

Official Title: American Sign Language-Accessible Diabetes Education

NCT Number: NCT03980808

Statistical Analysis Plan: December 16, 2021

# **STATISTICAL ANALYSIS PLAN**

## **AMERICAN SIGN LANGUAGE – ACCESSIBLE DIABETES EDUCATION**

### **1. Aims and Objectives**

This pilot study sought to demonstrate the impact of an educational information that provides diabetes management information to people who are Deaf in American Sign Language (ASL). Project activities produced two videos in ASL created from standard diabetes educational interventions. Using a pretest-posttest quasi-experimental design, we evaluated the effect of the educational intervention ASL videos on knowledge about diabetes and related behavioral health. These changes were measured through study specific instruments that were based on the content of the educational interventions. Behavioral changes were self-reported. These study instruments were administered to the participants through interviews facilitated by Advanced Certified ASL interpreters.

### **2. Sample Size**

A pilot study with 40 participants who are Deaf and use ASL as their primary means of communication.

### **3. Outcomes**

This section will present the outcomes investigated to answer the study aims and objectives. The analyses are described in Section 5 Analyses.

#### **Primary Outcomes**

Change in knowledge as measured by composite score of the study specific instrument based on the educational intervention.

Changes in self-reported behaviors related to diet, exercise, and smoking habits as measured by a composite score of a study specific instrument based on the information presented in the educational intervention ASL videos.

### **4. Populations and SubGroups to be Analyzed**

Subjects included those who were Deaf and used ASL as their primary means of communication. Subjects with and without diabetes were included in the protocol. All included study subjects completing the whole study period (i.e. pre and 30 day post) will be seen as the primary population for the analysis. Subjects who did not complete the 30 day post-test are excluded from the analysis.

### **5. Analysis**

All outcomes will be presented using descriptive statistics; normally distributed data by mean and standard deviation and skewed distributions by median and interquartile range (IQR). Binary and categorical variables will be presented using counts and percentages. SPSS statistical software version 26 (SPSS Inc., Chicago IL, USA) will be used for all statistical analysis.

## Primary Outcomes

Analysis of change of knowledge will compare differences between the intervention group and the control group as measured by the changes to the composite scores of the knowledge-based test. On factor Analysis of Variance (ANOVA) will be used to compare the differences with an a priori alpha level of 0.05.

Analysis of change in behavior will compare differences between the intervention group and the control group as measured by the changes in the composite scores of the behavioral intervention. On factor Analysis of Variance (ANOVA) will be used to compare the differences with an a priori level of 0.05.