

Patient Empowerment

Results of a randomized controlled trial

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OBJECTIVE — The purpose of this study was to determine if participation in a patient empowerment program would result in improved psychosocial self-efficacy and attitudes toward diabetes, as well as a reduction in blood glucose levels.

RESEARCH DESIGN AND METHODS — This study was conducted as a randomized, wait-listed control group trial. The intervention group received a six-session (one session per week) patient empowerment education program; the control group was assigned to a wait-list. At the end of 6 weeks, the control group completed the six-session empowerment program. Six weeks after the program, both groups provided follow-up data.

RESULTS — The intervention group showed gains over the control group on four of the eight self-efficacy subscales and two of the five diabetes attitude subscales. Also, the intervention group showed a significant reduction in glycated hemoglobin levels. Within groups, analysis of data from all program participants showed sustained improvements in all of the self-efficacy areas and two of the five diabetes attitude subscales and a modest improvement in blood glucose levels.

CONCLUSIONS — This study indicated that patient empowerment is an effective approach to developing educational interventions for addressing the psychosocial aspects of living with diabetes. Furthermore, patient empowerment is conducive to improving blood glucose control. In an ideal setting, patient education would address equally blood glucose management and the psychosocial challenges of living with diabetes.

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DAS, Diabetes Attitude Scale; DCP, Diabetes Care Profile; MDRTC, Michigan Diabetes Research and Training Center.

Diabetes is a self-managed disease with the patient usually providing 95% or more of the daily care (1). The fundamental prerequisite for diabetes self-management is patient education. For many years diabetes education has been viewed as a process designed to provide patients with the knowledge and skills to adhere to the treatment recommendations of health care professionals (2–6). This approach assumes that the primary focus of patient education should be glucose management. One consequence of conceptualizing diabetes patient education in this manner is a strong emphasis on metabolic control and patient adherence as the primary measures of the effectiveness of diabetes patient education programs (3,7–14).

Five years ago the Education Committee of the University of Michigan Diabetes Research and Training Center (MDRTC), which is responsible for the patient and professional education programs of the MDRTC, concluded that the traditional compliance-based approach was an inappropriate conceptual structure for the practice and evaluation of diabetes patient education. The MDRTC adopted a different approach, referred to as “patient empowerment” (15).

This approach argues that in caring for their diabetes, patients make choices each day that affect, and are affected by, their emotions, thoughts, values, goals, and other psychosocial aspects of living with this chronic disease (16). Further, patient empowerment posits that the purpose of diabetes patient education is to ensure that the choices patients make every day in living with and caring for diabetes are informed choices (17).

The knowledge needed to make informed choices about daily diabetes care falls into two global domains. The first domain is expertise about diabetes. This expertise is generally provided in comprehensive diabetes patient education programs. The second, and equally important, domain is psychosocial chal-

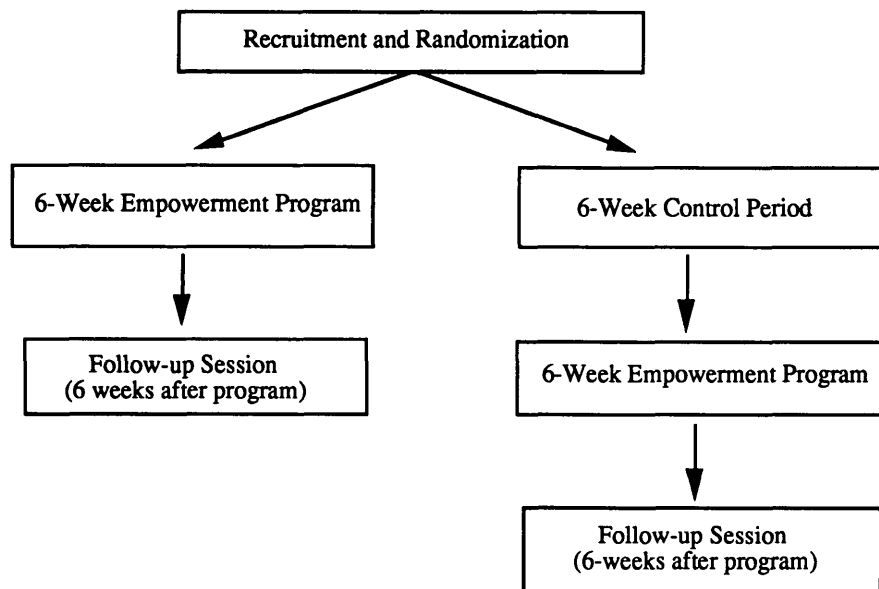


Figure 1—Study design.

Challenges and skills. Because diabetes and its treatment affect the physical, emotional, mental, and spiritual domains of a patient's life, education and care should address the impact of diabetes on the totality of that person's life (18,19). The empowerment philosophy is based on the assumption that to be healthy, people need to have the psychosocial skills to bring about changes in their personal behavior, their social situations, and the institutions that influence their lives. These skills probably play an important role in the development and implementation of a successful diabetes self-care plan, i.e., a plan that enhances the patient's health and quality of life.

There are a number of studies that address one or more of the behavioral (20–23) and psychosocial (24–27) aspects of diabetes self-care. A recent review (24) of psychosocial problems and interventions in diabetes by Rubin and Peyrot found that the majority of the published research focused on four types of psychosocial problems, i.e., psychosocial sequelae of medical crisis, psychopathology in diabetes, stress and hassles in living with diabetes, and family dysfunctions. Although their review identified strong

and consistent recommendations for psychosocial interventions, they were able to identify relatively few actual intervention studies. From their review, it appears that many investigators believe that psychosocial interventions should be undertaken after the identification of psychosocial problems rather than incorporating psychosocial education as a routine but significant component of diabetes care and education. A comprehensive review (13) of the impact of diabetes education by Glasgow and Osteen concluded that viewing diabetes education primarily in terms of knowledge transfer is clearly inadequate and inconsistent with what we know about human behavior. They suggested that diabetes education must move beyond knowledge improvement and metabolic control. They concluded that “the past decade also has witnessed a dramatic shift from knowledge/attitude/belief models of diabetes education to focus on patient-centered perspectives, self-efficacy, self-management, and empowerment issues.”

This study builds on previous work by evaluating a comprehensive, empowerment-based program of psychosocial education focusing on helping pa-

tients develop and enhance their goal-setting, problem-solving, coping, and other psychosocial skills. The study addressed the following three questions. Would participation in a patient empowerment program: 1) result in improved self-efficacy?; 2) have an impact on general attitudes toward diabetes?; and 3) lead to a reduction in blood glucose levels?

RESEARCH DESIGN AND METHODS

The empowerment program

A patient education program entitled “Empowerment: Facilitating a Path to Personal Self-Care” was designed by one of the authors (28). This program is designed to: 1) enhance the ability of patients to identify and set realistic goals; 2) apply a systematic problem-solving process to eliminate barriers to achieving those goals; 3) cope with circumstances that cannot be changed; 4) manage the stress caused by living with diabetes as well as the general stress of daily life; 5) identify and obtain appropriate social support; and 6) improve their ability to be self-motivated. More than 1,500 diabetes educators have been trained to provide this program in 1-day workshops offered at >90 locations around the U.S.

Study design

The following randomized controlled trial was carried out after a small uncontrolled pre-post pilot test suggested that the program was effective in improving patients' self-efficacy in program content areas. The study was designed as a randomized, wait-listed control group trial (Fig. 1). Recruitment strategies included advertisements in newsletters, newspapers, and bulletin boards and letters to the University of Michigan Medical Center's diabetes outpatient education program graduates. An orientation session was conducted, which included a discussion about the empowerment philosophy, testimony from patients who had completed the pilot program, a descrip-

tion of the study design, and a sample worksheet/discussion exercise. All patients who chose to participate signed an informed consent document, completed a baseline questionnaire, and had a blood sample drawn for a glycated hemoglobin assay. Patients were then randomly assigned to either the intervention or wait-listed control groups.

The program as provided in this study was organized as six 2-h group sessions offered weekly for 6 weeks. Each session involved a brief presentation of key concepts related to the topic, completion of individual self-assessment and planning worksheets during and between sessions, and large and small group discussions of worksheet responses and insights. Patients were encouraged to bring a spouse, family member or friend to the group sessions. Study participants were asked to complete 21 worksheets, attend six sessions, and take part in group discussions. Guests were also encouraged to participate fully.

At the end of 6 weeks, all subjects completed the questionnaire a second time and a second blood sample was drawn. The second questionnaire served as the postprogram evaluation for the intervention group and both the post-control period and preprogram questionnaire for the control group. The control group then completed the six-session program. At the end of 12 weeks, all subjects completed questionnaires for a third time and provided a third blood sample. This third data collection served as the postprogram data for the control subjects and as 6-week follow-up data for the intervention subjects. The control group then returned for follow-up 6 weeks later, completing the questionnaire a fourth time, and provided a fourth blood sample. To be included in the data analysis, patients had to attend a minimum of four classes, complete study questionnaires, and provide blood samples a minimum of two consecutive times. Ten subjects dropped out of the study.

During follow-up sessions, patients completed final data collection, dis-

cussed their experiences during the 6-week follow-up period, and viewed a 1-h videotape that reviewed the empowerment philosophy and program content. The experiment was repeated twice during 1993, once in the spring and once in the fall. Eighteen participants were not willing/able to be randomly assigned to intervention or control conditions. The between-groups analysis conducted for this study has been limited to only those patients who were randomly assigned to treatment conditions. The within-groups analysis includes all patients who completed the program.

Measures

Self-efficacy measures were developed for the specific content areas of this patient empowerment program. The self-efficacy subscales measured the respondents' perceived ability to: 1) identify areas of satisfaction and dissatisfaction related to living with diabetes; 2) identify and achieve personally meaningful goals; 3) apply a systematic problem-solving process to the elimination of barriers to their goals; 4) cope with the emotional aspects of living with diabetes; 5) manage stress; 6) attain appropriate social support; 7) be self-motivated; and 8) make cost/benefit decisions about making behavior changes related to living with diabetes. Diabetes attitudes were measured with selected subscales of the Diabetes Attitude Scale (DAS) (29) and selected subscales of the Diabetes Care Profile (DCP) (30). The DAS subscales measured patients' attitudes toward compliance, the impact of diabetes on their quality of life, and their views about patient autonomy. The two DCP subscales measured overall positive and negative attitudes about living with diabetes. Attitudes and self-efficacy were measured using a Likert scale ranging from 5 (strongly agree) to 1 (strongly disagree). Blood glucose control was measured by a glycated hemoglobin assay using the affinity chromatography method in the MDRTC core laboratory (normal range is 4–8%).

Statistical analysis

Means and frequencies were calculated for the demographic data. The internal consistency or reliability of the eight self-efficacy subscales was determined through the use of Cronbach's α coefficient. Student's *t* tests were used to determine if changes in scores differed between the intervention and control groups for the diabetes attitude subscales and the self-efficacy subscales. These change scores were the differences in mean scores at baseline and at 6 weeks (postprogram or post-control period). Values at baseline and follow-up (12 weeks) were used for the between-group comparisons of glycated hemoglobin levels as 6 weeks was too short a time to reflect changes related to program participation. A Student's *t* test was used to determine if glycated hemoglobin levels differed.

A second series of analyses combined all participants who completed the program. To determine the program's impact on the participants' attitudes and self-efficacy, a multiple analysis of variance with repeated measures was completed for each scale. Baseline (preprogram) scores were compared to both the postprogram (6 weeks) and the follow-up (12 weeks) scores. Glycated hemoglobin levels were also compared using baseline and follow-up values. A paired Student's *t* test was used to determine whether glycated hemoglobin levels differed.

RESULTS — A total of 64 patients (46 randomly assigned, 18 not randomly assigned) met criteria for having their data included in the study. The demographic characteristics of study participants are presented in Table 1. The majority of the patients were middle-aged, women, and overweight. The subjects were well educated, with 77% having at least some college education and 84% having had diabetes education. More than half (54%) were using insulin. As shown in Table 1, these patients indicated that diabetes did not interfere with their life, felt they understood diabetes, were able to fit diabetes into their life in a positive manner, and

Table 1—Patient demographics

n	64
% women	70
Mean age (years)	50
% mean ideal weight (M/W)	126/151
% with some college	77
% with non-insulin-dependent diabetes	64
% who have had diabetes education	84
% using insulin	54
Self-reported understanding of diabetes	5.33*
Diabetes prevents daily activities	1.76†
Fit diabetes in life in positive manner	4.81‡
Level of comfort in asking physician questions	5.95§

*Mean response, 1 = poor, 7 = excellent. †Mean response, 1 = never, 7 = frequently. ‡Mean response, 1 = not at all able, 7 = very able. §Mean response, 1 = not at all comfortable, 7 = very comfortable.

were comfortable asking questions of their physician.

Between-group analysis

The major dependent variable in this study was self-efficacy. The intervention group showed gains over the control group on four of the eight self-efficacy subscales (Table 2). There were no differences between groups on the remaining four subscales. Because this was a new measure developed specifically for this study, reliability scores were calculated for each of the subscales (Table 2). Generally the subscales were reliable, with Cronbach α coefficients ranging from a high of 0.85 to a low of 0.57.

Table 3 shows the comparison of the intervention and control group on attitude change scores. There were no significant differences on two of the three DAS subscales between the two groups. A modest improvement was indicated in attitude concerning the impact of diabetes on quality of life among the intervention group's subjects. The intervention group also showed a significant decline in negative attitude toward living with diabetes on that DCP subscale.

Glycated hemoglobin analyses for this study were done at baseline and 12 weeks. As such, the intervention group's glycated hemoglobin analysis was conducted 6 weeks after the completion of the empowerment program; the control

group analysis was conducted immediately after completion of the program. The intervention group showed a significantly greater reduction in glycated hemoglobin than the control group (intervention $11.75 \pm 3.01\%$ to $11.02 \pm 2.89\%$; control $10.82 \pm 2.94\%$ to $10.78 \pm 2.59\%$; $P = 0.05$).

Within-group analysis

To better understand the impact of the program, data from all patients who had completed the education program were combined and analyzed. For the major dependent variable, self-efficacy, the analysis indicates that the program resulted in significant improvements in all self-efficacy areas, which were sustained at

follow-up (Table 4). Table 5 also shows attitude change scores involving both pre- and postprogram comparisons and preprogram and follow-up comparisons. Improvements on the DCP positive and negative attitude scales were sustained at follow-up. The program had no apparent impact on two of the three DAS subscales but may have had a minor effect on the compliance subscale. An analysis of all subjects indicates that the program resulted in a modest (11.3% preprogram vs. 10.8% follow-up; $P < 0.005$) improvement in blood glucose.

CONCLUSIONS— This study used a self-selected sample of people with diabetes, whose demographic characteristics constrain its generalizability. The participants in this study were significantly better educated and a higher proportion used insulin than in our previous studies with a randomly selected community sample (31). The other parameters in Table 1 indicate that this was an assertive, educated group of patients who were willing and able to engage in a program of psychosocial education stressing a high degree of personal responsibility. In fact, the mean preprogram score of the patients in this study on our DAS patient autonomy subscale (which measures the patient's interest in being an autonomous decision-maker regarding diabetes care) was 4.14 on a 1 to 5 scale. The results of

Table 2—Comparison of self-efficacy change scores between intervention and control groups

Subscale	α	Intervention	Control	P value
n	—	22	23	—
Assessing satisfaction	0.68	+0.29	-0.04	NS
Setting goals	0.80	+0.69	-0.12	<0.001
Solving problems	0.76	+0.32	-0.02	NS
Emotional coping	0.57	+0.41	+0.12	NS
Managing stress	0.79	+0.29	+0.01	0.05
Obtaining support	0.85	+0.36	-0.11	0.002
Motivating oneself	0.82	+0.29	-0.09	NS
Making decisions	0.63	+0.47	+0.05	0.02

Data are differences between pre- and postprogram means. One subject in the intervention group had incomplete data and was not included in this analysis.

Table 3—Comparison of attitude change scores between intervention and control groups

Attitude subscale	Intervention	Control	P value
n	22	23	—
Compliance (DAS)	+0.12	+0.04	NS
Impact of diabetes (DAS)	+0.29	0.00	0.03
Patient autonomy (DAS)	+0.04	+0.30	NS
Positive attitude (DCP)	+0.30	+0.12	NS
Negative attitude (DCP)	-0.62	-0.05	0.01

Data are differences between pre- and postprogram means. One subject in the intervention group had incomplete data and was not included in this analysis.

this study suggest that the empowerment program would probably benefit patients who are willing and able to engage in a self-reflective program designed to change attitudes and self-efficacy.

In addition, the study design did not allow for an exact comparison of the two groups in terms of program impact on blood glucose. The intervention group subjects had glycated hemoglobin levels measured 6 weeks after the program with the control group measured immediately after the program. Ideally, glycated hemoglobin determinations would have been made in the control group after a 12-week period with no intervention. However, this limitation biases the study against finding an effect of the program on blood glucose. Given that the control group actually experienced an intervention during the second half of the control period, one would expect any potential effect of the empowerment program to cause blood glucose differences between the two groups to be smaller rather than larger.

Finally, the improvements seen in self-efficacy may be underestimates. Other investigators have found that pre-post assessments of self-efficacy often do not reflect the magnitude of change brought about by an intervention (32–34). This phenomenon occurs when subjects overestimate their self-efficacy before a program because they do not fully understand a particular skill or concept (35). Previous research has suggested that retrospective pre-post self-assessments of

self-efficacy are likely to demonstrate greater change and be more consistent with objective measures of acquired skills (36). We are developing a retrospective pre-post self-assessment instrument for future evaluations of this program.

The answer to the three research questions is “Yes.” This program was primarily intended to improve the psychosocial self-efficacy of its participants, which it did. It was hoped that such improvements would be related to more positive generalized attitudes about diabetes and possibly improved diabetes self-management. The data suggest that these effects occurred as well, although they are less striking than the changes in self-efficacy. These outcomes were accompanied by modest improvements in glycated hemoglobin levels.

This empowerment education program was based on key philosophical assumptions, which may differ from more traditional, compliance focused, blood glucose management-oriented patient education programs. The first assumption was that patients, if given the freedom to choose and the opportunity to reflect on their lives, would be willing and able to select appropriate goals related to living with and caring for their diabetes. The second assumption was that, the social/emotional/mental aspects of living with diabetes should and could be addressed as an integral part of patient care and education.

The results of this study offer support to both assumptions. Because the program did not focus on clinical management, and we did not know on which aspects of living with diabetes patients would choose to work, we did not use a structured instrument to measure diabetes self-care behavior. However, at the end we asked patients if they had made (or intended to make) changes in diet, blood glucose monitoring or exercise, as a result of the program. Ninety-five percent of the patients reported instituting behavior changes related to at least one of these three areas of diabetes self-care. It is important to note that participants were concerned with the clinical management of their diabetes. Even though partici-

Table 4—Comparison of self-efficacy change scores pre- vs. postprogram and preprogram vs. 6-week follow-up

Subscale	Pre/post	Pre/follow-up	Post hoc test	
			P value	P value
Assessing satisfaction	+0.25	+0.22	0.002	0.01
Setting goals	+0.51	+0.46	<0.001	<0.001
Solving problems	+0.34	+0.33	<0.001	<0.001
Emotional coping	+0.44	+0.37	<0.001	<0.001
Managing stress	+0.31	+0.35	<0.001	<0.001
Obtaining support	+0.32	+0.35	<0.001	<0.001
Motivating oneself	+0.37	+0.43	<0.001	<0.001
Making decisions	+0.43	+0.40	<0.001	<0.001

n = 61. Three subjects had incomplete data and were not included in this analysis. Pre/post shows differences between pre- and postprogram means. Pre/follow-up shows differences between preprogram and follow-up means.

Table 5—Comparison of attitude change scores pre- vs. postprogram and preprogram vs. 6-week follow-up

Attitudes	Pre/post	Pre/follow-up	Post hoc test	
			P value	P value
Compliance	0	+0.11	NS	0.03
Impact of diabetes	-0.11	-0.06	NS	NS
Patient autonomy	+0.01	+0.07	NS	NS
Positive attitude	+0.24	+0.27	0.002	<0.001
Negative attitude	-0.50	-0.47	<0.001	<0.001

n = 61. Three subjects had incomplete data and were not included in this analysis. Pre/post shows differences between pre- and postprogram means. Pre/follow-up shows differences between preprogram and follow-up means.

pants were not pressured to focus on clinical issues, almost all chose to institute behaviors designed to improve blood glucose control as a function of participation in this program. These changes most likely explain the improvement in glycosylated hemoglobin levels. Because the great majority of patients made changes in their diabetes self-care, we will measure self-care behavior more precisely in future empowerment studies. Patient empowerment should not be viewed as competing with traditional diabetes patient education. It is instead a complementary and mutually reinforcing component of such education. In fact, in an ideal setting the two educational activities would be integrated and ongoing.

The second assumption (the need to address psychosocial issues) was more directly supported by the improvements in attitudes and self-efficacy and by our observations regarding the value that participants placed on the program. One scale on the postprogram evaluation questionnaire asked subjects to rate the program as very helpful, helpful, a bit helpful, or not at all helpful. Of the respondents 80% chose very helpful and 20% chose helpful.

It is quite possible that the short-term gains demonstrated in this study will not be sustained. Other investigators (37,38) have suggested that long-term behavior changes require long-term interventions. However, because goals were

selected with no pressure from program facilitators, it is possible that some changes will continue. In any event, we agree that efforts to educate, support and encourage patients need to be ongoing if diabetes education and care is to result in long-lasting improvements in blood glucose levels and quality of life. The remarkable success of the Diabetes Control and Complications Trial in eliciting sustained improvements in blood glucose levels (39) offers support for the efficacy of ongoing programs of intensive care, education, and psychosocial support. Additional studies examining the impact of interventions designed to improve health and quality of life for people with diabetes over the long term need to be conducted.

In summary, this study suggests that patient empowerment is a workable philosophy leading to effective interventions for addressing the psychosocial components of living with diabetes. Furthermore, patient empowerment is consistent with improved blood glucose control. The major challenge in both the research and practice domains is to translate short-term gains into sustained improvements in metabolic control and quality of life for people with diabetes.

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