for final sample of approximately 300 completed pairs of pre-test and post-test questionnaires. If more than 300 completed pairs are obtained they will be analyzed.

To achieve completion of 600 pre-test questionnaires it is expected that each D2d site will enroll between 20 and 60 participants. However, there is not a cap on the number of participants a site can enroll. Enrollment in this ancillary study will cease when 600 pre-test questionnaires have been distributed.

Human Participant Protection:

This ancillary study to the D2d study is a minimal risk as the risk of physical or psychological harm from participating (completing the questionnaires) is not greater than that encountered in daily life, and a waiver of the requirements for informed consent is met.

Completion of the pre-test questionnaire at the baseline visit will not lengthen the D2d study visit, as it will be done during the 2-hour oral glucose tolerance test. Completion of the post-test questionnaire will take place during the D2d study month 3 visit and may lengthen the visit by 15-20 minutes.

Appendices

Appendix 1: NDEP Small Steps. Big Rewards. GAME PLAN. Tool kit

Appendix 2: Instructions for the Research Coordinator

Appendix 3: Pre-Test

Appendix 4: Post-Test

Appendix 5: Fax Cover Sheet