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Promoting glycemic control through diabetes self-management: evaluating a patient activation intervention

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Abstract

This study compared an activation intervention to passive education in a randomized attention-control trial of 232 patients with type 2 diabetes. The activation intervention was based on Expanding Patient Involvement in Care (EPIC) trials, and was compared to time-matched passive education viewing of ADA video-tapes. Patient demographics and clinical characteristics of their diabetes were assessed with questionnaires, active involvement was assessed via ratings of taped interactions between patients and providers, and serum samples were analyzed for HbA1c. Patients in the activation condition were rated as more actively involved in discussions of diabetes self-management, and rated active involvement was predictive of improvement in glycemic control. No effect of the activation intervention was found on HbA1c. Thus, the activation intervention increased the active involvement of patients with type 2 diabetes in visits with practitioners, and active involvement led to improved glycemic control. However, the activation intervention did not improve glycemic control directly.

Keywords: Diabetes self-management; Patient activation; Patient active involvement; Expanding patient involvement in care

1. Introduction

Additional approaches for improving the glycemic control of patients with type 2 diabetes need to be identified, refined, and translated into care as the United Kingdom Prospective Diabetes Study (UKPDS) has demonstrated that better glycemic control results in fewer complications of diabetes. Indeed, a 0.9% improvement in HbA1c for patients with diabetes receiving intensive treatment resulted in a 25% reduction in microvascular complications (nephropathy, retinopathy, and neuropathy) over 10 years compared to those who received standard care [1]. Increasing patient active involvement in the management of their disease, as done by the Expanding Patient Involvement in Care (EPIC) intervention, may represent one approach to improving glycemic control [2].

The EPIC intervention was shown to increase patient participation in health care encounters and to improve a variety of health outcomes, including glycemic control for patients with diabetes [3]. The intervention involved research assistants (RAs) meeting with patients before each visit to encourage patients to become more involved in the management of their diabetes. This intervention was referred to as *patient activation*. Ratings of patient behavior from audiotapes of the visits indicated that patients given the activation intervention became more actively involved in the discussions compared to patients given a standard education session. Thus, the term *active involvement* represented a continuous variable that was rated by observers from patient behavior during a health care visit, and patient activation refers to the intervention used to motivate active involvement.

The present study was conducted (a) to examine the validity of rated active involvement as a construct in diabetes treatment settings and (b) to determine whether the patient activation intervention resulted in patients being rated as more active during practitioner visits, and (c) to replicate the EPIC trials' patient activation intervention effect of improving glycemic control for patients with type 2 diabetes [3]. The patient activation intervention is hypothesized to increase rated active involvement and improve glycemic control compared to the education control. Rated active involvement was hypothesized to mediate the relationship between the intervention and glycemic

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control. Intention-to-treat analyses were used to determine the effects of the intervention on change in glycemic control.

A previous study of physicians providing smoking cessation counseling [4] found that "rated active involvement" could be simply and reliably measured by trained raters' responses to three items as a global construct. In that smoking-cessation study, rated active involvement from a single physician visit was predictive of continuous abstinence from tobacco over a 30-month follow-up. However, this rating system has not been applied to patients with a chronic disease such as diabetes in a randomized controlled trial.

A separate report related to the present study [5] confirmed the self-determination theory process model of health behavior change [6–8] in the context of care for patients with diabetes. Briefly, changes in the self-determination motives of autonomy and competence were found to predict the maintenance of change in HbA1c. However, the patient activation intervention was not found to increase autonomous or competence motivation for diabetes self-management. Thus, the patient activation intervention did not promote internalization of motivation for patients with diabetes.

2. Methods

2.1. Participants

Participants were recruited with signs posted in a diabetes care center at a university affiliated community hospital between 1996 and 1999. Eligibility criteria included having type 2 diabetes with the most recent HbA1c reading being at least 1 point above the upper end of the lab reference range, having primary responsibility for self-management of diabetes, having greater than a 1-year life expectancy, and having ability to speak and read English. Of the 232 patients randomized in this trial, 197 (85%) had blood draws at baseline and 12 months and were used in the intention-to-treat analyses. Of the 35 patients who did not have HbA1c information available at 12 months, 17 were from the activation intervention condition and 18 were from the passive education condition. Further, 151 (71%) of the patients had at least one taped practitioner visit prior to receiving the intervention and at least two taped visits on days in which they received the intervention just prior to the visit, and these patients were used in analyses involving rated active involvement.

2.2. Procedure

Participants were informed that the study would involve completing four questionnaires over 12 months. HbA1c levels were drawn at baseline, 6 and 12 months. They were asked to meet with study personnel for 20 min before three of their upcoming office visits. After completing the informed consent process, participants attended their baseline visit with each of the three types of practitioners: an endocrinologist, a diabetes nurse educator, and a registered dietician. Prior to their second visit to any of the health care practitioners, patients were randomly assigned to receive either the activation or education intervention. Participants then had three activation sessions or saw three educational videos prior to subsequent practitioner visits at the center. The video sessions lasted the same amount of time as the activation sessions, so the control group served as an attention control. Each participant received US$ 50 (prorated for those who dropped out) upon completion of the questionnaires and lab work. Payment for medical care was provided through standard insurance.

The research assistants who conducted the intervention and administered the attention control were two BA-level psychology graduates and one clinical psychology graduate student. They each received 20 h of training about diabetes and about the intervention interview. They attended a twice-monthly supervision session during which a taped intervention was reviewed.

2.2.1. The activation intervention

The activation intervention was modeled after the EPIC procedure [2], which was designed to encourage patients to become more involved in the management of their diabetes and, specifically, to help them generate and ask 3 to 5 care-related questions during each practitioner visit [2]. After greeting the patient, the RA briefly answered questions regarding participation in the study without disclosing information about the treatment conditions or hypotheses. The RA explained that the goal of the 20-min session was to identify and clarify any questions about their diabetes care that the patients had for their health care practitioners.

After recording any initial questions the patients had for their practitioners on a file card for the patients' later use, the RA, worked through an algorithm about diabetes care with the intent of stimulating the patient to form further questions. The algorithm had an HbA1c thermometer that indicated "normal", "excellent control", "good control", "fair control", and "Help!" at increasing levels of HbA1c. The patients' most recent HbA1c value was placed on the scale, and they were asked if they had any questions regarding their level. Any questions were recorded on the card.

Next, the RA outlined typical care options including modifying diet, regular exercise, and glucose monitoring that patients' with HbA1c's that were greater than 1.5% above the upper limit of normal would typically make to improve their glucose control. If those efforts failed to bring their blood sugars into a healthy range, several different medications were available that could be prescribed, including pills and/or insulin, to improve blood sugar. The patients read their most recent chart note, and were asked if that brought any questions to mind. The RA sought to clarify and record all questions generated during the session.

Once three to five questions had been elicited or 15 min had passed, the RA read the questions back to the patients to see if they had been recorded accurately. Then, patients were given a new blank file card and were invited to write down in their own words the questions they felt were most important. Once recorded, the RA inquired if the patients foresaw any difficulties in asking the questions. They encouraged the patients to rehearse asking the questions. Patients were thanked and invited to refer to the card during their appointment if needed.

2.2.2. The education intervention

In the attention control condition, the RA met with the patients for 20 min prior to three separate appointments, as was done in the activation condition. After greeting the patient and answering questions as done with activation patients, the RA selected a current American Diabetes Association videotape on diabetes care and played it for the patients. The patients were given a blank card with the instruction: "Here's a card if you'd like to take any notes." Once the video was completed, the patients were escorted to their scheduled appointment. Video-tapes all were of a length that kept the contact time between RA and patient at 20 min. Three different videos from the American Association of Diabetes Educators Patient Education Video Series (produced and distributed by Milner–Fenwick, Inc.) were shown: preventing long-term complications of diabetes, diabetes and exercise in training, and diabetes foot and skin care.

2.3. Assessments

2.3.1. Audio tape analyses

Of the 232 participants in the study, 214 had at least one taped interaction with a care practitioner and 151 had at least one taped practitioner visit prior to receiving the intervention and at least two taped visits on days in which they received the intervention.

To assess active involvement, raters listened to the entire practitioner–patient visit and then responded to three items using a 7-point Likert-type response scale anchored with 1 (not true at all) and 7 (very true). The three items the raters responded to were: "To what extent was the patient active in the negotiation about his/her diabetes?"; "To what extent did the patient seem interested in the management of his/her diabetes?"; and "To what extent was the patient involved in controlling his/her diabetes?". The three items were averaged for each rater to create a rater-specific active involvement index. As in previous research [4], the scale exhibited good internal consistency across the three raters, Cronbach's alpha = 0.89.

Raters were trained for 20 h on aspects of diabetes and its treatment and on use of the rating scale. They did ratings of practice tapes on which practitioner–patient interactions were recorded; the rating of practice tapes continued until reasonable agreement on each scale item had been obtained. Importantly, the raters were blind to the patients' condition and to the hypotheses of the study. Inter-rater reliability measured via intra-class correlation (ICC) [9] for the three raters on rated active involvement in this study was 0.76. The three, rater-specific indices were averaged to form the overall index of active involvement used in the analyses.

As a means to further validate the active involvement scale, and to determine if the activation intervention increased patient participation in the interviews, raters also recorded the number of questions the participants asked, and they estimated the percentage of time the patient versus the practitioner was speaking. Inter-rater reliability via ICC was 0.66 for number of questions asked and 0.68 for percentage of time speaking. The questions asked index and the number of questions index were constructed by averaging the reports of the three raters.

2.3.2. Relative HbA1c

HbA1c was collected at baseline, 6 and 12 months. The HbA1c tests were analyzed by four different laboratories, on five different instruments, and using two different techniques. Thus, test results from the five different instruments reported five different reference ranges for HbA1c. Each lab, the type of instrument and its reference range were as follows: The Genesee Hospital's high-performance liquid chromatography (Bio-Rad Variant Analyzer, Hercules, CA, USA) reference range was 4.1–6.5%. Strong Labs high-performance liquid chromatography (Bio-Rad Variant-classic) reference range was <6.0%. Rochester General Hospital's lab analyzed HbA1c using boronate affinity chromatography (Primus CLC, models 330 and 385) with a reference range of 4.2–5.5%. ACM lab's used two high performance liquid chromatography instruments (Bio-Rad Variant and Tosoh A1c 2.2) that had reference ranges of 3.8–6.7 and 4.6–6.5%, respectively. In order to compare change in HgbA1c across sites and across time, each result was "corrected," consistent with the method used by Muller et al. [10]. Specifically, relative HbA1c was calculated by dividing the patient's HbA1c by the median of the instrument reference range. Analyses involving the HbA1c data will be reported first using relative HbA1c, and then using absolute HbA1c scores to preserve the clinical meaning of the test.

3. Results

3.1. Preliminary analyses

Of the 232 patients randomized to condition, intention-to-treat analyses were conducted on 197 (85%) who completed the study, defined as having had HbA1c drawn at baseline (T1) and 12 months (T3). Patients who did not complete the study ($n = 35$) were younger (48.7 years versus 55.7, $t(225) = 3.42$, $P < 0.001$), were less likely to be married or living as married (51.4% versus 70.4%,

Table 1
Comparison of participants randomized to activation vs. education condition

Variables	Activation ($n = 120$)	Education ($n = 112$)	P
Demographic variables			
Age (years)	54.50	54.90	0.75
Education level (1–6)[a]	3.80	3.70	0.55
Household income (1–9)	6.20	5.70	0.12
Marital status (% married or living as married)	68.90	66.10	0.49
Sex (% female)	49.20	47.70	0.83
Race (% white)	62.40	72.60	0.14
Diabetes variables			
Age of onset (years)	44.70	44.90	0.91
Duration (years)	9.60	10.60	0.37
Complications	0.75	0.97	0.09
Visits to diabetes center during study	8.70	8.70	0.93
Months treated at diabetes center prior to study	26.70	28.40	0.74
Treatment type (%)			
Diet and exercise	3.40	2.80	0.79
Oral medication	61.00	50.90	0.13
Insulin	22.00	17.60	0.40
Insulin and oral medication	15.00	26.80	0.03
Glycemic control			
Actual HbA1c at base line	8.99	9.31	0.18
Relative HbA1c at baseline	1.75	1.80	0.29

Note: Complications is defined as the sum of neuropathy, nephropathy, retinopathy; T1: time 1 (baseline); med/gluc: medication and glucose testing; exer/diet: exercise and diet.

[a] The education variable had the following 6 levels: (1) up to 8 years of education, (2) up to 11 years of education, (3) up to 12 years/high school graduation or GED, (4) some college, (5) 4-year college degree, (6) graduate school.

$\chi^2 = 4.88$, $P < 0.03$), had had diabetes for a shorter time (6.3 years versus 10.8 years, $t(221) = 3.18$, $P < 0.01$), had a higher baseline relative HbA1c (1.96 versus 1.74, $t(229) = 3.37$, $P < 0.001$), higher baseline actual HbA1c (10.06 versus 8.98, $t(230) = 3.29$, $P < 0.01$), and made fewer study visits (7.2 versus 8.9, $t(221) = 3.21$, $P < 0.01$).

Comparisons between baseline characteristics of the intervention group and the education control group are presented in Table 1. They indicate that randomization was effective as there were no significant differences between the two groups, except that a greater percentage of patients using insulin and oral medications taken together were assigned to the education group.

3.2. Rated active involvement

Rated active involvement assessed prior to the intervention was significantly correlated with the average of patients' rated active involvement across at least two visits after the intervention ($r = 0.66$, $P < 0.001$). Rated active involvement during the intervention visits was found to be significantly correlated with number of questions asked ($r = 0.39$, $P < 0.001$, $n = 151$) and with percent time speaking ($r = 0.67$, $P < 0.001$, $n = 151$). These results indicate that rated active involvement was reliably measured. The clinical relevance of rated active involvement is reflected in its correlation with HbA1c at baseline ($r = -0.18$, $P < 0.05$).

3.3. Effect of the activation intervention on active involvement

Simultaneous regression analysis was used to detect change in the mean-rated active involvement as a function of activation condition. In this model, rated active involvement at intervention was regressed on pre-intervention rated active involvement and activation condition. This analyses revealed a significant effect for pre-intervention rated active involvement [$\beta = 0.65$, $F(1, 148) = 110.48$, $P < 0.01$], indicating that patients rated as active in visits prior to the intervention were rated as more active at intervention visits. Importantly, the analysis also revealed a significant effect of activation condition [$\beta = 0.13$, $F(1, 148) = 4.54$, $P < 0.05$], indicating that patients experiencing the activation intervention were rated as more active than those receiving passive education. The means and standard deviations for rated active involvement in each condition are presented in Table 2.

Two independent simultaneous regression analyses were used to detect changes in rated number of questions asked and rated percent time speaking. In each case, the intervention visit variable was regressed on the pre-intervention visit variable and activation condition. Pre-intervention number of questions asked significantly predicted number of questions asked at the intervention visit [$\beta = 0.64$, $F(1, 122) = 95.91$, $P < 0.01$], and pre-intervention percent

Table 2
Means and standard deviations of tape rating variables by activation vs. education condition

Variables	Activation ($n = 73$)	Education ($n = 78$)
Pre-intervention ratings		
Rated active involvement	4.59 (0.61)	4.49 (0.71)
Rated number of questions asked	4.19 (2.70)	4.54 (3.75)
Rated percent time talking	34.34 (7.79)	33.33 (9.10)
Intervention visit ratings		
Rated active involvement	4.78 (0.42)	4.61 (0.54)
Rated number of questions asked	4.32 (2.49)	3.07 (2.34)
Rated percent time talking	38.58 (6.85)	36.69 (8.41)

Note: Standard deviations are presented in parentheses.

time speaking significantly predicted percent time speaking at intervention [$\beta = 0.67$, $F(1, 122) = 89.37$, $P < 0.01$]. Importantly, both analyses revealed a significant effect of activation condition, such that patients experiencing the activation intervention were rated as asking more questions [$\beta = 0.32$, $F(1, 122) = 23.54$, $P < 0.01$], and as speaking a greater percentage of time [$\beta = 0.18$, $F(1, 122) = 6.80$, $P = 0.01$] than patients receiving passive education. The means and standard deviations for rated number of questions asked and for rated percent time talking are presented in Table 2.

3.4. Intention to treat analyses

First, a *t*-test was used to test whether mean relative HbA1c dropped significantly for participants in the study from 1.75 at T1 to 1.50 at T3 [$t(196) = 8.81$, $P < 0.01$]. The means, standard deviations, and ranges for relative HbA1c and absolute HbA1c for the full sample at each point in time appear at the end of Table 3. These results indicate that HbA1c was lowered significantly across the entire population. Mean levels decreased by 14%. Then, the intention to treat analyses were performed and revealed that neither relative HbA1c, nor absolute HbA1c, improved significantly more in the activation condition than in the education condition [$F(1, 194) = 0.45$, $P = 0.50$ and $F(1, 199) = 0.29$, $P = 0.59$, respectively]. Similar results were found for the 151 participants who had audio tapes available [$F(1, 148) = 0.003$, $P = 0.95$ and $F(1, 148) = 0.04$, $P = 0.85$, for relative and absolute HbA1c, respectively]. Intention-to-treat analyses also revealed no effect for condition when each of the three time points were included in a repeated measures ANOVA [$F(1, 176) = 1.63$, $P = 0.20$]. The intervention effect was also tested by comparing the percentage of patients in the activation and education groups who achieved a 12-month criterion value of "healthy" HbA1c, defined as one point above the upper limit of normal [Activation group

Table 3
Means, S.D., and ranges for study variables ($n = 151$)

Variables	Mean	S.D.	Observed range
Demographic variables			
Age (years)	55.74	10.55	24.23–79.77
Education level (1–6)	3.74	1.28	1–6
Household income (1–9)	6.02	2.40	1–9
Marital status (% married or living as married)	68.90	–	–
Sex (% female)	51.00	–	–
Race (% white)	66.90	–	–
Diabetes variables			
Age of onset (years)	45.64	10.73	17.16–72.62
Duration (years)	10.56	7.91	0–38
Complications	0.85	0.97	0–3
Visits to diabetes center during study	9.37	2.48	3–15
Months treated at diabetes center prior to study	28.84	37.15	0–151
Treatment type (%)			
Diet and exercise	2.00	–	–
Oral medication	54.30	–	–
Insulin	17.20	–	–
Insulin and oral medication	23.80	–	–
Outcome variable			
Actual HbA1c			
Baseline	9.06	1.79	5.5–15.30
6 months	7.55	1.29	5.4–13.20
12 months	7.53	1.63	5.3–16.40
Relative HbA1c			
Baseline	1.75	0.35	1.05–3.15
6 months	1.48	0.23	1.06–2.49
12 months	1.50	0.32	1.09–3.38

Note: Complications were defined as neuropathy, nephropathy, and retinopathy.

38.8% versus Education group 37.2%, $\chi^2 = 0.05$, $P = 0.82$], and no significant effect was found. In addition, the percentage of patients who achieved a reduction of 0.9 or greater in HbA1c was compared between groups (activation group 58.5% versus Education group 61.5%, $\chi^2 = 0.19$, $P = 0.67$), and no significant effect was found. Thus, the EPIC intervention effect on Hba1c was not replicated [3].

3.5. Effect of demographic, disease, and treatment variables on change in HbA1c

The values for the demographic, diabetes, and treatment variables are shown in Table 2. Hierarchical multiple regression was used to test the effects of three categories of variables—demographics, diabetes variables, and type of treatment—on change in HbA1c over 12 months to determine if these variables needed to be controlled for in further analyses. Twelve-month HbA1c was regressed onto baseline HbA1c, and then onto the demographic variables of age, education, marital status, gender, and race (non-white versus white). None of the demographic variables predicted change, so they were excluded from further analyses. Similarly, 12-month HbA1c was regressed onto baseline HbA1c, and then onto the diabetes variables of age of onset, duration of diabetes, number of microvascular complications of diabetes, number of prior visits to the diabetes center. Again none accounted for a significant amount of variance in the relative HbA1c change. Treatment type was divided into four categories: (1) diet and exercise only, (2) diet and exercise and oral medications, (3) diet and exercise and insulin, and (4) diet and exercise and combination of oral and insulin medications. Twelve-month HbA1c was regressed onto baseline HbA1c and contrasts codes representing each category of treatment types. None of the treatment types accounted for significant change in HbA1c. Based on these analyses, the demographic, disease, and treatment type variables were excluded from the further analyses regarding the effect of patient active involvement on change in HbA1c.

3.6. Effect of patient active involvement on change in HbA1c

Simultaneous regression was used to test the effect of patient active involvement during intervention visits on change in HbA1c from baseline to 12 months. In this model, 12-month relative HbA1c was regressed on baseline relative HbA1c and the rated active involvement at intervention index. Because the intention-to-treat analysis showed no difference in reduction of HbA1c over 12 months for the activation intervention condition, relative to passive education, the data were collapsed across condition and analyzed as one group. The analysis revealed a significant effect of baseline relative HbA1c [$\beta = 0.26$, $\Delta F(1, 148) = 11.64$, $P < 0.01$], and more importantly, a significant effect of patient activation on change in 12-month HbA1c [$\beta = -0.21$, $F(1, 148) = 7.50$, $P < 0.01$]. This finding indicates the patients judged as being more active at the intervention visit had greater decreases in HbA1c from baseline to 12 months. A similar analysis involving absolute HbA1c revealed a similar effect of rated active involvement at intervention [$\beta = -0.23$, $F(1, 148) = 8.64$, $P < 0.01$], and this analysis indicated that the mean decrease in HbA1c as a function of unit change in active involvement was 0.74%.

4. Discussion

The primary hypothesis that activation of patients prior to their medical appointments would improve glycemic control was not supported. Patient activation did, however, increase ratings of patients' active involvement in the visits, and active involvement, in turn, predicted improvement in HbA1c. Thus, the hypotheses were in part supported, but the effect of the activation intervention on glycemic control and its mediation by rated active involvement were not.

Possible reasons behind the failure to replicate the activation effect found in the EPIC trial are that there was an unexpected improvement of glycemic control in the education patients, the power may have been inadequate, there may have been contamination of the two groups, and the activation intervention may have been too weak to be experienced as different from the passive education process. We discuss each possibility in turn.

The unexpected improvement in the education patients could be explained by the specialty level care setting of the study. It is possible that the high intensity of care, and improved medications or training, provided by the multi-specialty team compensates for the advantage patient activation provides in a less intensive treatment setting.

It seems unlikely that the failure to replicate was a power issue, because there were 197 patients in the intention-to-treat analyses of this study that is nearly four times as many patients as in the initial Greenfield et al. [3] study. However, it is noteworthy, that the activation patients did have lower HbA1c scores at 6 and 12 months than did education patients. It also seems unlikely that cross-contamination occurred as the research staff heard little discussion of the intervention from the participants or from diabetes staff. Further, even if practitioners or center staff members were aware of the intervention, they would not have been aware of patient group assignment or of how to treat activated or educated patients differently in order to improve their HbA1c. It is possible that the RAs in our study were not as effective at activating patients as were the RAs in the Greenfield et al. [3] study. For example, the number of questions recorded on each card is not known. However, the tape analyses do indicate that "activated" patients, relative to "educated" patients, were found to be more involved, to ask more questions, and to speak a significantly greater percentage of the time. Thus, at least intermediate markers of "activation" were present in the dynamics of the interviews.

In this study, both the activation and the education group had an absolute mean reduction in HbA1c of over 1.0% (activation group absolute mean reduction in HbA1c = 1.42, S.D. = 2.11, and education group = 1.48, S.D. = 1.71, $t(200) = 0.23$, $P = 0.82$). In the original EPIC diabetes trial, the education condition did not demonstrate improvement in HbA1c over the time frame of the study (HbA1c = 10.3% at baseline and 10.6% after two 20 min education sessions, a 2.8% increase). In contrast, the education group in this study reduced its mean absolute HbA1c from 9.31 to 7.61 over the 12 months, a decrease of 18.3%. The activation group in the Greenfield et al. [3] study had a fall in HbA1c from 10.3 at baseline to 9.1 after 2 activation sessions (11.7% decrease) compared to a reduction of absolute HbA1c from 8.99 to 7.42 (a 17.5% decrease) for the 103 patients included in the activation condition of this study. Thus, the failure to find a significant activation effect resulted from the unexpected and substantial improvement in HbA1c in the education condition. This lack of condition effect on HbA1c may or may not reflect a lack of the efficacy of the EPIC intervention, but instead may reflect a lack of effectiveness in the specialty treatment setting, as mentioned above. In addition, the decade of improved treatments, and improved practitioner training could account for the improvement in the education condition.

The second aim of this analysis was to provide further validation of the construct of rated active involvement. In general, results presented here replicate those found in the smoking cessation study [4]. These results include that rated active involvement can be globally measured in a reliable manner with three raters. As expected, the construct correlated with changes in number of questions asked and in percent time speaking from before to after the intervention. In this study, it significantly predicted improvement in glycemic control over 12 months, as it had predicted 30-month continuous abstinence from smoking in the previous study [4]. In the smoking cessation study, patients were activated by physicians being trained to be autonomy supportive in counseling their patients. In this study, patients were activated by medical assistants prior to their visits. Thus, two methods by which patients can be "activated" have been demonstrated.

Diabetes self-management requires multiple complex behaviors be performed on a long-term basis. We expect that finding methods that increase active involvement may be useful in managing a variety of chronic disease outcomes and may be helpful in training health care practitioners in how to involve patients in the management of their diseases and to improve outcomes. However, more effective methods of patient activation will need to be identified.

The relevance of our study findings for clinicians includes that when patients are more actively involved, they are more likely to improve their HbA1c, than when they are passive. Intensive diabetes management resulted in 59% of these study patients improving their HbA1c by 0.9% and if maintained over 10 years would result in 25% less complications from diabetes.

In summary, this study provides evidence that rated active involvement can be reliably measured, that patient active involvement can be increased by patient activation, and that patient active involvement relates to improved control of diabetes. The effect of the activation intervention from the EPIC trials was not replicated in this study, possibly because of the intensive level of care provided in the background of the trial.

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