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Evaluating the Efficacy of an Empowerment-Based Self-Management Consultant Intervention: Results of a Two-Year Randomized Controlled Trial

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Abstract

Objectives—This study was conducted to determine if an empowerment-based Diabetes Self-Management Consultant (DSMC) was more effective than a group receiving Mailed metabolic Assessments Only (MAO) in improving diabetes-related quality of life and blood glucose control.

Materials and Methods—A two-year clinical trial, in which 310 patients with type 2 diabetes were randomized to the DSMC intervention or the MAO group. The DSMC met with the patient to review the baseline assessments, then met with this review was patient and the patient's physician. Subsequently patients received monthly telephone calls from the DSMC who used the empowerment approach to help patients identify self-management problems, consider options, set goals and make adjustments to their diabetes self-management plans.

Results—The Diabetes Self-Management Consultant (DSMC) intervention resulted in improvements in diabetes related quality of life (PAID) $p = .008$, the Empowerment Scale $p = .024$, A1C $p = .016$, Perceived understanding of diabetes $p = .001$ and satisfaction with diabetes care $p = .019$ as compared to the MAO group.

Discussion/Conclusion—The DSMC the intervention resulted in a broad array of modest diabetes related improvements. A promising area for future research would be to test the efficacy of combining an empowerment-based DSMC intervention with case management using algorithm-based medication adjustments for higher risk patients.

Keywords

collaborative care; empowerment; patient education; psychosocial

Introduction

Although substantial resources have been devoted to improving diabetes care and outcomes, a recent study indicated that less than half of American diabetes patients achieve the American Diabetes Association's recommended glycosylated hemoglobin A1C target value of $<7.0\%$ [1]. Research has shown promising results for diabetes case management. Interventions using nurse case management have yielded improvements in metabolic and cardiovascular functioning including A1C [2–9], fasting blood glucose [4,5], serum cholesterol [6,8], LDL

[6,8], triglycerides [10], systolic blood pressure [2], and diastolic blood pressure [8,10]. Other studies have demonstrated that case management increases knowledge regarding diabetes care [8] and improves a variety of self-care practices such as consuming foods with less carbohydrate and fat [7], monitoring blood glucose [5,7,9,11], inspecting feet [9,11], and monitoring weight [5]. Improvements have also been seen in the timeliness of performing care recommendations such as lipid panels [11], foot exams [5,9,11], retinal exams, renal assessment, and dental exams [9]. Finally, these interventions have shown patients to report improved health status [4], better glycemic control [5], fewer symptoms of hyperglycemia and hypoglycemia [5,11], and greater satisfaction with care [8,11,12].

However these studies all lacked a theory-based approach to facilitating health-related behavior change as part of the case management. Without an understanding of what structured process (if any) guided the nurse case managers approach to interacting with patients it is difficult if not impossible to compare more successful programs with less successful programs, understand why various programs had different impacts on different outcomes, or replicate the more successful programs. Such a lack results in a “Black Box” problem, in which the necessary and sufficient mechanisms of change are unknown and therefore difficult to optimize. The intervention strategies used by the DSMCs in the current study were guided by the empowerment philosophy [13] and the theory of autonomy motivation [14], which have been shown to be effective frameworks for a variety of diabetes interventions designed to improve communication and facilitate behavior change. [15–19]

Virtually all interventions designed for patients with diabetes emphasize behavior change. However, a key question is: Behavior change towards what end? Is the intervention designed to improve compliance with diabetes self-management recommendations or is it designed to foster patient autonomy, self-reliance, enhanced knowledge, as well as problem solving and goal setting skills? The empowerment approach is designed to help patients become more autonomous and informed decision makers and more skilled at solving problems and setting goals. The empowerment approach infused every aspect of the DSMC intervention.

Objectives

The purpose of this study was to determine if a DSMC intervention using the empowerment approach to facilitating self-directed behavior change along with mailed metabolic assessments resulted in better outcomes for the patients who completed the DSMC interventions than patients receiving metabolic assessment results only (MAO) in improving diabetes-related quality of life and glycemic control.

Materials and methods

Subject Recruitment

This study was conducted at the University of Michigan in the Department of Family Medicine in Ann Arbor, Michigan and at the Detroit Department of Community Health in Detroit, Michigan and was approved by the Institutional Review Boards of both settings. Potentially eligible patients with type 2 diabetes were identified by participating primary care physicians who reviewed a list of their patients and eliminated any whose current health would make it inappropriate for them to participate in this study, e.g., psychiatric problems, ambulatory impairment, terminal illness, or pregnant. Subsequently these eligible patients were sent invitations to learn more about the study. In addition patients were recruited using announcements posted in appropriate locations (e.g., clinics, health fairs), newspaper ads and by word of mouth.

Potential study patients were invited to attend group orientation meetings, held in Ann Arbor and in Detroit, where they asked questions about the study, gave informed consent, provided baseline data and at the very end were randomized to either the intervention (DSMC) arm or the control (MAO) arm. The randomization order was generated using a computerized random numbers generator. The statistician then put the assignments to group in sealed opaque envelopes in the random order generated by the computer. Neither staff nor patients knew their assignment until the patients opened their envelopes just before leaving the orientation.

About half of the patients were randomly assigned to receive the Diabetes Self-Management Consultant (DSMC) manager intervention, whereas all patients and their physicians received the mailed results of all the study's metabolic assessments (A1C, lipids, blood pressure, height, weight). Because of the possible beneficial impact of providing metabolic results to patients and their physicians in a control group, [20] the second group of randomly assigned patients in this study was named Mailed Assessments Only (MAO). Data were collected at enrollment, and at one and two years afterwards. Patients received a \$50.00 stipend for attending each of the three data collection sessions over the two-year study period, for a maximum incentive of \$150.

Intervention

The DSMC's were a nurse and a dietitian, both Certified Diabetes Educators, each of whom had more than ten years experience using the empowerment-based strategies approach successfully in previous intervention studies. [16–19,21]

Patients were assigned to one of the two DSMC's for the duration of the study. One of the DSMC's had an office in Detroit and the other was based in Ann Arbor (approximately 40 miles apart). As a practical matter the majority of (though not all) patients in the study were seen by the DSMC based in their area.

The intervention consisted of a one-to-one meeting between patients and their DSMC's shortly after enrollment to review their self-management plans and the psychosocial and metabolic results of their baseline assessments. The patient and the DSMC reviewed the baseline data together to identify the patient's concerns, identify areas for improvement, and set behavioral goals. Following that initial meeting, the DSMC, the patient, and the patient's physician met together during an office visit. The DSMC would summarize the results of the initial meeting between the DSMC and the patient, invite the patient to correct or add to the summary and review the patient's self-management goals and progress toward attainment.

After meeting with the patient and physician, the DSMC called each patient once a month or more often if requested. Occasionally (if the circumstances warranted it) the DSMC would meet with a patient in the clinic waiting room or at home in lieu of a telephone call.

The DSMC, patient, and physician met together at baseline, one year and two years. Additional physician meetings were held if requested by the patient. The role of the DSMC was to help patients identify self-management problems and concerns, translate these diabetes self-management priorities and concerns into goals, identify behavioral steps to achieve the goals, overcome barriers, and acquire information about diabetes for self-directed decision-making. The DSMC provided diabetes self-management education on an ongoing basis and was responsible for maintaining and updating the collaboratively developed self-management plan. The DSMC was also responsible for scheduling the yearly comprehensive review of the patient's diabetes self-management plan. However, the DSMC's did not adjust medications.

The goal setting process was based on the five-step empowerment model which has been shown to be effective in previous studies [16–19] (insert table 1 about here) The patient and the DSMC

collaboratively identified self-management goals and a plan to achieve those goals. The questions below are included here to convey a sense of the empowerment approach to helping patients make decisions and solve problems. The DSMC's engaged in appropriate, natural (based on extent of relationship, education level, etc.) dialogue with patients about all aspects of their self-management.

Patients in both groups were provided with the results of their metabolic assessments (i.e. A1C, weight, blood pressure, and lipids) using the Diabetes Complications Risk Form developed by the Michigan Diabetes Research and Training Center and used in our prior work. (http://www.med.umich.edu/mdrtc/profs/documents/emh/riskprofile_072004.doc). The written feedback given to patients in both groups included an explanation of the measure, their results, normal or desired results, and specific behavioral strategies that could influence the results (e.g., eat less saturated (hard) and trans fats and cholesterol containing foods like butter, bacon, shortening). In the experimental group, the results were reviewed by the DSMC's with their patients while the MAO group only received this information through the mail. Physicians for both groups of patients received a written copy of their patients' results.

Case management defined the structure component of the intervention, and the empowerment approach to facilitating self-directed behavior change defined the process component of the intervention.

Study Design

The study was a two year randomly controlled trial (RCT) insert figure 1 about here.

Primary outcome measures

1. Diabetes-Related Quality of Life measured by the Problem Areas in Diabetes Scale (PAID) [22]. The PAID is scored as 0 not a problem to 4 a serious problem. Thus, if all 20 parts were answered "4" (i.e., serious problem) the sum would be 80, and multiplication by 1.25 would give 100. Higher values imply greater distress.
2. A1C (normal 4–6%; measured by MDRTC Core lab).

Secondary outcome measures

1. Self-management behavior was assessed using the revised Summary of Diabetes Self-Care Activities (SDSCA) Measure [23]. Scale: # times per day, # times per week, # times per month.
2. The Treatment Self-Regulation (TSR) Questionnaire was used to assess external vs. internal motivation for self-management [24]. Scale: 1=Strongly disagree, 5=Strongly agree.
3. Diabetes-Related Psychosocial Self-Efficacy was measured by the Diabetes Empowerment Scale-Short Form (DES-SF) [25], e.g., obtaining social support, managing stress, etc. Scale: 1=Strongly disagree, 5=Strongly agree.
4. Depressive Symptom Severity was assessed with the PRIME-MD Patient Health Questionnaire (PHQ-9) [26]. Patients who indicated suicidal ideation on the PHQ-9 were contacted by a clinical psychologist and assessed for risk of suicide. Sum of 9 variables, for a range of 0 to 27. Scale: 0=Not at all, 3=Nearly every day. Higher values imply greater distress.
5. Satisfaction with care was measured using an average of items from the Satisfaction Scale of the MDRTC's Diabetes History Questionnaire. The Cronbach Alpha for the overall four-item scale was unacceptably low (.31) to permit use of a single mean.

However, items a, c, and d formed a scale with Cronbach Alpha= .67 and were used for this study. Scale: 1=Strongly disagree, 5=Strongly agree.

6. The Diabetes Self-Management Competence Questionnaire (DSMC) was used to assess the patient's instrumental diabetes self-management self-efficacy [24], e.g., measuring blood glucose, injecting insulin, etc. Scale: 1=Not at all true, 7=Very true. In addition, the patient responded to a direct question about self-perceived understanding of what was needed to care for diabetes. Scale: 1=Poor, 5=Excellent.

Statistical Methods

Demographics, clinical indices, health practices/health care climate, and psychosocial values were compared by group at baseline. For continuous variables, means were compared by group using independent samples t-tests. For distributions of dichotomous categorical measures, comparison was by Fisher's Exact Test.

The A1C and PAID assessments, the clinical measures, and also health behavior, health care climate, and selected psychosocial variables were compared by group assignment for changes over time from baseline through the first and second year follow-ups, using repeated measures ANOVAs with group factors. Repeated measures ANOVAs were also used to assess changes within groups.

In a previous study we conducted [20], a repeated measures analysis indicated improvement in the metabolic status of the intervention group but not the control group. However, when the same analysis was conducted for *only* high-risk patients, participants in both the control and intervention groups showed metabolic improvements. For comparison purposes, the same subgroup analysis and high-risk definitions (i.e., A1c $\geq$ 7.5%, Cholesterol $\geq$ 240 mg/dl, SBP $\geq$ 140 mmHg, and DBP $\geq$ 90 mmHg) were used in this study. As was done in the earlier study, paired t-tests were used to compare baseline and year two follow-up for all of the variables with the exception of serum cholesterol. The baseline year two difference of cholesterol was not normally distributed; therefore the Wilcoxon Signed-Rank Test was used.

Results

Out of a total of 404 patients who signed up to attend an orientation meeting (virtually everyone who attended an orientation meeting enrolled), a total of 310 patients were enrolled and provided baseline data, and 249 patients returned at the end of two years. The dropout rate was 20% over the two years and did not differ significantly by group. In the DSMC group five died, seven were lost to follow up and 21 withdrew, In the MAO group one patient died, 23 were lost to follow-up, and three withdrew.

Compared to patients who returned, dropouts were more likely to have higher HbA1C values at baseline ($8.3\pm 2.5\%$ versus 7.5 ± 1.8 for returnees, $p=.024$).

Baseline descriptive statistics are presented in Table 2. Other than an isolated difference in perceived understanding of diabetes, there were no statistically significant differences between the DSMC group and the MAO group on the demographic, metabolic, or psychosocial variables at baseline. This cohort of patients was obese and had higher than desirable systolic blood pressure. Their diastolic blood pressure was in the normal range and they had good (<100) LDL cholesterol values, which improved in both groups over the course of the study.

Group results over time are presented in Table 3 The DSMC patients had significantly higher diabetes-related quality of life at the end of the two-year trial, even though the MAO group also reported improved quality of life. Additional benefits were seen in diabetes-related psychosocial self-efficacy and satisfaction with diabetes care, while the MAO group had none.

A1C values remained stable for the DSMC group but increased significantly for the MAO group. Both groups improved in confidence in and self-perceived understanding of diabetes care management, but the DSMC patients showed significantly greater improvement in self-perceived understanding. There were no significant between-group differences in any of the self-care behaviors. Depression scores were well within the normal range and remained unchanged.

Neither group showed changes in BMI. The DSMC group had significant changes in systolic and diastolic blood pressure and both groups had significant changes in LDL cholesterol but there were no between group differences.

Five of the eight values measured for the high-risk patients improved and three did not change (Table 4).

Discussion

The results of this study indicate that the Diabetes Self-Management Consultant (DSMC) intervention resulted in a broad array of modest diabetes-related improvements (i.e., diabetes-related quality of life, metabolic status, psychosocial adaptation, perceived understanding of diabetes, and satisfaction with care) over the two years of the study. The DSMC intervention group's A1C levels remained unchanged, whereas the MAO group's A1C levels worsened. The UKPDS study [27] indicated that the natural history of type 2 diabetes results in a worsening of A1C levels of approximately 0.2% a year. This amount is consistent with the increase seen in the A1C levels of the control group over the two years of the study. Thus, while the MAO group experienced the anticipated worsening in control, the DSMC group did not. One factor of note is that the mean baseline A1C level for all 310 patients in the study was 7.6%, which could have produced a ceiling effect constraining the amount of change possible. In the nine case manager studies cited for this paper the median baseline A1C was 8.8% and a mean of the means was 9% with a range of 8% to 11.8%. Norris and colleagues conducted a meta-analysis of 31 well-designed studies of patient education programs for adults with type 2 diabetes. The mean improvement in A1C was .96%, which decreased to a mean of .26% at 1 to 3 month follow-up. However 25 of those studies had higher baseline values A1C (converted from GHb scores) than did ours. This suggests to us that there is a point of diminishing returns at which it is very unlikely that interventions such as this one will be cost effective. Given the financial strain on today's health care systems it will be necessary to allocate those resources judiciously recognizing that with patient education programs one size does not fit all.

Surprisingly, there were no between-group changes in self-management behaviors as measured by Summary of Diabetes Self-Care Activities (SDSCA). This finding is counterintuitive since the mechanism for metabolic improvements that can be attributed to diabetes self-management is specifically measured by the SDSCA. While it is possible that the SDSCA was not sensitive to the self-management changes made by the DSMC group, this explanation is unlikely because the SDSCA has been shown to be sensitive to changes in self-care behavior in a number of other intervention studies [20]. A more plausible explanation is that the improvements in attitudes, beliefs, and psychosocial indicators can be attributed directly to the DSMC intervention, and that the metabolic effects seen in the DSMC intervention group (over and above any impact attributable to the MAO intervention) were the result of the interactions between the DSMC, the patient and the patient's primary care physician. The DSMC's met with the intervention group's physicians along with their patient at least yearly. The DSMC's did not adjust patient medications, but between the annual assessments the DSMC's often contacted physicians directly and/or encouraged patients to contact their physicians about a variety of concerns, including medical management,

The poorer A1C among dropouts suggests that they might have been less healthy than those who remained in the study, or that they had greater barriers to self-management. However a larger group of patients had elevated A1C levels and remained in the study. There is a substantial difference between the DSMC and MAO groups in terms of patients who withdrew and patients lost to follow-up. We suspect that more patients withdrew from the DSMC group because they were actively involved in an intervention and a number of reasons could explain their decision to withdraw. They may not have thought the intervention was benefiting them or changes in their health, schedule, and family situation could have also interfered with their participation. On the other hand MAO group only had to interact with the study team once a year. That fact that more patients MAO were lost to follow-up could also be a function of how frequently patients interacted with the study team.

The results obtained for high-risk patients provide modest support (i.e. the MAO group improved in three out of four metabolic indices) for the efficacy of mailed results only (MAO) being an intervention in and of itself for high-risk patients. But because seven out of the eight values moved in the desired direction and because providing mailed assessment results is such a low cost intervention, the practice should be evaluated in a study designed solely for that purpose.

Study limitations included the fact that physicians cared for both DSMC and MAO patients. Theoretically contamination could bias the results if by having DSMC patients influence them to improve their diabetes care. While possible the chances of contamination actually occurring are remote. Our center has been trying to influence physician practice for over thirty years with little success. Furthermore, the intervention focused on providing support services to help patients enhance their self-management. Physicians only has systematic involvement one a year. Volunteer bias is a study limitation that may restrict the generalizability of results of this study to the larger population of patients with diabetes. That is, patients willing to join the study were probably more motivated to take steps to improve their diabetes care than patients who did not decide to join the study. However, the practical impact of this limitation is debatable, because diabetes management itself requires motivated patients.

Our DSMC intervention was unique in that it applied a systematic, theory-based approach to establishing a therapeutic alliance and a collaborative, patient-centered approach to facilitating self-directed behavior change. This most likely explains the improvements in attitudes, psychosocial adaptation, self-efficacy, and perceived quality of care. The majority of case-management approaches of which we are aware focus on algorithm-driven medication adjustment, but they lack a well-defined, systematic, and consistent theory-based approach to the relationship, communication, and behavioral aspects of the intervention. Also, none of the nurse case manager studies reviewed chose diabetes related quality of life as an outcome variable. One of the studies assessed overall health-related quality of life using the SF-36 but reported no improvements, perhaps because the generic nature of the instrument makes it less sensitive to diabetes-specific aspects of quality of life [28].

Conclusions

Based on the results of this study and earlier studies, we suggest that case-management study that combines medication adjustment with a well-specified, theory-based approach to facilitating behavior change would have the potential to make a positive impact on both metabolic and psychosocial outcomes for higher risk patients e.g. A1C levels >85%. This potential highlights a promising direction for further case management intervention research.

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Abbreviations

DES-SF	Diabetes Empowerment Scale-Short Form
DSMC	Diabetes Self-Management Consultant
MAO	Mailed Assessments Only
PAID	Problem Areas in Diabetes Scale
PHQ-9	PRIME-MD Patient Health Questionnaire
SDSCA	Summary of Diabetes Self-Care Activities
TSR	Treatment Self-Regulation

References

1. Resneck HE, Foster GL, Bardsley J, Ratner RE. Achievement of American Diabetes Association clinical practice recommendations among U.S. adults with diabetes, 1999–2002: the National Health and Nutrition Examination Survey. *Diabetes Care* 2006;29:531–537. [PubMed: 16505501]
2. Hiss RG, Armbruster BA, Gillard ML, McClure LA. Nurse case manager collaboration with community-based physicians providing diabetes care: A randomized controlled trial. *Diabetes Educ* 2007;33:493–502. [PubMed: 17570880]
3. Hiss RG, Gillard ML, Armbruster BA, McClure LA. Comprehensive evaluation of community-based diabetic patients. *Diabetes Care* 2001;24:690–694. [PubMed: 11315832]
4. Aubert RE, Herman WH, Waters J, et al. Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. *Ann Intern Med* 1998;129:605–612. [PubMed: 9786807]
5. Piette JD, Weinberger M, McPhee SJ, Mah CA, Kraemer FB, Crapo LM. Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes? *Am J Med* 2000;108:20–27. [PubMed: 11059437]
6. Taylor CB, Miller NH, Reilly KR, et al. Evaluation of a nurse-care management system to improve outcomes in patients with complicated diabetes. *Diabetes Care* 2003;26:1058–1063. [PubMed: 12663573]
7. Polonsky WH, Christensen R, Earles J, et al. Integrating medical management with diabetes self-management training: A randomized control trial of the Diabetes Outpatient Intensive Treatment program. *Diabetes Care* 2003;26:3048–3053. [PubMed: 14578238]
8. Philis-Tsimikas A, Walker C, Rivard L, et al. Improvement in diabetes care of underinsured patients enrolled in Project Dulce: A community-based, culturally appropriate, nurse case management and peer education diabetes care model. *Diabetes Care* 2004;27:110–115. [PubMed: 14693975]
9. Wilson C, Curtis J, Lipke S, Bochenski C, Gilliland S. Nurse case manager effectiveness and case load in a large clinical practice: implications for workforce development. *Diabet Med* 2005;22:1116–1120. [PubMed: 16026383]
10. Gary TL, Bone LR, Hill MN, et al. Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans. *Prev Med* 2003;37:23–32. [PubMed: 12799126]
11. Piette JD, Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a Department of Veteran Affairs Health Care System: a randomized controlled trial. *Diabetes Care* 2001;24:202–208. [PubMed: 11213866]
12. Krein SL, Klamerus ML, Vijan S, et al. Case management for patients with poorly controlled diabetes: A randomized trial. *Am J Med* 2004;116:732–739. [PubMed: 15144909]

13. Anderson RM, Funnell MM. Patient empowerment: reflections on the challenge of fostering the adoption of a new paradigm. *Patient Educ Couns* 2005;57:153–157. [PubMed: 15911187]
14. Williams GC, Grow VM, Freedman Z, Ryan RM, Deci EL. Motivational predictors of weight loss and weight loss maintenance. *J Pers Soc Psychol* 1996;70:115–126. [PubMed: 8558405]
15. Williams GC, Ryan RM, Rodin GC, Grolnick WS, Deci EL. Autonomous regulation and long-term medication adherence in adult outpatients. *Health Psychol* 1998;17:269–276. [PubMed: 9619477]
16. Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care* 1995;18(7):943–949. [PubMed: 7555554]
17. Anderson RM, Funnell MM, Nwankwo R, Gillard ML, Oh MS, Fitzgerald JT. Evaluation of a problem-based empowerment program for African Americans with diabetes. Results of a randomized controlled trial. *Ethnicity & Disease* 2005;15:671–678. [PubMed: 16259492]
18. Tang TS, Gillard ML, Funnell MM, Nwankwo R, Parker E, Spurlock D, Anderson RM. Developing a new generation of ongoing diabetes self-management support interventions (DSMS): A preliminary report. *The Diabetes Educator* 2005;31(1):91–97. [PubMed: 15779250]
19. Gillard ML, Nwankwo R, Fitzgerald JT, Oh M, Musch DC, Johnson MW, Anderson RM, et al. Informal diabetes education: impact on self-management and blood glucose control. *Diabetes Educ* 2004;30:136–142. [PubMed: 14999901]
20. Hiss RG, Gillard ML, Armbruster BA, McClure LA. Comprehensive evaluation of community based diabetic patients: Effect of feedback to patients and their physicians: A randomized controlled trial. *Diabetes Care* 2001;24:690–694. [PubMed: 11315832]
21. Tannas, C. Empowerment-based diabetes care for medically underserved minority persons: Making a difference. Abstract Poster Presentation at the 17th International Diabetes Federation Congress; November 6 2000; Mexico City, Mexico.
22. Welch GW, Weinger K, Anderson B, Polonsky WH. Responsiveness of the Problem Areas In Diabetes (PAID) questionnaire. *Diabet Med* 2003;20:69–72. [PubMed: 12519323]
23. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care* 2000;23:943–950. [PubMed: 10895844]
24. Williams GC, Rodin GC, Ryan RM, Grolnick WS, Deci EL. Autonomous regulation: the motivational basis of adherence to medical regimens. *Health Psychol* 1998;17:269–276. [PubMed: 9619477]
25. Anderson RM, Fitzgerald JT, Grupp LD, Funnell MM, Oh MS. The diabetes empowerment scale-short form (DES-SF). *Diabetes Care* 2003;26:1641–1642. [PubMed: 12716841]
26. Spitzer R, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD: The PHQ primary care study. *JAMA* 1999;282:1737–1744. [PubMed: 10568646]
27. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998;352:837–853. [PubMed: 9742976]
28. Anderson RM, Fitzgerald JT, Wisdom K, Davis WK, Hiss RG. A comparison of global versus disease-specific quality-of-life measures in patients with NIDDM. *Diabetes Care* 1997;20:299–305. [PubMed: 9051376]

Figure 1.
Consort Diagram

Table 1

Five step empowerment model

1	<u>Identify the problem</u>
	What is the most difficult or frustrating part of caring for your diabetes at this time?
2	<u>Determine feelings and their influence on behavior</u>
	How do you feel about this issue? How are your feelings influencing your behavior? How important is it to you to address this issue (on a scale of 1–10)?
3	<u>Set a long-term goal</u>
	What do you want? What do you need to do? What problems do you expect to encounter? What support do you have to overcome these problems? Are you willing/able to take action to address this problem?
4	<u>Make a plan for a behavioral step, (i.e., self-management experiment)</u>
	Set a SMART goal: specific, measurable, achievable, realistic and timely. What will you do this week to get started working toward your goal? How confident do you feel that you can address this issue (on a scale of 1–10)?
5	<u>Assess how the experiment worked</u>
	How did it work? What did you learn? What might you do differently next time?

Table 2Baseline Comparison^{a,b} by Group for Study Participants (N=310)

Demographics	DSMC (N=156)		MAO (N=154)	
	n	(n) % or mean±sd	n	(n) % or mean±sd
Women	156	(88) 56.4%	154	(94) 61.0%
African Americans	154	(63) 40.9%	154	(77) 50.0%
Using Insulin	155	(43) 27.7%	152	(40) 26.3%
Mean Age in Years	156	55.5 ± 11.3	154	55.7 ± 11.5
Mean Years Since Diagnosis	149	8.6 ± 8.1	145	8.0 ± 7.8
Currently Married	156	(82) 52.6%	154	(73) 47.4%
Completed High School	156	(143) 91.7%	153	(135) 88.2%
Uninsured	156	(27) 17.3%	154	(32) 20.8%

Psychosocial Indices	DSMC (n=156)		MAO (n=154)	
	n	(n) % or mean±sd	n	(n) % or mean±sd
Problem Areas in Diabetes (PAID)	153	28.3 ± 21.3	152	28.2 ± 22.6
Perceived Understanding of DM Self-Management ^c	154	3.19±1.06	153	3.54±1.10
Depression (PHQ-9)	153	6.48 ± 6.15	152	6.59 ± 6.39
Self Care Motivation	153	3.25±0.70	151	3.32±0.81
Diabetes Empowerment Scale	154	3.69±0.78	152	3.82±0.77
Confidence in Managing Diabetes	155	4.75±1.53	152	4.89±1.52

Clinical Indices	DSMC (n=156)		MAO (n=154)	
	n	(n) % or mean±sd	n	(n) % or mean±sd
A1C	156	7.7 ± 2.1	153	7.5 ± 1.8
Serum Cholesterol (mg/dl)	156	177.9±45.5	153	178.9±44.2
HDL Cholesterol (mg/dl)	156	48.5 ± 14.2	153	50.2 ± 13.3
LDL Cholesterol (mg/dl)	156	94.7 ± 36.4	153	92.1 ± 35.2
Systolic BP	154	138.6±21.5	152	136.9±19.2
Diastolic BP	154	79.4 ± 11.8	152	77.8 ± 11.8
BMI	155	34.9 ± 9.0	150	33.8 ± 7.8
SMBG Times Per Week	153	7.99 ± 8.64	153	6.72 ± 8.48
Previously Had Some DM Education	153	(77) 50.3%	153	(75) 49.0%

^aIndependent sample t-tests for means of continuous variables^bFisher's Exact Test for distributions of dichotomous categorical variables^cMAO had a statistically significant higher perceived understanding of diabetes

Table 3

Between- and Within-Group Differences From Baseline to Two Years

Variables	Group	N	Means and SD at baseline	Means and SD at two years	Within-Group Difference by Time ^a	Difference by Group by Time ^b
Problem Areas In DM (PAID) ^c	DSMC	118	29.3 ± 19.8	20.2 ± 18.9	p < .001	p = .008
	MAO	124	26.6 ± 21.2	22.9 ± 19.9	p = .007	
A1C	DSMC	122	7.57 ± 1.94	7.62 ± 1.80	n.s.	p = .016
	MAO	126	7.38 ± 1.68	7.91 ± 2.03	p < .001	
Diabetes Empowerment Scale (DES-SF)	DSMC	119	3.66 ± 0.78	3.94 ± 0.76	p < .001	p = .024
	MAO	124	3.84 ± 0.73	3.88 ± 0.71	n.s.	
Confidence in Managing DM (DSMC)	DSMC	120	4.76 ± 1.45	5.36 ± 1.54	p < .001	n.s.
	MAO	124	4.92 ± 1.53	5.43 ± 1.34	p < .001	
Perceived Understanding Managing DM	DSMC	119	3.21 ± 1.04	3.98 ± 0.91	p < .001	p < .001
	MAO	125	3.58 ± 1.07	3.81 ± 1.02	p = .007	
Depression (PHQ-9) ^c	DSMC	117	5.80 ± 5.36	4.84 ± 5.41	p = .037	n.s.
	MAO	124	6.12 ± 5.91	5.46 ± 4.64	n.s.	
Satisfied with DM Care Received	DSMC	120	3.48 ± 0.84	3.78 ± 0.82	p = .001	p = .019
	MAO	125	3.62 ± 0.93	3.61 ± 0.92	n.s.	

^aPaired t-test stratified by group.^bRepeated measures ANOVA X group.^cHigher values indicate more distress.

Table 4
For Selected Variables, Changes By Year Two Within Study Groups for Participants Who Were High-Risk at Baseline

Variable	Group	N At T2	Mean At Baseline	Mean at T2	Mean Change by T2	p ^a
AIC	DSMC	52	9.27±1.79	8.75±1.97	-0.52±2.02	n.s.
	MAO	47	8.98±1.64	9.18±2.44	0.20±2.12	n.s.
Cholesterol ^b	DSMC	10	262.3±23.0	209.8±87.2	-52.5±91.1	n.s.
	MAO	13	260.0±20.1	185.6±36.1	-74.4±39.2	.000
Systolic BP	DSMC	60	155.6±15.3	137.7±18.8	-17.8±22.5	.000
	MAO	52	152.5±17.0	141.8±24.5	-10.7±25.6	.004
Diastolic BP	DSMC	24	95.5±7.0	83.0±10.3	-12.5±13.3	.000
	MAO	21	96.0±8.9	87.0±15.3	-9.0±14.4	.010

^a Paired t-tests within study group for AIC, Diastolic BP, Systolic BP.

^b Wilcoxon nonparametric tests within study group for Cholesterol.