

Technologically Enhanced Coaching (TEC): A Program for Improving Diabetes Outcomes

NCT01855399

Protocol

6/4/12

## Measures and Data Collection

### Overview

Measurement will occur at baseline, 6 months (at the completion of the intervention), and 12 months after enrollment. Variables chosen for measurement are based on our conceptual framework (Section 3.4.1). At baseline, 6 months, and 12 months, patients (participants and peer mentors) will complete a written survey and assessments of A1c and blood pressure. Patients will receive \$25 for each assessment they complete. To understand features of successful vs. less successful peer partnerships, we will conduct semi-structured telephone interviews at 6 months of a purposive sample of participants and mentors in both study arms (choosing a sample with high rates of contact and a sample with low rates of contact). Using standard qualitative methods for identifying key themes in participant's experiences with this new program, we will identify central themes from these interviews associated with the success of the peer relationships and in meeting intervention goals. Participants and peer mentors in the peer mentor +iDecide arm will be asked about their experiences with iDecide and how use of the program affected their subsequent contacts and activities (e.g., setting and meeting 'action plan' goals, effectively raising questions and concerns with PCPs). Quantitative information about use of the IVR system will be collected via computerized records that the system maintains of all contacts with dates and time durations of all contacts as well as of attempted contacts. To assess peer mentors' experiences, we will conduct semi-structured interviews with a purposive sample of peer mentors with differing rates of participation (e.g., those who made regular contact with their assigned peers vs. those who did not).

### 3.6.2 Description of Measures by Aim

**Aim 1:** Test the effectiveness of a technology-enhanced peer coaching (TEC) program in improving glucose control relative to peer support alone. At baseline, 6 months, and 12 months, a trained staff member will measure patients' A1c, using a Bayer DCA 2000+ analyzer, a portable analyzer producing A1c assays in approximately six minutes using finger stick blood samples. These assays have a test coefficient of variation (CV, measure of test precision) <5% as required by the National Diabetes Data Group and accurately measure A1c levels.[78] The DCA 2000 is reliable, easy to use, and much less burdensome to patients than venous blood draws. Our team has familiarity with the DCA 2000 from our prior studies.[40,56] To ensure quality control, venous A1c samples will be drawn from 5% of participants and analyzed at the Detroit VA's lab.

For our "usual care" observed group, we will use CDW data to measure A1c levels. More than 85% of diabetes patients who meet our eligibility criteria receive A1c testing at recommended intervals, which should ensure adequate numbers of patients with follow-up A1c levels in our control sample. For those with missing A1c data, we will use several approaches to examine possible biases (see section 3.7.5).

**Aim 2:** Assess the impact of the intervention on blood pressure and medication adherence as well as on key patient-centered outcomes, including patients' satisfaction and involvement with care, perceived social support, and diabetes-specific quality of life. These measures will be assessed at baseline, 6 months, and 12 months. We will measure blood pressure using an Omron® automatic blood pressure

monitor with memory and take the average of the two readings following American Heart Association guidelines. (Ideally we would also measure lipid levels, but have not found sufficiently reliable point-of-service machines for these measurements. At baseline we will collect information on most recent LDL, HDL, and total cholesterol levels from electronic medical records. If there are no recent values, the iDecide program text in that section will emphasize the importance of having these risk factor levels checked.) The baseline and 6-month surveys will take approximately 25 minutes to complete, and the 12-month survey will take approximately 15 minutes. Measures for the key patient-centered outcomes are:

The Health-Care Climate Questionnaire (HCCQ) (twelve items). The Health-Care Climate Questionnaire (HCCQ) ( $\alpha=0.82$ ) assesses patients' perceptions of the degree to which they experience their health-care providers (or their peer mentor) to be autonomy supportive versus controlling in providing general health support or with respect to a specific health-care issue. It was originally validated in a study of patients visiting their primary-care physicians, was used in a published study of obese patients participating in a weight-loss program, has since been used in multiple studies of professional and lay health care supporters, and a version that includes six items measuring practical support for diabetes self-management has since been validated in two studies. [79] We will ask participants to complete this about their PCP at baseline, six-months, and 12-months. Participants will complete this assessment about their peer mentor at six months.

Involvement in Care Decisions (five items). To assess changes in how involved patients feel they are in diabetes goal and treatment decision-making with their health care providers, we will use the goal-setting subscale of the Patient Assessment of Chronic Illness Care (PACIC).[80]

Diabetes-Specific Social Support (twelve items). To assess perceived diabetes-specific support we will use the Diabetes Support Scale (DSS), a 12-item scale developed to assess whether an Internet-based diabetes support group changed participants' perceptions of social support, social network size, or actual provision of support ( $\alpha> 0.90$ ). The instrument correlates with illness intrusiveness and self-care behaviors and is responsive to intervention effects.[81]

Diabetes-Specific Distress (two items). This instrument captures the patient's perspective on the emotional burden of diabetes and its treatment.[82] It has consistently high internal reliability with a Cronbach's  $\alpha$  of 0.90 and good convergent validity with a measure of general psychological distress ( $r=.63$ ). It is also associated with changes in A1c and other outcomes over time. In a review of seven effective diabetes intervention studies, mean scores improved from baseline to follow up in all studies.[83]

Aim 3: Identify patient characteristics associated with engagement in the intervention and mediators and moderators of the intervention's impact on patient outcomes.

Table 2 presents the measures we will use to assess factors we hypothesize may be associated with willingness to engage in the intervention (which may also be moderators) and mediators and

moderators of intervention effects as well as time points at which we will measure each of these. We include measures found to be significant mediators and moderators of effects in our P2P RCT.[40,84]

Mediators      Time Points\*      Original Source

Medication-taking Self-efficacy    1, 2      Perceived Competence Scale[85]

Autonomous Motivation      1, 2      Treatment Self-Regulation Questionnaire (TSRQ[85])

Medication adherence    1,2      Morisky Medication Adherence Measure[86]

Assessment of level and type of support received by Peer coach    2      Process measures used in P2P and by Robert Wood Johnson Foundation Diabetes Initiative [40]

Self-efficacy for shared decision-making with providers    1,2      Self-efficacy for Decision-making scale[87]

Medication doses and insulin starts      1,2      Survey items and electronic medical records

Moderators/Engagement Factors

Race    1      2010 US Census measures

Preferred and actual decision-making with providers    1      Preferred and Actual Participation in Decision-making Scales[88]

Attachment Style      1      Relationship Questionnaire[89]

Perceived Need for DM self-management support      1      Support Needs Scale from Diabetes Care Profile[90]

Perceived Benefits and Barriers to Taking DM medications      1      Two subscales from instrument assessing perceived barriers to and benefits from taking diabetes medications based on health beliefs model[91]

Health Literacy    1      Functional Health Literacy Screener[18]

Numeracy      1      Subjective Numeracy Scale (SNS)[92]

Food insecurity 1      Food Security Survey Module [93]

Neighborhood Safety, Availability of Healthy Foods, and Walking Environment 1      Neighborhood Safety Measure, Availability of Healthy Foods, Walking Environment [94]

\*Time point 1 is baseline, 2 is at 6 months, 3 is at 12 months.

We will measure standard demographic information including age, gender, and marital status. Socio-economic status (SES) will be measured using highest grade in school completed, income, and household size. We will collect data on diabetes duration and whether all diabetes care is received at VA and distance Veteran travels to Detroit VA. We will also collect data on any adverse symptoms experienced during the study period such as hypoglycemic symptoms or episodes, although have had no hypoglycemic episodes in our prior peer support interventions. Data on diabetes-related complications and other co-morbidities will be drawn from EMRs.