

**Assessing Home Food Environment and Diabetes Self-management Among Adult Type 2
Diabetes Patients**

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Study Protocol

The current research project was approved by the University of Nebraska in Lincoln, Nebraska and the Methodist Health System in Omaha, Nebraska. Study participants were recruited from the Methodist Health System Center for Diabetes and Nutritional Health in Omaha, Nebraska. The center is an ambulatory outpatient clinic for treatment of patients with diabetes. Inclusion criteria were adults aged ≥ 30 years with Type 2 diabetes; self-reported hemoglobin A1C $>6.5\%$, having a cellular phone with the ability to receive text messages and English speaking.

A quasi experimental design was used in this pilot study due to timeframe restraints. Eligible participants who came into the clinic for outpatient diabetes management care were identified and approached. A survey regarding participants' demographics and, relevant risk factors for Type 2 diabetes was completed by all the participants (intervention and control group) at baseline.. The intervention group started approximately two months earlier than the control group. Participants in both the intervention and control groups received the usual care for Type 2 diabetes including an initial visit from either a Registered Dietitian or Certified Diabetes Educator and follow-up visits. The intervention group received three messages weekly (on Mondays, Wednesdays and Fridays) for 12 weeks based on topics regarding nutrition education and diabetes self-care information and skills. The messages were different each week during the first six weeks (Weeks 1 to 6) and repeated during the remaining weeks (Weeks 7 to 12). The messages consisted of strategies to increase fruits and vegetables and reduce high-fat and sugary foods intakes and to improve diabetes self-care skills, increasing physical activity, and increase awareness of CVD risk perception and knowledge (Table X). The text messages were derived from the topics and guidelines provided by the American Association of Diabetes Educator

(AADE) including “Reducing Risks”, “Monitoring”, “Healthy Coping”, “Problem Solving”, “Taking Medication”, “Healthy Eating”, and “Exercise”. Each text message included the novel approach of including a link to a specific AADE7 topic and handout that allowed participants to open and retrieve the specific AADE7 information. Unidirectional text messages were sent by the project investigators to the participants in the intervention group via a computer-based text messaging program through a password protected computer which was only accessed by the investigators. Participants’ phone numbers used for text message intervention was kept private, and they were advised not to reply to the text message. If a participant had a medical concern about his/her diabetes, he/she was advised to contact his/her physician or call 911. The control group (usual care group) did not receive text messages. Participants in both the intervention (text messaging + usual care) and control group completed surveys regarding their awareness of CVD risk, diabetes self-care activities, dietary intake, and physical activity at baseline and at 12-week follow-up (conclusion of the intervention). Further, the participants in the intervention group completed a survey to evaluate their satisfaction with receiving text messaging for managing diabetes after the text messaging intervention was concluded. A \$25 gift card were offered to participants in both intervention and control groups.

Statistical Analysis

Primary analyses were based on participants in the intervention group or control group at the time of the initiation of the intervention (baseline) regardless of adherence status (intent-to-treat analysis). Baseline characteristics were calculated using descriptive statistics and compared between groups using t test for continuous variables and Chi-square analyses for categorical variables. Treatment effects were evaluated by assessing the differences in the outcome variables from baseline to the 12-week follow-up between participants in the intervention group and the

control group using Proc Glimmix procedure. The model included the intercept, time effect (baseline and follow-up), and interactions between treatment groups (intervention and control groups) and the time effect (the absolute treatment effect). Least squares means were calculated for each time and treatment combination and the differences were calculated between treatments within each time point. Estimates of the absolute treatment/intervention effect were determined as follow: [(intervention group follow-up) – (intervention group baseline)] – [(control group follow-up) – (control group baseline)]. To provide perspective on the magnitude of the treatment/intervention effects, we also calculated proportional treatment/intervention effects, defined as (absolute treatment/intervention effect/intervention group baseline) × 100% (e.g., a proportional effect of 55% would mean a 55% increase in the intervention group relative to the control group). The analyses were repeated after the adjustment for unbalanced baseline characteristics (race/ethnicity, education) and the results did not change materially. SAS software (SAS Institute, Cary, NC) was used for analyses. All tests were 2-sided, and $P < 0.05$ was considered statistically significant.