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Diabetes Nurse Case Management and Motivational Interviewing for Change (DYNAMIC): Study Design and Baseline Characteristics in the Chronic Care Model for Type 2 Diabetes

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Abstract

Background—Despite evidence that diabetes is costly and devastating, the health care system is poorly equipped to meet the challenges of chronic disease care. The Penn State Institute of Diabetes & Obesity is evaluating a model of managing Type 2 DM which includes nurse case management (NCM) and motivational interviewing (MI) to foster behavior change. The primary care intervention is designed to improve patients' self care and to reduce clinical inertia through provider use of standardized clinical guidelines to achieve better diabetes outcomes.

Methods—This RCT tests the efficacy of an enhanced NCM intervention on Type 2 DM (n=549) patient outcomes mediated by changes in self-care behavior and diabetes management. Outcome measures include: (a) effect on clinical parameters such as HbA1c (<7), BP (<130/80), and LDL (<100), depression scores and weight; (b) process measures such as complication screening; (c) patient psychological and behavioral outcomes as measured by emotional distress (PAID), diabetes-specific quality of life (ADDQoL), patient satisfaction (DTSQ), self-care activities (SDSCA); and (d) physician satisfaction and cost-effectiveness of the intervention.

Conclusions—Baseline includes (mean) age = 58; BMI = 34.4; 57% females; 47% Caucasian, and 39% Hispanic. Patients had elevated HbA1c (8.4), BP (137/77) and LDL (114). Overall, patients were depressed (CES-D = 21.6) and had an extremely negative quality of life (ADDQoL = -1.58). We believe that enhanced NCM will both improve self-care and reduce emotional distress for patients with diabetes. If proven effective, enhanced NCM may be translated to other chronic illnesses.

Keywords

nurse case management; diabetes; primary care; behavior change

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Introduction

In 2005, the prevalence of diabetes in the U.S. was 20.8 million (7% of the population), with 1.5 million new cases diagnosed in people aged 20 years or older [1]. The total annual economic cost of diabetes in 2007 was greater than \$174 billion, with expenditures for patients with diabetes at a rate 2.3 times higher than those without the disease [2]. Diabetes is both a financial and emotional burden, with studies showing an adverse impact on QOL [3,4] and the incidence of depression [5]. This in turn negatively affects the patient's ability to carry out self-management [6], which can lead to significantly worse glycemic control [6,7].

Self management is the primary goal of diabetes education interventions, as costs and complications associated with diabetes (i.e. end-stage renal disease, blindness, and amputations) are largely preventable. Evidence-based studies indicate that control of glucose (HbA1c < 7), BP (<130/80), and LDL cholesterol (< 100) decreases the incidence and progression of both microvascular and macrovascular complications of diabetes, and is cost-effective [8,9]. In addition, the use of aspirin to prevent heart disease, yearly screening for nephropathy, foot and ophthalmological complications, and the use of ACE inhibitors or ARBs to prevent kidney disease is recommended [9,10].

However, despite RCTs that have established “gold standard” approaches for diabetes, the majority of patients (93%) do not achieve the collective recommended self-management goals for HbA1C, LDL, and BP [11-13]. Over one-third (36.5%) of adults have A1C levels $\geq$ 8%, the level suggested by the American Diabetes Association for focused treatment intensification [13]. Thirty-two percent are above goal for BP (130/80), 66.2% have LDL values >100, and nearly a third of patients do not receive yearly dilated eye (32.3%) or foot (31.7%) exams [14]. Depression is recognized and treated in only one-third of cases at the primary care level, even though psychotherapy and psychopharmacy have been shown to have significant beneficial effects on mood and glycemic control [15-17]. Contributing to these poor outcomes is clinical inertia, or the failure of health care providers to initiate or intensify therapy when indicated [18] and patient adherence to prescribed treatments [10,19].

Current barriers to managing diabetes in the primary care setting for physicians include insufficient time to monitor and treat the complex clinical issues during visits, general lack of behavioral change skills, and lack of guideline adherence [20, 21]. Nurses are the optimal choice to implement clinical guidelines, in part, because they spend more time with patients and have a professional background that enhances this method of patient care.

Nursing Interventions

The American Nurses Association has defined NCM as “a dynamic and collaborative approach to providing and coordinating health care services to a defined population. It is a participative process to identify and facilitate options and services for meeting individuals' health needs, while decreasing fragmentation and duplication of care and enhancing quality, cost-effective clinical outcomes” [22]. NCM offers a intervention to self-management care through: (a) a cost-effective approach to patient education and support that fosters adherence to the self management regimen; (b) care coordination, linking the service systems of PCP, diabetes educator, and community resources; and (c) implementation and evaluation of diabetes and comorbidity guidelines, offering education and motivating patients to engage in diabetes self-management [23-25]. In this regard, nurse case managers can identify patients at risk, conduct a medical and psychological assessment, provide an individualized patient-centered care plan, implement the care plan and monitor the outcomes. Nurse case managers remove some of the burden of time and effort from the physicians to create an individualized plan to improve clinical outcomes.

Effective strategies which have used registered nurses to improve clinical outcomes include patient empowerment, education, and psychosocial understanding [4]. For example, an initial pilot study using NCM during a one-year randomized-controlled trial showed significant improvements in BP (137/77 to 129/72 in the intervention group and reduced emotional distress as assessed by the Problem Areas in Diabetes (PAID) scale (from 23 to 10 in intervention group) [26]. Effects beyond the time of the immediate intervention were not determined. In a multi-regression analysis assessing the impact of 11 distinct strategies for improving the care of adults with type 2 diabetes, the use of case management significantly reduced A1C in patients with diabetes more than other outpatient care interventions that did not involve NCM [27]. In addition, a recent meta-analysis of diabetes NCM interventions has indicated a robust effect size [28]. However, few studies have utilized an RCT to examine the efficacy of NCM on some of the most important co-morbidities of diabetes care (i.e. BP and cholesterol control), complication screening, and alleviating emotional distress with diabetes that can hamper adherence [26]. Cost effectiveness is rarely researched and the interventions are limited in time and scope or poorly described.

Motivational Interviewing

One of the goals of the NCM intervention will be to significantly promote self-management support and education through a Motivational Interviewing (MI) technique [29,30]. Although current models of behavior change emphasize the individual internal behavior change processes (which generally include social contexts and perceptions of individual locus of control), the motivation for health behavior has also been recognized as an important factor for change [29]. Originally developed as an alternative to traditional “top-down” approaches to addictions treatment [31], MI is a patient-centered counseling approach that actively engages patients in defining the current problem areas and any potential strategies to tackle issues related to diabetes [32]. Specifically, MI stresses the importance of understanding each patient's unique perspective and priorities when developing a treatment plan. Consistent with the patient-centered approach, MI uses reflective listening, therapeutic communication, and rapport-building skills to empower the patient to make behavior changes.

The rapidly growing evidence base for MI has been summarized in a meta-analysis of 72 clinical trials spanning a range of target health issues [33]. In this meta-analysis, the average short-term between-group effect size of MI was 0.77, decreasing to 0.30 at follow-ups to one year compared to the control group. Successful MI works through prompting a dialogue that reduces the patient's ambivalence toward change and a patient-clinician collaboration to minimize or remove current barriers to healthier behaviors. There is support for MI with chronically ill persons and those who need to improve self-care health behaviors [34,35], thus, this study aims to translate empirical knowledge regarding diabetes treatment and management (with MI being a significant intervention) into sustainable and effective clinical practice.

Target Populations

Among ethnic minority populations in the U.S, significantly more Hispanics have diabetes [2], and more Hispanics are uninsured (20%) less than other groups [36]. Even when covered by insurance, Hispanics (especially non-English speaking) have lower outpatient utilization rates [37] and longer and more expensive hospital stays than non-Hispanic whites. Little comparative research has been conducted on the emotional distress experienced by Hispanic patients living with type 2 diabetes [38]. For these reasons, participants have been recruited from three Reading Hospital-affiliated primary care sites with a predominantly underserved Hispanic population so that 39% of the total study population is Hispanic.

The populations targeted by the study are those in the greatest need of intervention. The focus is on the primary care environment, where most patients with diabetes seek on-going health

care. High-risk patients were identified by database and chart abstraction and randomized to NCM vs. usual care for the two-year intervention. To recruit appropriate participants (including a substantial minority sample), the Penn State Institute of Diabetes & Obesity patient registry system queried the laboratory database from two medical centers (the Penn State Hershey Medical Center and Reading Hospital) to identify potential patients [39]. Eligibility criteria included one or more of the following: uncontrolled DM ($HbA1c > 8.5$), hypertension ($BP > 140/90$), and/or hyperlipidemia ($LDL > 130$). Patients were excluded if they could not communicate in English or Spanish, or if they were residents of nursing homes. Age range was 18-75. The final sample size ($n=549$) provides power of 80% to detect significant differences in A1C of 0.85 at the $p < 0.05$ level (two sided t-test), assuming a 20% dropout rate.

Study Design and Methods

The purpose of the current study is to determine whether the addition of enhanced NCM to primary physician care will improve outcomes for patients with type 2 diabetes over a two year period. Our goal is to translate principles of NCM and MI into a clinical intervention that will mitigate the shortcomings of current published research. By documenting the training process and intervention delivery carefully, the intervention will be generalizable to other primary care practices. The study also will address significant health disparities with a focus on an underserved Hispanic population. The hypothesis is that the additional of NCM to usual care will improve clinical outcomes (% of patients at goal for A1C, BP and cholesterol) compared to usual care ($p < .05$). The secondary hypothesis is that the intervention will be cost-effective and result in improvements in self-care behavior.

Each participating patient was randomly assigned to one the control or treatment group using a stratified permuted block randomization scheme, with primary care provider the sole stratification factor. Fourteen primary care provider strata were defined according to the 13 providers with the largest number of eligible patients; the fourteenth strata consisted of eligible patients served by any of the remaining primary care providers. The permuted block (size 6) aspect of the randomization scheme ensured that treatment assignment remained balanced throughout the enrollment period.

Intervention

Patients randomized to NCM will be followed by one of the two trained nurse case manager for the two year duration of the study. Each nurse has a patient caseload of approximately 110 to permit incorporation of MI in the intervention. This case load is consistent with what has been used previously in other NCM interventions [27,40]. In order to provide optimum care for Hispanic patients at the Reading location practices, a bilingual (English/Spanish) and bicultural nurse with experience providing care to Hispanic patients is working at that site. Intervention group patients continue to see their PCP as usual but also meet individually with a nurse case manager. The control group patients have no access to the nurse case manager. Usual care typically involves visits with a PCP every three months (PCPs are not taught MI), and patients randomized to the control group remain solely under the treatment of their PCP. Eligible patients are identified through the registry based on laboratory and BP entry criteria. After an initial letter inviting eligible participants to the study, they are approached during usual care visits for informed consent. Randomization occurs after enrollment; only after informed consent are they randomized to usual care. Patients who do not wish to enroll continue their usual care with their PCP. The enhanced NCM intervention will use the conceptual model of the Chronic Care Model [41] to foster productive interactions between an informed, activated patient and a prepared, proactive practice team (Figure 1).

The Chronic Care Model has been shown to provide interactions between patients and providers that support optimal patient functional and clinical outcomes [42-44]. Nurse case managers were chosen to deliver the intervention because of the ongoing need for assessment of goal attainment, and because of their ability to work with patients to reduce ambivalence to behavior change, collaborate with PCPs, and reinforce diabetes education. The nurse case managers are integrated into the primary care setting and have a continuous relationship with study participants including both direct clinical interventions and collaboration with their PCP, endocrinologist, diabetes educator, and dietitian.

This study will incorporate the use of MI to deliver the self-management intervention in order to further support behavior change. Five core aspects of the intervention are designed to enhance self-management.

1. Diabetes Self-Management Education and Behavior Change Counseling with Motivational Interviewing

Basic skills such as glucose monitoring, insulin administration, teaching about diabetes and its complications, and features of medical nutrition therapy are taught to the study participants with an emphasis on focusing on the patient's own life priorities and internal motivations. MI is used to facilitate resolution of the ambivalence that often prevents patients from engaging in the self care necessary to manage a complex, chronic disease. In addition, the principles of autonomy, support, and collaboration, essential to MI, are used to assist the patient in selecting appropriate, concrete behavioral goals, in developing plans for reaching those goals, and in evaluating the progress and adequacy of those plans. Specific behavior goals are based on ADA Clinical Guidelines [11] and include (a) Dietary adherence; (b) Moderate exercise 30 minutes for 3 days/week, adjusted for patient ability, (c) Medication adherence, and (d) Monitoring. Improving patient self care is critical to improving patient medical outcomes.

2. Tracking of Patient Outcomes

A computerized patient registry system allows nurse case managers to have up-to-date information regarding their patients [45]. Data entry by the nurses into the registry allows printing of a single sheet prior to each patient visit that summarizes self-care goals, clinical parameters over time (BP, HbA1C, LDL, last ophthalmologic exam, aspirin use, foot exam), and provides prompts for issues to be addressed at a given visit.

3. Standing Orders for Process Measures

Standing orders for established clinical practice guidelines regarding frequency of laboratory testing (HbA1C, LDL, nephropathy screen), yearly ophthalmologic exam and performance of foot exam by the nurses facilitates implementation of these national recommendations.

4. Clinical Care Guidelines to Prompt Physicians on Interventions

Evidence-based clinical guidelines inform the nurse case managers in their interactions with providers. Nurse case managers collaborate with the PCP by sharing clinical and/or management issues and providing the guideline recommendations for diabetes [1] and depression [46] so the physician can make appropriate decisions. The guidelines have been presented to all physicians through a series of meetings by the primary clinical investigators.

5. Individualized Patient Follow-Up

Nurse case managers meet individually with patients in the treatment group throughout the study. At the initiation of the study, the visits were scheduled at baseline, 2-wk, 6-wk, 3-mo, 6-mo, and 12-mo and then at a minimum of every 6 months thereafter. On average, one hour is spent in each patient visit, with telephone and e-mail correspondence supplementing office

visits where appropriate. Follow-up visits include reinforcement of behavior change goals, clinical assessments and attainment of clinical goals.

Two strategies used to ensure consistency of the intervention and reproducibility of the results include nurse training and a standardized MI training curriculum. Although other interventions have included MI, the methodologies are not clear and therefore cannot be replicated. This NCM clinical training uses a standardized curriculum that not only addresses management of blood glucoses, hypertension, hyperlipidemia, and depression, but also cultural competency related to interviewing, recruitment and communication techniques appropriate to the Hispanic population. The medical management curriculum is based on the ADA's Clinical Practice Recommendations [9]. Consistent care is reinforced through review of case scenarios, taped interviews, and feedback. It focuses on patient-centered counseling, and the promotion of self-care behavior change. The standardized MI training curriculum involves active review of the nurse case manager's performance using review of counseling sessions with patients captured by audiotape. Thus, the nurse and trainer can quickly identify areas for improvement and practice correct techniques in the same session. This provides a level of structure and standardization that will both provide guidance for nurses implementing new skills and strengthen the integrity of the MI component of the intervention.

Study Outcomes

Mediator variables for patients include changes in self-behavior (diet, exercise, home glucose monitoring and medication adherence) and change in emotional distress. Physician outcomes are measured by changes in medication treatment (for glucose, lipids, BP, depression) as well as more predictable and consistent complication screening.

The primary study outcomes are percent of patients reaching their goal for HbA1c, BP, LDL, and percent of patients at goal for all three parameters. Important secondary outcome measures include number of patients with depression as measured by the CES-D, the rate of ophthalmologic and foot exams, nephropathy assessment and treatment and aspirin use, cost-effectiveness and psychological/behavioral outcomes of the intervention.

Patient Outcomes

To evaluate patient outcomes, five surveys were used: (a) the Audit of Diabetes Dependent Quality of Life (ADDQoL) [47]; (b) the Problem Areas in Diabetes (PAID) scale [48,49]; (c) the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [50,51]; (d) the Summary of Diabetes Self Care Activities (SDSCA) [52]; and (e) a validated Provider Satisfaction Inventory which analyzes four categories, including chronic disease management, collaborative team practice, outcomes, and supportive environments [53]. ADDQoL measures the perceived effects of diabetes and its treatment on QOL and assesses 18-19 personally applicable life domains. Patients were given 1 of 2 different versions of the ADDQoL. Both versions indicated the importance and expected quality of life without diabetes, weighted together for a single impact score. The more negative the score, the more negative impact of diabetes on life. Emotional distress, as determined by PAID (reliability >.90) was measured. The scale includes 20 items (range 0-100) with higher scores indicating higher distress. Satisfaction with diabetes treatment was assessed by the widely used DTSQ, containing 6 items with a total maximal score of 36 (higher scores indicating higher satisfaction with treatment). Depressive symptoms were evaluated by the CES-D scale which contains 20 items (range 0-60) where a score >16 is considered depressed. In the population, 61.9% had a score > 16 (326/527, 22 missing). Usual self care behaviors were measured by the SDSCA used to evaluate adherence to diet, exercise, blood glucose testing, foot care, smoking, and self care recommendations in Type 2 diabetes.

Evaluation data are collected by the Pennsylvania State Survey Research Center, including surveys measuring psychological and behavioral outcomes (Table 1, Aim 2) to the study population at baseline and will continue yearly through the two-year study. A multi-modal approach involving e-mails, mailings, and telephone follow-up is used to maximize response rates. The laboratory information is electronically transferred into a secure system that employs regular validation procedures.

Cost Effectiveness Outcomes

In addition to determining whether NCM improves key clinical outcomes, NCM will be analyzed for cost effectiveness. Providers, payors and society have a potential interest in the economic outcomes of this type of intervention, i.e. whether to provide NCM support in hospital care and how much to reimburse for NCM support. Immediate and long-term (two year) estimated costs include fixed costs, direct medical costs, and indirect costs.

Fixed costs includes all costs to the provider of implementing the clinical components of the NCM protocol, including computer requirements over and above existing infrastructure, and initial training of the nurse case managers. Direct costs involve tracking resource utilization, i.e. office visits, NCM visits, lab tests, diagnostic tests, medications, and physician referrals. The menu of hospital costs will be applied to estimate direct costs to providers, and Medicare reimbursement rates will be determined for these services to estimate costs to payors. Indirect costs to patients will be estimated by administering a survey at the first patient visit to assess: (a) distance traveled, (b) time spent in the waiting room, (c) time spent away from work, (d) time required by other family members, and (e) out of pocket expenses. This data, combined with data on patient income and health insurance collected in the initial screening, allows for an estimate of indirect costs to patients. By analyzing combinations of these cost components, an economic evaluation will be made to inform all the parties that support diabetes care.

Analysis

The primary outcome variables to be measured during the trial will represent the severity and condition of disease as defined by meeting the established criteria for high-risk diabetes (see Table 2 for baseline measures of these outcomes). Absolute measurements of HbA1C, blood pressure, and LDL cholesterol will also be included as primary clinical outcome variables. Other important outcomes measures related to clinical process include change in weight, proportion of patients with CES-D depression score above 16, the rate of ophthalmologic and foot exams, neuropathy assessment and treatment and aspirin use.

For binary outcome measures such as success meeting HbA1C, BP and LDL goals, logistic regression will be used to model the relationships between the outcome and treatment group, clinical center, age, ethnic group and gender. Other potentially important covariates will be identified through exploratory analyses. The longitudinal aspect of the data can be incorporated into the model in various ways, we will utilize the model generalized estimating equations (GEE) approach [59].

For continuous outcomes such as HbA1C levels, systolic blood pressure and lipid levels, a repeated measures analysis of variance is appropriate [60]. Fixed effect parameters will include treatment group, clinical center, age, ethnic group, gender, and other potentially important covariates. A repeated measures models will also be used to compare treatment groups with respect to the secondary patient outcomes measures of emotional distress (PAID), diabetes specific QOL (ADDQoL), patient satisfaction (DTSQ), and the health care behavior (SDSCA).

The primary data analysis will follow the intent-to-treat (ITT) paradigm under which all available data from all individuals is analyzed according to treatment group assignment

regardless of whether or not each individual actually received the assigned treatment. In this proposed study, non-compliance with the nurse case manager treatment assignment (e.g., refusal to meet with nurse case manager) is a possibility. Any participant who is non-compliant with the assigned treatment will be followed with respect to collection of clinical assessment data unless he/she withdraws consent and drops out of the study. There are several alternatives to intent-to-treat analyses. The as-treated (AT) approach makes use of all the available data while the per-protocol (PP) approach utilizes data from only those subjects who are compliant with the assigned treatment. The ITT, AT and PP approaches are subject to selection bias, the extent of which depends directly on the proportion of subjects who are non-compliant. If anything, non-compliance in this study would most likely lead to underestimation of treatment effects in an intent-to-treat analysis and overestimation of treatment effects in either the PP or AT analyses. This is because only the treatment can be non-compliant. There is no possibility of non-compliance in the control group since they will not have access to the nurse case manager.

The intent-to-treat approach is free from selection bias if an appropriate stratification can be defined. The major disadvantage of the ITT approach is that it is inefficient compared to the other methods, particularly for small samples. Our study will entail a fairly large sample and we have access to a number of covariates which might be expected to be related to non-compliance such as age, gender and ethnicity. Therefore, we feel that ITT analysis is viable for this study.

Another difficulty in our study is that subjects are not likely to be either fully compliant or fully non-compliant, which is necessary for AT, PP and ITT analyses. Therefore, we will empirically define, post-hoc, a threshold for identifying “compliers” and “non-compliers”. This will, admittedly, create an artificial distinction, but there are no viable alternatives to this approach. In addition to non-compliance, incomplete data will also occur in this study. Incomplete longitudinal data patterns can result from (a) participant withdrawals or drop-outs, (b) missed and/or mis-timed participant visits, and (c) incomplete data collection during a participant visit. Data that were intended to be collected, but were not collected for any of the above reasons are termed “missing” data. Longitudinal data analyses can accommodate such missing data; however, it is possible for these analyses to be biased depending on why the data is missing. Missingness mechanisms are classified as missing completely at random, missing at random, or nonignorable. The distinction between missing completely at random and missing at random is related to whether the probability of any particular data point being missing depends on measureable parameters. Under either of these random missingness scenarios, the analyses that we propose can be used to obtain unbiased estimates of treatment effect. If there is nonignorable missing data, which occurs when the probability of any particular data point being missing depends on the unobserved data. For example, participants who are lost to follow-up may tend to exhibit other behaviors which put them at higher risk for worsening disease. We feel that it is reasonable to suspect that nonignorable missing data might be present in our study. Therefore, we will perform sensitivity analyses to determine the extent of the potential bias that might affect results. We will also analyze the outcomes to compare the relative effectiveness of Hispanic and non-Hispanic populations as part of the data analysis plan.

Results

The baseline demographics and baseline survey scores of the patient population were determined (also Table 2). Primary outcomes were HbA1C, lipids, and blood pressure (BP). Baseline characteristics (gender, race, age, BMI, educational level, and income) were not significantly different in the intervention and control groups. The treatment group receiving the NCM intervention (N=276) reported a mean A1C of 8.29 ± 2.11 , LDL levels of 115.67

± 36.57 , and BP 136/79. The control group (N=273) reported a mean A1C of 8.50 ± 2.16 , LDL levels of 112.11 ± 42.10 and BP 139/76. Although 47% of the population was White, a substantial percentage (39%) self-identified as Hispanic. Also noteworthy is the percentage of the population (42%) that generated either less than \$15,000 of yearly income. The baseline survey scores were determined for emotional distress (PAID), treatment satisfaction (DTSQ), and depression (CES-D). Overall there was not a statistically significant difference between treatment groups.

Mean PAID score reported in studies of patients with Type 2 DM varied between 25.0 and 35.9 [49,24]; baseline for the DYNAMIC population was consistent with these scores, totaling 29.6 in the control group and 28.7 in the NCM treatment group (not a statistically significant difference between treatment groups). The DYNAMIC patient score on the DTSQ was 9.1 in the control group and 8.3 in the NCM treatment group, thus, patient satisfaction with treatment was very low. The population for the study reported a mean CES-D score of 21.9 in the control groups and 21.4 in the NCM treatment group (not a statistically significant difference between treatment groups), thus the population is highly depressed.

The DYNAMIC baseline total score for each version of the ADDQoL (Version 1 based on a 7-point impact scale and Version 2 based on a 5-point impact scale) was -1.58 and -0.64 respectively, thus indicating an extremely negative quality of life with diabetes (Table 3). Among Version 1 respondents, the domain in which diabetes had the most negative impact was enjoyment of vacations. Among Version 2 respondents, the domain in which diabetes had the most negative impact was enjoyment of food and drinks. Among all respondents combined, the domains in which diabetes had a slightly positive impact were self-confidence (impact score of 0.01) and the way in which other people generally react to them as a diabetes patient (impact score of 0.025). Version 1 respondents rated their working life and work-related opportunities with the highest importance among the 18 domains, but the *impact* of diabetes on their employment/career was rated with a low score of -0.5, indicating that diabetes has a fairly negative impact on employment/career. Version 2 respondents rated their family life with the highest importance, and the impact of diabetes on their family life was rated with a score of zero (no impact). As shown in Table 4, six categories (not all reported) in the SDSCA survey were compared to the DYNAMIC population.

In summary, the DYNAMIC high-risk population has higher scores for depression and an extremely negative perceived impact of diabetes on QOL. They are generally not adherent to diet recommendations in particular, not satisfied with their current level of care, and need improvements in A1C, LDL and BP. This reinforces that many patients not at goal for important clinical parameters likely have multiple barriers including depression, poor adherence to treatment recommendations and less satisfaction with treatment. Therefore, this specific patient population was in need of improved outcomes mediated by changes in self-care behavior and diabetes management. This study should provide the quantitative information necessary for the formulation of evidence-based policy regarding NCM as an intervention to improve outcomes in patients with diabetes.

Conclusions

Evidence exists that optimum glucose control is important to prevent diabetes complications and improve overall health. The primary goal of the DYNAMIC study is to evaluate the effectiveness of an enhanced nurse case management intervention to improve clinical and psychological outcomes in patients with diabetes in primary care setting, thus determining the impact and sustainability of the intervention on glycemic and lipid control over two years. The intervention is designed to incorporate aspects of the chronic care model with the addition of self-management support through MI and education. In addition, extensive nurse training and

increased attention to clinical care guidelines for PCPs will improve outcomes. The study will also evaluate cost-effectiveness of the intervention and feasibility of incorporating the strategy into the primary care setting.

The DYNAMIC intervention addresses important questions regarding the use of nurse case managers in overall diabetes care, the role of health care providers to initiate or intensify therapy when indicated, and the psychosocial effects of diabetes on emotional distress, quality of life, and self-care behaviors. Interventions sensitive to the needs of Hispanic individuals, who have a higher incidence of problems with diabetes, are critical in order to improve diabetes outcomes for this population. If proven beneficial, NCM could be integrated in practices worldwide with a substantial impact on improving costs, outcomes, and the lives of those with diabetes. The intervention could also be adapted to other chronic illnesses and conditions through other randomized, controlled interventions.

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Abbreviations

BP	blood pressure
DM	diabetes mellitus
LDL	low-density lipoprotein
NCM	nurse case management
PCP	primary care physician
MI	motivation interviewing
RCT	randomized controlled trial
QOL	quality of life

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Figure 1.
Revised Chronic Care Model with added MI and NCM interventions.

Table 1
Nurse Case Management (NCM) study outcomes

<u>Specific Aim 1 - Primary Outcomes (study powered for these, data obtained through computerized registry)</u>
% of patients reaching goal HbA1C (<7)
% of patients with BP goal (<130/80)
% of patients with LDL at goal (<100)
% of patients at goal for all three parameters (HbA1C <7, BP <130/80, LDL <100)
Secondary outcomes: % of patients at or above CES-D depression score 16 for severe depression Change in weight
<u>Other Clinical Process Measures (determined by chart review)</u>
% of patients with yearly ophthalmologic exam
% of patients with yearly foot exam
% of patients with assessment for nephropathy
% of patients with nephropathy on ACE inhibitor or ARB
% of patients on aspirin
<u>Specific Aim 2- Patient outcomes obtained by surveys (Penn State Survey Institute)</u>
Emotional distress (PAID survey)
Diabetes specific quality of life (ADDQoL)
Patient satisfaction survey (DTSQ)
Diabetes self care activities survey (SCSCA)
Physician satisfaction – survey filled out by physician
<u>Specific Aim 3-- Costs (determined by chart abstraction and financial databases)</u>
Costs and Cost Effectiveness
<u>Specific Aim 4 – Qualitative evaluation of the process implementation</u>

Table 2
Baseline Outcome Variables of the DYNAMIC patient population

Characteristic	Control	Treatment	P-Value
<i>Population Data</i> (n = 549)	273	276	
Age in years, mean (SD)	58 (11.06)	58 (11.45)	
Female	53%	61%	
Race (% White)	49%	45%	0.2887
(% Hispanic)	39%	38%	0.8497
Education (% some college)	34%	31%	0.4125
Income (\$<15,000/y per family)	5%	5%	0.9763
(\$<35,000/y per family)	16%	13%	0.2514
<i>Medical Data Outcomes</i>			
BMI, mean (SD)	34.8 (9.15)	33.9 (7.48)	0.2363
A1C, mean	8.50 (2.16)	8.29 (2.11)	
A1C in control (<7)	29%	34%	
Lipids in control (LDL < 100 mg/dL)	45%	38%	
Systolic BP control (<130)	27%	35%	
Diastolic BP control (<80)	55%	51%	
Overall control (A1C, LDL, and BP)	1.2%	1.2%	
LDL, mean	112.2 (42.16)	115.5 (36.64)	
Systolic BP, mean	139.0 (17.00)	135.7 (16.29)	
Diastolic BP, mean	76.1 (10.63)	78.8 (11.91)	
<i>Survey Data</i>			
PAID (Emotional Distress)	29.6 (24.19)	28.7 (23.13)	
DTSQ (Treatment Satisfaction)	9.1 (8.01)	8.3 (7.70)	
CES-D (Depression)	21.9 (8.97)	21.4 (9.14)	

Table 3

Summary of Audit of Diabetes Dependent Quality of Life (ADDQoL) Measures

Domain	<u>Weighted Scores (Impact × Importance)</u>	
	Version 1 (7-point Impact Scale)	Version 2 (5-point Impact Scale)
Leisure	-2.75	-0.42
Employment/Career	-1.32	-0.14
Travel	-1.24	0.06
Vacation	-3.05	-0.87
Physical Ability	-1.41	-0.62
Family Life	-1.04	0
Friends/Social Life	-1.18	0.21
Personal Relationship	-0.20	-0.32
Sex Life	-1.22	-0.79
Physical Appearance	-1.37	-0.02
Self-Confidence	0.24	-0.32
Motivation	-2.28	-0.50
People Fuss	-0.70	0.89
Feelings about Future	-0.12	-1.19
Financial Situation	-0.56	-0.27

Table 4
Baseline Summary of Diabetes Self Care Activities (SDSCA) data

Categories of SDSCA	DYNAMIC population (N=549)
1. General diet, compliance with	3.4 (2.26) days of the week
2. Specific diet, compliance with	3.59 (1.63)
3. Exercise	1.9 (2.00)
4. Self-monitoring of blood glucose	3.98 (2.95)
5. Foot care	4.0 (2.62)
6. Cigarette smoking	18% smokers