Psychological Family Intervention for Poorly Controlled Type 2 Diabetes

Karen M. Keogh, PhD; Susan M. Smith, MD; Patricia White, PhD; Sinead McGilloway, PhD; Alan Kelly, PhD; James Gibney, MD; and Tom O'Dowd, MD

Objective: To evaluate the effectiveness of a psychological, family-based intervention to improve diabetes-related outcomes in patients with poorly controlled type 2 diabetes.

Methods: This study was a randomized controlled trial of a psychological family-based intervention targeted at individuals with poorly controlled type 2 diabetes. Recruitment and follow-up occurred at specialist diabetes clinics. Patients were randomly allocated to an intervention group (n = 60) or a control group (n = 61). Poor control was defined as at least 2 of the patient's last 3 glycated hemoglobin (A1C) readings at ≥8.0%. The intervention consisted of 2 sessions delivered by a health psychologist to the patient and a family member in the patient's home, with a third session involving a 15-minute follow-up telephone call.

Results: At 6-month follow-up, the intervention group reported significantly lower mean A1C levels than the control group (8.4% [SD = 0.99%] vs 8.8% [SD = 1.36%]; $P = .04$). The intervention was most effective in those with the poorest control at baseline (A1C >9.5%) (intervention 8.7% [SD = 1.16%, n = 15] vs control 9.9% [SD = 1.31%, n = 15]; $P = .01$). The intervention group also reported statistically significant improvements in beliefs about diabetes, psychological well-being, diet, exercise, and family support.

Conclusions: After participating in a family-based intervention targeting negative and/or inaccurate illness perceptions, patients with poorly controlled type 2 diabetes showed improvements in A1C levels and other outcomes. Our results suggest that adding a psychological, family-based component to usual diabetes care may help improve diabetes management.

(Am J Manag Care. 2011;17(2):105-113)

For author information and disclosures, see end of text.

Poor glycemic control is a significant challenge in the management of type 2 diabetes, with 36% to 69% of patients[1-4] failing to reach glycemic control targets. These individuals are at an increased risk of developing diabetes-related complications, which impact negatively on their quality of life and have cost implications for healthcare providers.[1,3] There are well-recognized barriers to the successful management of type 2 diabetes, including psychological difficulties and failure to use the expertise of multidisciplinary team members.[1]

Evidence suggests that people with poorly controlled type 2 diabetes have distinctly different perceptions or beliefs about diabetes compared with people who have good control.[5] The current theoretical framework guiding research in this area is the Self-Regulatory Model of Leventhal et al[6] (eAppendix at **www.ajmc.com**). According to this model, illness perceptions influence self-management behaviors, which in turn may influence health outcomes. For example, the perception that type 2 diabetes is an acute illness and the belief that diabetes has a negative impact on a person's life have been found to be associated with poorer metabolic control.[7] People with poorly controlled type 2 diabetes are also more likely to report that their diabetes is caused only by genetic factors,[8,9] thereby potentially limiting their motivation to change unhealthy behaviors.

Thus, interventions focusing on changing negative and/or inaccurate beliefs about diabetes may lead to better self-management and glycemic control. However, family members' perceptions about diabetes may also influence diabetes outcomes,[8-10] for example, by impacting their decisions to provide support for disease management. Importantly, family-oriented research in type 2 diabetes has been relatively underinvestigated.[11] The current study assesses the effectiveness of a psychological family-based intervention for patients with poorly controlled type 2 diabetes.

METHODS

Study Design, Participants, and Settings

This study involved a 6-month prospective randomized controlled trial. Participants were recruited from specialist diabetes clinics at a large suburban hospital. In Ireland, usual care for poorly controlled type 2 diabetes generally involves annual attendance at a specialist

In this article
Take-Away Points / p106
www.ajmc.com
Full text and PDF
Web exclusive
eAppendix

Take-Away Points

As an adjunct to usual care, a psychological family-based intervention improved glycemic control in patients with poor glycemic control.

- Those with particularly poor control derived the most benefit from the intervention.
- Participants regarded the home setting as a key element of the intervention.
- This intervention could potentially be delivered by any trained member of the multidisciplinary diabetes team.

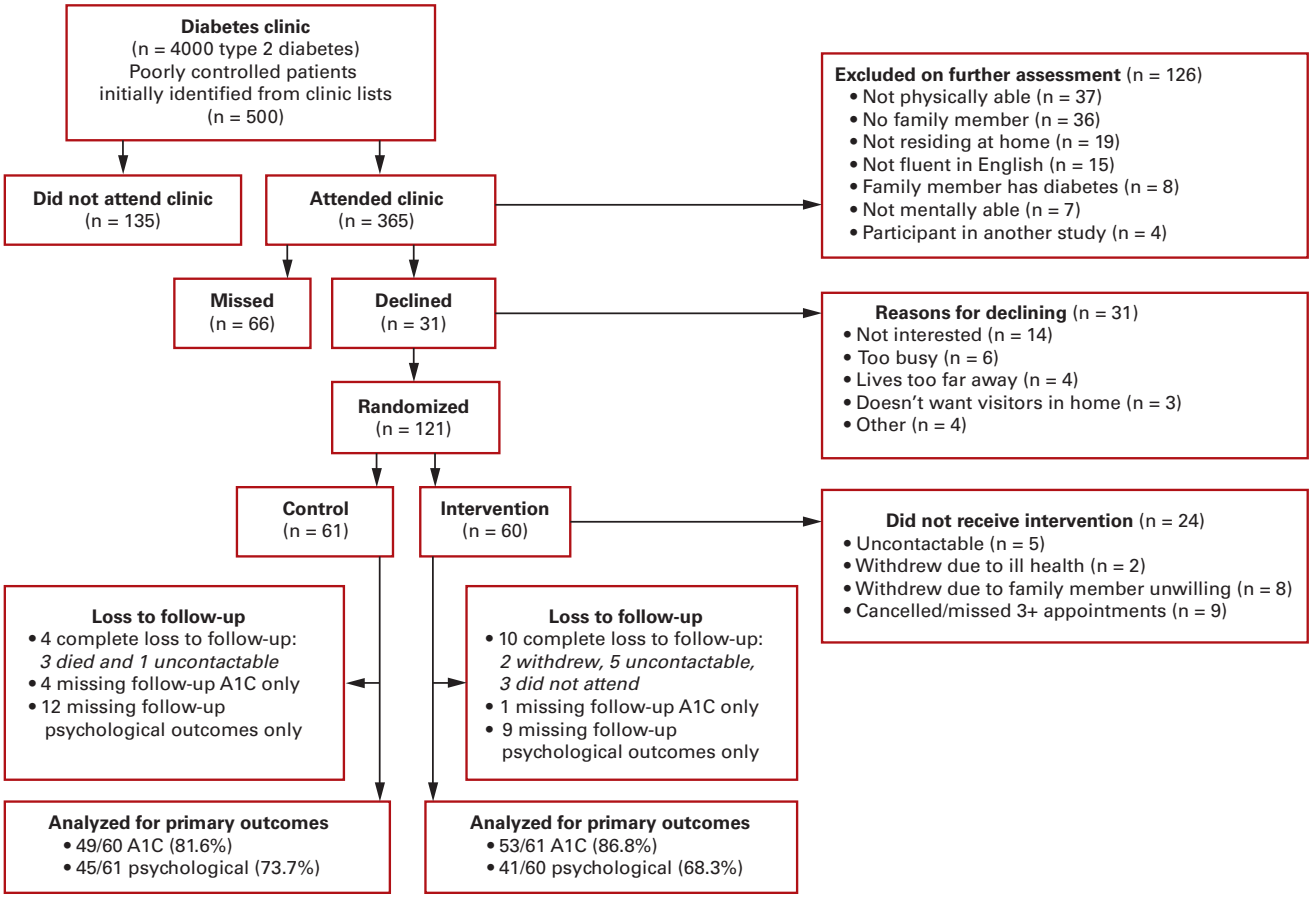
outpatient clinic, with interim care provided by family practitioners. There is no national remunerated structured care delivery program; thus, clinicians follow protocols based on international guidelines (eg, those of the American Diabetes Association).

Patients were included in the study if they had type 2 diabetes for more than 1 year, were over 18 years old, and had persistently poor glycemic control, defined as having at least 2 of their last 3 glycated hemoglobin (A1C) readings at 8.0% or higher. Assessments of A1C coincided with patients' last 3 clinic visits, generally at the time of recruitment and at 6 and 12 months previously. Patients with a recruitment A1C of less than 8.0% were included if their previous assessments were greater than 8.0%. Patients nominated the family member who was most involved in helping them with their diabetes management to participate. Family members were defined as those having a close relationship and regular contact with the patient, although they were not required to be living with patients or to be a blood relative (eg, a close friend could participate). Family members were required to be over 18 years old and to have no history of diabetes. Participants provided written informed consent to participate. Ethical approval was granted by the Hospital Ethics Committee.

Outcome Measures

Primary outcomes included A1C, illness perceptions (using the Brief Illness Perception Questionnaire),[12] and psychologi-

Figure 1. Selection Process for Study Participants



A1C indicates glycated hemoglobin.

Table 1. Sociodemographic and Clinical Characteristics of Intervention and Control Group Participants and Family Members

Characteristic	Control (n = 61)	Intervention (n = 60)
Male sex, %	62 (38/61)	65 (39/60)
Age, mean (SD), y	57.29 (11.34)	59.96 (11.67)
No. of years diagnosed, mean (SD)	9.65 (6.45)	9.17 (7.10)
Complications, %		
Retinopathy	8 (5/61)	7 (4/61)
Neuropathy	3 (2/61)	8 (5/61)
Nephropathy	2 (1/61)	2 (1/61)
Hypertension	41 (25/61)	40 (24/61)
Treatment type, %		
Insulin	49 (30/61)	55 (33)
Oral hypoglycemic agents only	51 (31/61)	43 (26)
Missing	—	2 (1)
A1C, median (SD)	9.29 (1.13)	9.06 (0.96)
BMI, mean (SD), kg/m^2	32.60 (4.78)	32.01 (5.15)
Systolic BP, mean (SD), mm Hg	138.00 (17.93)	139.51 (19.17)
Diastolic BP, mean (SD), mm Hg	77.65 (10.64)	75.96 (9.71)
Family members[a]		
Age, mean (SD), y	47.93 (15.81)	54.09 (12.53)
Male, %	38 (12/32)	25 (9/36)
Husband/partner, %	21 (7/32)	14 (5/36)
Wife/partner, %	47 (15/32)	69 (25/36)
Daughter, %	19 (6/32)	17 (6/36)
Son, %	13 (4/32)	0 (0/36)

A1C indicates glycated hemoglobin; BMI, body mass index; BP, blood pressure.
[a]All family members resided in the same home as patients, although this was not a prerequisite for inclusion.

cal well-being (using the 12-item Well-Being Questionnaire).[13] Secondary outcomes included blood pressure, body mass index, diabetes self-management (using the Summary of Diabetes Self-care Activities Questionnaire),[14] self-efficacy (using the UK version of the Diabetes Management Self-Efficacy Scale),[15] and family support (using the Diabetes Family Behavior Checklist).[16] All questionnaires are psychometrically robust and have demonstrated sensitivity to change (see the trial protocol[17]).

Randomization, Allocation Concealment, and Blinding

An independent statistician (AK) allocated participants to groups by a remote computer-generated random number sequence. Concealment of the allocation sequence was also ensured by randomizing participants after they had been recruited and had completed baseline assessments. Outcome assessors were blinded to group allocation. Due to the psychological nature of the intervention, the psychologist and participants were not blinded.

Intervention

The intervention consisted of 3 weekly sessions delivered by a health psychologist (KMK) who had received 16 hours of training in motivational interviewing. The first 2 sessions lasted 45 minutes each and took place in the patient's home with their family member. The third session involved a 10- to 15-minute follow-up telephone call. Intervention sessions were individually tailored to participants' needs and attempted to (1) challenge and clarify any inaccurate and/or negative perceptions about diabetes, (2) examine how these perceptions influenced self-management, and (3) develop written personalized action plans to improve self-management and mobilize family support. The intervention used techniques from health psychology[18] and motivational interviewing[19] such as exchanging information, eliciting change talk, reducing resistance, building self-efficacy, problem solving, and goal setting/action planning. Details are published in the intervention manual.[17] Both the intervention and control groups continued to receive their usual diabetes care.

Table 2. Adjusted Mean Intervention Effect on Primary Outcomes[a]

	Control		Intervention	
Primary Outcome	**Baseline Mean (SD)**	**6-Month Mean (SD)**	**Baseline Mean (SD)**	**6-Month Mean (SD)**
A1C[b]	9.29 (1.13)	8.80 (1.36)	9.06 (0.96)	8.41 (0.99)
Illness perceptions				
Consequences	5.45 (3.21)	5.31 (3.21)	5.01 (3.36)	3.68 (3.13)
Timeline	8.55 (2.42)	9.28 (2.27)	8.63 (2.31)	9.80 (1.24)
Personal control	4.45 (2.77)	4.75 (3.19)	5.25 (3.01)	7.02 (2.39)
Treatment control	6.80 (2.80)	6.64 (3.63)	7.01 (2.65)	8.41 (2.22)
Symptoms	4.37 (3.54)	5.33 (3.64)	4.20 (3.34)	3.48 (3.09)
Concern	4.95 (3.61)	6.20 (3.55)	4.21 (3.68)	3.85 (3.56)
Understanding	5.91 (2.99)	6.28 (2.80)	5.91 (2.78)	8.39 (1.89)
Emotional rep.	5.09 (3.72)	5.60 (3.89)	4.25 (3.92)	3.39 (3.23)
Cause of illness				
Don't know	11.5% (7%)	6.6% (4%)	16.7% (10%)	6.7% (4%)
Overweight	44.3% (27%)	34.4% (21%)	33.3% (20%)	23.3% (14%)
Genetics	45.9% (28%)	39.3% (24%)	38.3% (23%)	21.7% (13%)
Diet factors	29.5% (18%)	32.8% (20%)	40% (24%)	35% (21%)
Lack of exercise	11.5% (7%)	6.6% (4%)	6.7% (4%)	13.3% (8%)
Other lifestyle	9.8% (6%)	1.6% (1%)	8.3% (5%)	6.7% (4%)
Other physical	21.3% (13%)	9.8% (6%)	16.7% (10%)	13.3% (8%)
Psychological	19.7% (12%)	16.4% (10%)	16.7% (10%)	8.3% (5%)
Well-being				
Negative	4.24 (3.96)	4.08 (4.02)	4.06 (4.10)	2.48 (2.72)
Energy	4.40 (3.82)	3.48 (3.30)	4.23 (3.56)	7.31 (3.37)
Positive	8.26 (3.33)	6.60 (3.68)	8.28 (3.06)	9.53 (3.00)
General	20.29 (8.52)	18.15 (9.03)	20.45 (8.28)	26.36 (7.01)

Boldfacing indicates a statistically significant difference.
A1C indicates glycated hemoglobin; B, unstandardized coefficient; β, standardized coefficient; CI, confidence interval; ✓, improvement; –, no improvement.
[a]Baseline covariates are the corresponding baseline measure, duration of diabetes, and change to insulin.
[b]Controlling for interaction between baseline A1C and group: A1CBL*Group B = −0.47; SE = 0.21; 95% CI = −0.90 to −0.03; $P = .03$.

Statistical Analysis

A power analysis based on A1C and psychological well-being as the primary outcomes indicated that a sample size of 86 gave 80% power to detect an *absolute* change of 0.9% in glycemic control and of 3 points on the Well-Being Questionnaire. These changes have been related to clinical outcomes.[20] Thus, a sample size of 122 (61 per group) was required to ensure at least 80% power, if a response rate of 70% was achieved.

All analyses were "intention-to-treat" using Stata/SE version 10 (StataCorp LP, College Station, TX). Regression modeling was used to compare primary and secondary outcomes in the comparison groups, with prespecified adjustments made for known prognostic factors, including duration of diabetes and change in response to insulin as fixed effects, and baseline A1C as a covariate. Statistical significance was set at 5% for primary outcomes and at 1% for secondary outcomes. When testing the data for the statistical assumptions underlying regression, it emerged that there was a significant interaction between the independent variable (randomized controlled trial group) and a covariate (baseline A1C). This interaction was not anticipated and was not prespecified in the analysis protocol. However, as recommended by statisticians,[21,22] this interaction effect was controlled for by including it as a covariate and was further investigated by "blocking" participants according to the covariate. A per-protocol analysis excluding participants who did not receive the full intervention was also conducted. These results did not differ from the intention-to-treat analysis and are not described.

RESULTS

A total of 121 patients were recruited (**Figure 1**), 60 of whom were randomized to the intervention group and 61 to the control group. There were no baseline differences between the groups with regard to sociodemographic and clinical characteristics, nominated family members

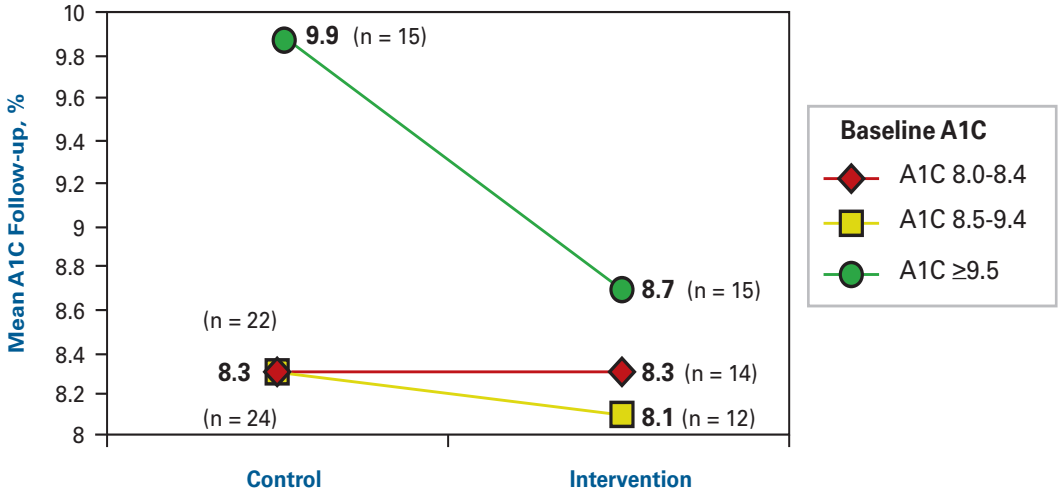
No.	B	SE of B	β	95% CI	*P*	Result
102	4.01	1.99	1.65	**0.05 to 7.98**	**.04**	✓
86	−0.66	0.51	−0.10	−1.68 to 0.35	.19	–
86	0.51	0.37	0.13	−0.23 to 1.25	.17	–
86	1.51	0.58	0.25	**0.35 to 2.67**	**<.001**	✓
86	1.49	0.61	0.23	**0.26 to 2.71**	**.01**	✓
86	−1.62	0.66	−0.23	**−2.94 to −0.29**	**.01**	✓
86	−1.98	0.76	−0.26	**−3.49 to −0.46**	**.01**	✓
86	2.27	0.47	0.43	**1.31 to 3.21**	**<.001**	✓
86	−1.79	0.74	−0.24	**−3.28 to −0.30**	**.01**	✓
85	−0.049	0.05	−0.08	−1.59 to 0.04	.37	–
85	−0.003	0.09	0.01	−0.18 to 0.17	.97	–
85	−0.196	0.07	−0.21	**−0.34 to −0.05**	**<.001**	✓
85	0.082	0.006	0.24	−0.05 to 0.21	.21	–
85	0.091	0.10	0.08	−0.11 to 0.03	.38	–
85	0.158	0.01	0.00	**0.027 to 0.29**	**.01**	✓
85	0.066	0.04	0.00	−0.02 to −0.16	.16	–
85	−0.083	0.06	0.00	−0.22 to 0.05	.22	–
86	−1.38	0.58	−0.19	**−2.54 to −0.23**	**.01**	✓
86	3.57	0.64	0.32	**2.29 to 4.86**	**<.001**	✓
86	2.33	0.57	0.46	**1.20 to 3.47**	**<.001**	✓
86	6.98	1.30	0.38	**4.39 to 9.58**	**<.001**	✓

(**Table 1**), or the proportion of participants showing a trend toward improvements in glycemic control (control group = 14/61 vs intervention group = 18/60). There were also no differences between participants with completed and missing follow-up data or between participants who received the intervention and those who did not (Figure 1). Nonparticipants were still asked to attend for follow-up assessment.

At 6-month follow-up (**Table 2**), there was a modest statistically significant difference in A1C of 0.4% between the groups (control group mean of 8.80% [SD = 1.36%] vs intervention group mean of 8.41% [SD = 0.99%]; *P* = .04). Interaction effects were investigated by grouping participants into 3 blocks (**Figure 2**): (1) baseline A1C 8.0% to 8.4%, (2) baseline A1C 8.5% to 9.4%, and (3) baseline A1C ≥9.5%. There were no significant differences in follow-up A1C between groups in block 1 or block 2. In block 3 there was a statistically significant difference of 1.2% in follow-up A1C levels between the groups (intervention mean of 8.70% [SD =1.16%], n = 15, vs control mean of 9.95% [SD = 1.31%], n = 15; B = –1.28, SE (B) = 0.49; *P* = .01; 95% confidence interval, = –2.29 to -0.26). There were no significant differences between the baseline A1C levels in this block 3 group.

The intervention group reported statistically significant changes across all illness perception dimensions except "consequences" and "timeline." Thus, the intervention group reported better personal control, a better understanding of diabetes, and an increased belief in treatment effectiveness. They also reported fewer symptoms and lower levels of diabetes concern and distress. Significantly fewer participants in the intervention group attributed their diabetes to genetic factors, whereas a significantly greater number perceived their diabetes to be caused by a sedentary lifestyle. The intervention group also reported statistically significant improvements in all aspects of psychological well-being, adherence to general dietary and exercise recommendations, diabetes self-efficacy, and family support. There were no differences in fruit,

Figure 2. Interaction Effects by Participant Group



A1C indicates glycated hemoglobin.

Table 3. Adjusted Mean Intervention Effect on Secondary Outcomes[a]

	Control		Intervention	
Secondary Outcome	**Baseline Mean (SD)**	**6-Month Mean (SD)**	**Baseline Mean (SD)**	**6-Month Mean (SD)**
BMI, kg/m²	32.60 (4.78)	33.88 (5.32)	32.01 (5.15)	31.57 (5.16)
Systolic BP, mm Hg	138.0 (17.93)	135.85 (16.48)	139.51 (19.17)	139.72 (20.79)
Diastolic BP, mm Hg	77.65 (10.64)	77.00 (9.91)	75.96 (9.71)	75.43 (10.32)
Self-care activities				
General diet	8.19 (4.36)	8.42 (4.19)	8.51 (4.01)	10.63 (2.84)
Five fruits/vegetables	4.27 (2.32)	3.46 (2.62)	4.35 (2.36)	4.70 (2.46)
Fat intake	3.26 (2.12)	3.51 (2.26)	3.63 (2.12)	3.36 (2.16)
Exercise	3.36 (3.26)	3.11 (3.29)	3.46 (3.81)	5.39 (4.02)
Blood glucose testing	8.40 (5.29)	8.82 (5.45)	9.88 (4.46)	10.70 (4.72)
Foot care	5.57 (4.77)	5.68 (5.35)	4.56 (5.13)	6.34 (5.08)
Number of smokers	13/46 (28.2%)	12/45 (26%)	5/41 (8.3%)	3/41 (7%)
Self-efficacy	78.75 (19.06)	91.26 (28.51)	86.63 (20.85)	116.97 (18.51)
Family support				
Support	26.46 (6.89)	20.75 (7.32)	24.65 (7.51)	24.951 (8.4)
Nonsupport	16.22 (6.45)	17.56 (7.16)	15.45 (5.92)	14.68 (5.96)

Boldfacing indicates a statistically significant difference.
A1C indicates glycated hemoglobin; B, unstandardized coefficient; β, standardized coefficient; BMI, body mass index; BP, blood pressure; CI, confidence interval; ✓, improvement; -, no improvement.
[a]Baseline covariates are the corresponding baseline measure, duration of diabetes, and change to insulin.
[b]Controlling for interaction between baseline A1C and group: A1CBL*Group B = −0.47; SE = 0.21; 95% CI = −0.90 to −0.03; P = .03.

vegetable, and fat intake, blood glucose testing, foot care, body mass index, or blood pressure (Table 3).

Process Evaluation

Process evaluation methods are detailed in the trial protocol.[17] Findings indicate that the intervention was delivered per protocol and was acceptable to participants. Reasons for participants not receiving the intervention (24/60) are detailed in Figure 1.

DISCUSSION

Our findings suggest that a psychological family-based intervention for patients with poorly controlled type 2 diabetes led to improvements in glycemic control, diabetes perceptions, psychological well-being, self-management behaviors, and family support.

However, both groups continue to have unacceptably high A1C levels at follow-up, with neither group achieving optimal glycemic control targets. Nonetheless, the 0.4% decrease in A1C in this study is comparable to improvements associated with other psychosocial interventions for patients with diabetes,[23,24] and a decrease in A1C of 0.5% is increasingly recognized as clinically significant. Although the numbers were small, patients in the most vulnerable subgroup of this population with poor control (baseline A1C >9.5%) showed the greatest improvement in A1C, with a 1.2% decrease. That is comparable to improvements seen after the introduction of new oral hypoglycemic medications.[25] Arguably, the intervention was most effective in those with the poorest control because they had the greatest scope for improvement at a psychological and biologic level. As patients in this group are often the most challenging to manage, the approach adopted in this trial may be of value to clinicians and patients alike. A recent pharmacist-managed collaborative care intervention for poorly controlled diabetes also found that some patients benefited more than others.[26] When evaluating complex interventions, future research might address the question of what best works for whom, and under what circumstances, so that clinicians and service planners can target such interventions more cost-effectively.

The intervention group also reported significant improvements in most illness perception dimensions (except consequences and timeline), indicating that patients had a more

No.	B	SE of B	β	95% CI	*P*	Result
87	−0.77	0.55	−0.06	−1.82, 0.39	.20	–
95	3.47	3.61	0.09	−3.86, 10.80	.34	–
95	−0.34	2.01	−0.01	−4.43, 3.66	.86	–
86	1.93	0.67	0.25	**0.58, 3.28**	**.005**[b]	✓
86	0.92	0.52	0.17	−0.12, 1.97	.09	–
86	−0.26	0.42	−0.06	−1.12 , 0.60	.54	–
86	1.93	0.69	0.25	**0.56, 3.31**	**.006**[b]	✓
86	1.31	0.91	0.12	−1.20, 0.70	.60	–
86	1.06	1.10	0.10	−1.13, 3.26	.96	–
86	−0.28	0.21	−0.08	−0.71, 0.21	.19	–
86	22.17	5.34	0.40	**11.53, 32.82**	**<.001**[b]	✓
86	4.45	1.62	0.27	**1.21, 7.69**	**.008**[b]	✓
86	−2.42	1.34	−0.18	−5.11, 0.05	.07	–

accurate and positive view of diabetes. Our results are consistent with results of the small number of interventions in other illness populations that have had similar success in changing illness perceptions.[27] Baseline scores on the timeline dimension indicated that participants had an accurate view of diabetes as a chronic condition; thus, there was little scope for improvement. With regard to consequences, there *was* a significant improvement in the intervention group when nonparticipants were excluded from the analysis.

There was little scope for changes in blood pressure, as both groups had acceptable control at baseline. The lack of any change in body mass index is in keeping with other family intervention studies[23] and highlights the difficult task faced by patients in controlling their weight. The lack of improvements in specific self-management behaviors may have arisen as participants were given the opportunity to select the behaviors targeted for change. This raises questions about interventions that emphasize patients' own goals for change, as specific self-management behaviors (eg, foot care) may be undervalued and not addressed.

Strengths and Limitations

The key strengths of this study include its firm theoretical base, its mixed-methods approach, its multidisciplinary team input, and its adherence to the high-quality practices recommended for randomized controlled trials.[28] These factors, as well as the pattern of improvements across primary and secondary outcomes, suggest that internal validity was high. However, given the high "did not attend" rates at recruitment clinics, and the consistent association between infrequent clinic attendance and adverse clinical outcomes,[29] it is likely that the most vulnerable of those with poor glycemic control (ie, those who default from care) were not recruited. However, it was not possible to analyze this group, as we had no consent to access their records**.** Additionally, in terms of controlling for medication change, only a change from oral hypoglycemic agents to insulin was included in the analysis. It was not possible to collect data on other types of medication changes, although this is an important factor that future studies may want to consider. Also, the current study would ideally have included a longer follow-up (eg, +12 months) to investigate whether observed improvements were maintained.

We were unable to identify from the literature any other home-based interventions for patients with poorly controlled type 2 diabetes. However, home-based interventions for other groups[30] have been found to be acceptable and convenient to patients, and may help to educate family members and encourage family involvement in disease management. Such interventions may also be more effective at accessing vulnerable populations, including the elderly, ethnic minorities, patients from socially deprived areas, patients with multimorbidity, and those who fail to attend regular clinic-based care. The increased costs associated with home-based interventions, however, ought to be balanced against their overall effectiveness. Future studies may consider implementing this kind of intervention in a clinic setting, alongside a full cost-effectiveness analysis, to determine whether it has similar positive effects. While this intervention was delivered by a psychologist, other health professionals could be trained to deliver it in other contexts. This is an important consideration in terms of the effective future implementation of such psychological interventions into routine care.

Without a patient-only intervention arm, it was not possible to conclusively elucidate the effects of including a family member. However, the robust theoretical framework underlying the intervention, coupled with appropriate process and outcome measures, suggests that the family member was a key active ingredient. The majority of the sample (75%) nominated their spouses, and the remaining proportion proposed their children. The study was not powered to detect whether there were any differences in outcomes depending on the family relationship, and this factor may be an area for future research. Eight patients did not receive the intervention because their family member declined to participate. It is possible that mobilizing family support is most important in this group. However, it also may be possible to deliver the intervention to these patients individually. Although additional arms increase trial complexities and costs, it may be worthwhile to conduct future studies comparing a family intervention with a patient-only intervention.

Finally, it must be noted that the delivery of this intervention was challenging and time consuming, due in part to the difficulties in accessing participants despite repeated efforts. Clinicians and service planners will recognize the existence of a hard-to-reach group of high-risk patients who frequently require unplanned care with repeated hospital admissions to deal with the complications of poor control. Continued persistence and flexibility may be the solution to accessing these vulnerable populations in both research and clinical settings, although these interventions initially may be more costly and time consuming. In the long term, such interventions may improve illness outcomes for patients, thereby reducing costs and improving quality of life for patients and families.

CONCLUSIONS

This study indicates that targeting inaccurate and/or negative beliefs about poorly controlled type 2 diabetes, in the home setting and in the presence of a family member, can change illness perceptions and improve poor glycemic con-

trol, self-management, psychological well-being, and family support. Given the resource-intensive nature of this intervention and the modest improvement in glycemic control, future studies are needed to assess the effectiveness of the delivery of this type of intervention delivered in alternative settings, and by other health professionals. Tailoring these kinds of interventions to those with the poorest of control may deliver the most benefit, at least in the short term.

Acknowledgments

The authors would like to thank all participating patients and their families; staff at the diabetes clinics; and Professor Steward Mercer, MD, University of Glasgow, and Michael Donnelly, PhD, Queen's University Belfast, who provided valuable feedback on the study.

Author Affiliations: From the Department of Public Health and Primary Care (KMK, SMS, PW, AK, TO), Trinity College Dublin, Ireland; Department of Psychology (SM), National University of Ireland, Maynooth, Ireland; and Department of Endocrinology (JG), Trinity College Dublin, Ireland.

Funding Source: This study was funded by the Irish Health Research Board, project grant RP/2005/178.

Author Disclosures: The authors (KMK, SMS, PW, SM, AK, JG, TO) report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Authorship Information: Concept and design (SMS, PW, AK, JG, TO); acquisition of data (KMK, PW); analysis and interpretation of data (KMK, SMS, PW, SM, AK); drafting of the manuscript (KMK, SMS, PW, SM, AK, TO); critical revision of the manuscript for important intellectual content (KMK, SMS, PW, SM, AK, JG, TO); statistical analysis (KMK, SMS, PW, SM, AK); provision of study materials or patients (KMK, SMS, JG); obtaining funding (SMS, PW, AK, TO); administrative, technical, or logistic support (KMK, SMS, PW, AK); and supervision (SMS, PW, SM, TO).

Address correspondence to: Karen M. Keogh, PhD, Department of Public Health and Primary Care, Trinity College Dublin, Trinity College Centre for Health Sciences, AMNCH, Tallaght, Dublin 24, Ireland. E-mail: keoghkm@tcd.ie.

REFERENCES

1. Berger JE, Ahmann AJ, Balfour DC, et al. Treating to target: implementing an effective diabetes care paradigm for managed care. *Am J Manag Care.* 2010;16(3 Suppl Treating):S4-S35.

2. Liebl A, Mata M, Eschwège E; ODE-2 Advisory Board. Evaluation of risk factors for development of complications in type II diabetes in Europe. *Diabetologia.* 2002;45(7):S23-S28.

3. Massi-Benedetti M; CODE-2 Advisory Board. The cost of diabetes type II in Europe: the CODE-2 Study. *Diabetologia.* 2002;45(7):S1-S4.

4. Saydah SH, Fradkin J, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA.* 2004;291(3):335-342.

5. Harvey JN, Lawson VL. The importance of health belief models in determining self-care behaviour in diabetes. *Diabet Med.* 2009;26(1):5-13.

6. Leventhal H, Safer MA, Panagis DM. The impact of communications on the self-regulation of health beliefs, decisions, and behavior. *Health Educ Q.* 1983;10(1):3-29.

7. Paddison CA, Alpass FM, Stephens CV. Psychological factors account for variation in metabolic control and perceived quality of life among people with type 2 diabetes in New Zealand. *Int J Behav Med.* 2008;15(3):180-186.

8. White P, Smith SM, O'Dowd T. Living with type 2 diabetes: a family perspective. *Diabet Med.* 2007;24(7):796-801.

9. White P, Smith SM, Hevey D, O'Dowd T. Understanding type 2 diabetes: including the family member's perspective. *Diabetes Educ.* 2009;35(5):810-817.

10. Searle A, Norman P, Thompson R, Vedhara K. Illness representations among patients with type 2 diabetes and their partners: relationships with self-management behaviors. *J Psychosom Res.* 2007;63(2):175-184.

11. Keogh KM, White P, Hevey D, McGilloway S, Smith SM. Family based interventions to improve outcomes in patients with type 2 diabetes mellitus. *Cochrane Database of Systematic Reviews: Protocols.* 2007:(1). The Cochrane Collaboration, John Wiley & Sons Ltd Art No. CD006382; DOI: 10.1002/14651858. http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD006382/frame.html. Accessed February 4, 2011.

12. Broadbent E, Petrie KJ, Main J, Weinman J. The Brief Illness Perception Questionnaire. *J Psychosom Res.* 2006;60(6):631-637.

13. Bradley C. The 12-Item Well-Being Questionnaire: origins, current stage of development, and availability. *Diabetes Care.* 2000;23(6):875.

14. 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(7):943-950.

15. Bijl JV, Poelgeest-Eeltink AV, Shortridge-Baggett L. The psychometric properties of the Diabetes Management Self-efficacy Scale for patients with type 2 diabetes mellitus. *J Adv Nurs.* 1999;30(2):352-359.

16. Schafer LC, McCaul KD, Glasgow RE. Supportive and nonsupportive family behaviors: relationships to adherence and metabolic control in persons with type I diabetes. *Diabetes Care.* 1986;9(2):179-185.

17. Keogh KM, White P, Smith SM, McGilloway S, O'Dowd T, Gibney J. Changing illness perceptions in patients with poorly controlled type 2 diabetes, a randomised controlled trial of a family-based intervention: protocol and pilot study. *BMC Fam Pract.* 2007;8:36.

18. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From theory to intervention: mapping theoretically derived behavioural determinants to behaviour change techniques. *Appl Psychol-Int Rev.* 2008;57(4):660-680.

19. Rollnick S, Miller WR, Butler CC. *Motivational Interviewing in Health Care: Helping Patients Change Behavior.* New York: Guilford Press; 2008.

20. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA. 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med.* 2008;359(15):1577-1589.

21. Bryk AS, Raudenbush SW. Heterogeneity of variance in experimental studies: a challenge to conventional interpretations. *Psychol Bull.* 1988;104(3):396-404.

22. Tabachnick BG, Fidell LS. *Using Multivariate Statistics.* 5th ed. Boston, MA: Allyn & Bacon/Pearson Education; 2007.

23. Armour TA, Norris SL, Jack L Jr, Zhang X, Fisher L. The effectiveness of family interventions in people with diabetes mellitus: a systematic review. *Diabet Med.* 2005;22(10):1295-1305.

24. Ismail K, Winkley K, Rabe-Hesketh S. Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. *Lancet.* 2004;363(9421):1589-1597.

25. Bolen S, Feldman L, Vassy J, et al. Systematic review: comparative effectiveness and safety of oral medications for type 2 diabetes mellitus [published correction appears in *Ann Intern Med.* 2007;147(12):887]. *Ann Intern Med.* 2007;147(6):386-399.

26. Jameson JP, Baty PJ. Pharmacist collaborative management of poorly controlled diabetes mellitus: a randomized controlled trial. *Am J Manag Care.* 2010;16(4):250-255.

27. Petrie KJ, Cameron LD, Ellis CJ, Buick D, Weinman J. Changing illness perceptions after myocardial infarction: an early intervention randomized controlled trial. *Psychosom Med.* 2002;64(4):580-586.

28. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ.* 2010;340:c332.

29. Griffin SJ. Lost to follow-up: the problem of defaulters from diabetes clinics. *Diabet Med.* 1998;15(suppl 3):S14-S24.

30. Dalal HM, Zawada A, Jolly K, Moxham T, Taylor RS. Home based versus centre based cardiac rehabilitation: Cochrane systematic review and meta-analysis [published correction appears in *BMJ.* 2010;340:c1133]. *BMJ.* 2010;340:b5631. ■