Effectiveness of a Self-Management Intervention in Patients With Screen-Detected Type 2 Diabetes

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OBJECTIVE — To examine the effectiveness of a theory-driven self-management course in reducing cardiovascular risk in patients with screen-detected type 2 diabetes, taking ongoing medical treatment into account.

RESEARCH DESIGN AND METHODS — A total of 196 screen-detected patients, receiving either intensive pharmacological or usual-care treatment since diagnosis (3–33 months previously), were subsequently randomized to a control or intervention condition (self-management course). A 2 × 2 factorial design evaluated the behavioral intervention (self-management course versus control) nested within the medical treatment (intensive versus usual care), using multilevel regression modeling to analyze changes in patients' BMI, A1C, blood pressure (BP), and lipid profiles over 12 months, from the start of the 3-month course to 9-month follow-up.

RESULTS — The self-management course significantly reduced BMI (-0.77 kg/m^2) and systolic BP (-6.2 mmHg) up until the 9-month follow-up, regardless of medical treatment. However, intensive medical treatment was also independently associated with lower BP, A1C, total cholesterol, and LDL before the course and further improvements in systolic BP (-4.7 mmHg). Patients receiving both intensive medical treatment and the self-management course therefore had the best outcomes.

CONCLUSIONS — This self-management course was effective in achieving sustained reductions in weight and BP, independent of medical treatment. A combination of behavioral and medical interventions is particularly effective in reducing cardiovascular risk in newly diagnosed patients.

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About 200 million people have been diagnosed with type 2 diabetes worldwide. The actual prevalence is believed to be considerably higher, with a large number of patients remaining undiagnosed, untreated, and unaware of their illness and its long-term health consequences. These patients may not feel ill, but the presence of obesity, chronic hyperglycemia, hypertension, and hypercholesterolemia can ultimately result in devastating micro- and macrovascular complications. In recognition, there has been a widespread call for screening programs to detect and treat patients at an earlier stage of their disease, thereby assuming that this will reduce their cardiovascular risk and improve their long-term health (1,2). There is good evidence that intensive treatments combining medication and lifestyle modifications are effective in both the prevention and management of type 2 diabetes (3–5). However, no studies have focused on the effectiveness of such treatments after a screening-based diagnosis. Furthermore, the success of treatments ultimately depends on patients' ability to accept their diagnosis and actively manage their disease. Treatment adherence in patients with type 2 diabetes is notoriously low (6,7). Interventions to improve self-management have had some success in improving patient's lifestyles and also lead to significant reductions in cardiovascular risk factors; however, improvements have generally been small and short-lived, disappearing once intensive contact with professionals is removed (8–10). The challenge therefore remains to develop interventions that help patients to achieve sustained lifestyle change and ultimately decrease their cardiovascular risk.

In the present study, we examine the effectiveness of a brief 3-month theory-driven self-management intervention proven effective in helping people with screen-detected type 2 diabetes to achieve a sustained lifestyle change (11; B.T., D.D.R., J.B., K.G., G.R., unpublished data). We now assess whether such an intervention is also effective in reducing cardiovascular risk and how far these improvements can be sustained beyond the program. The unique position of this study within an ongoing medical trial makes it possible to examine the relative effectiveness of the behavioral intervention on top of and apart from intensive medical treatment geared to reducing cardiovascular risk in patients with screen-detected diabetes. We hypothesized that the self-management intervention would be most successful among patients receiving standard medical care but would be less effective among intensively treated patients who were already receiving numerous medications to target their metabolic control, blood pressure, and lipid profiles.

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Abbreviations: BP, blood pressure; ADDITION, Anglo-Danish-Dutch Study of Intensive Treatment in People With Screen-Detected Type 2 Diabetes in Primary Care.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Demographic and medical characteristics by treatment group* (n = *196*)

	Usual-care medical treatment		Intensive medical treatment	
	Course	Control	Course	Control
n (dropout)	50 (4)	56	39 (7)	52
Age (mean)	61.8	62.5	61.6	61.5
Sex				
Male (%)	66	62	47	62
Female (%)	34	38	53	38
Education level*	3.4 ± 1.6	3.2 ± 1.4	3.2 ± 1.7	3.1 ± 1.6
Disease duration (months)	21.8 ± 9.1	20.7 ± 8.4	18.3 ± 8.8	17.4 ± 9.0

Data are means ± SD unless otherwise indicated. Subjects include 107 patients in the control group and 89 patients who completed or dropped out of the intervention. *Level of education was measured on a 6-point scale (1 = lowest, 6 = highest level).

RESEARCH DESIGN AND METHODS

— Participants were recruited from the Dutch arm of the ADDITION study (Anglo-Danish-Dutch Study of Intensive Treatment in People With Screen-Detected Type 2 Diabetes in Primary Care), an ongoing multi-center randomized trial evaluating both the feasibility of a population-based screening program for type 2 diabetes and the effectiveness of a target-driven approach to reduce cardiovascular risk in people with screen-detected diabetes (12). Patients (aged 50–70 years) from participating practices were invited to take part in a stepwise screening from 2002 to 2004, with diagnosis set according to World Health Organization criteria. Practices were randomly assigned to deliver either intensive multifactorial pharmacological treatment or usual care from the moment people were diagnosed. Intensive treatment included target-driven tight control of *1*) A1C (oral hypoglycemic agents when A1C was >6.5%, insulin therapy when A1C remained >7.0%), *2*) blood pressure (BP) (antihypertensive agents [aspirin and ACE inhibitors] when BP was >120/80 mmHg, stepwise increase when >135/85 mmHg), and *3*) cholesterol (statins when plasma cholesterol >3.5 mmol/l). In contrast, usual care followed national guidelines (A1C <8.5% and BP <150/85 mmHg considered acceptable, cholesterol treatment depending on patient's estimated risk of coronary heart disease (>25%) (13).

In 2004, 468 screen-detected patients included in ADDITION and not suffering from serious physical or mental comorbidities were invited to participate in the present study, Beyond Good Intentions. At that point, patients had already been diagnosed 3–33 months previously and had consistently been receiving either intensive or usual-care treatment ever since. Beyond Good Intentions specifically examined whether a self-management intervention could (further) reduce these patients' cardiovascular risk. To that end, participants were randomized to a control or intervention group. The control group received a brochure on diabetes self-management. The intervention group received a self-management course.

The self-management course lasted 12 weeks, including two (1-h) individual sessions and four (2-h) biweekly group meetings ($n = 6–8$) lead by a trained nurse. During the sessions, various domains of self-care (including diet, exercise, and medication) were discussed, and patients were taught to formulate, plan, and carry out personally relevant goals with regard to each theme using a proactive five-step plan. Based on theories of proactive coping (14) and self-regulation (15), the course emphasized the elements of anticipation, goal setting, planning, and problem solving, helping patients move beyond their intentions to achieve optimal self-care. The development and evaluation of the course has been published previously, indicating that the course was highly effective in helping patients to both initiate and maintain self-care behaviors up to 9 months after the course (11; B.T., D.D.R., J.B., K.G., G.R., unpublished data).

In this article, the focus is on whether such an intervention can improve patients' medical outcomes, assessing changes in cardiovascular risk factors over 12 months, from the start of the 3-month course to 9-month follow-up, taking ongoing medical treatment into account. The study was approved by the Ethics Committee of the University Medical Center Utrecht.

Sample

In total, 227 of the 468 patients (49%) agreed to participate in the study. Participants were more educated than nonparticipants and reported slightly less self-management behavior, but there were no differences with regard to other sociodemographic characteristics or perceptions of diabetes (16).

Participants were randomly allocated to the control ($n = 108$) or intervention ($n = 119$) condition. Owing to the widespread geographical area, the course was given at different locations. Nevertheless, 30 patients who wished to participate were unable to attend due to difficulties with transportation and were therefore excluded from the study.

At the start, the study thus included 108 patients in the control group and 89 in the intervention group. The course was run 13 times, with an average seven patients per course. Eleven patients dropped out during the course because of personal circumstances (e.g., time, illness, and limited mobility) but were included for intention-to-treat analyses. One patient in the control group was terminally ill, died 2 months into the study, and was excluded from analyses. Patients who were excluded or dropped out were less educated but did not differ significantly from participants with regard to other sociodemographic characteristics or their perceptions of diabetes (16).

The baseline characteristics of the final 196 participants are shown in Table 1, differentiated by their allocation in ADDITION (intensive or usual-care treatment) and Beyond Good Intentions (control or intervention condition). There were no significant differences between groups with regard to sociodemographic variables, but intensively treated patients were diagnosed more recently than usual-care patients ($F = 6.2$, $P < 0.05$). Given the two phases in the screening procedure (May to December 2002 and June 2003 to May 2004, respectively), most patients were logically diagnosed for <1 or >2 years.

Measures

Measures including BMI, A1C, systolic and diastolic BP, and lipid profiles, including total, HDL, and LDL cholesterol and triglycerides were retrieved from patient files. The number and dates of measurement varied by patient, coinciding with their routine checkups but not necessarily with exact start and end points of this study. To maximize the number of measures and reliably estimate the start, end points, and change in between, we included measures taken from time of enrollment, 31 days before the self-management intervention, and up until 3 months beyond the end point at the 9-month follow-up. BMI and BP were recorded an average of 3 times per patient (3.2 and 3, respectively), A1C an average of 3.6 times, and lipid profiles an average of 2 times. Biochemical tests were performed in the regional laboratory—A1C by high-performance liquid chromatography and lipid profiles by enzymatic techniques.

Analyses

A 2 × 2 factorial design evaluated the self-management course (intervention versus control) nested within the medical treatment (intensive versus usual care), using multilevel regression modeling to analyze changes in patients' BMI, A1C, BP, and lipid profiles over 12 months, from the start of the 3-month course to 9-month follow-up. Following the intention-to-treat procedure, we included all patients participating at the start of the study (including 11 participants who dropped out). Multilevel modeling can be considered a sophisticated regression analysis that takes the nested structure of the data into account (17). In our study, the time point and number of measurements varied per individual, individuals were grouped within different general practices, and individuals were also grouped in different course locations. Multilevel modeling allowed us to make use of all the available information (including the variation in time points) to make a more precise estimation of the regression line and beginning and end points.

A preliminary analysis was done for each outcome separately, examining whether outcomes varied over time, individuals, course location, and general practices (data not shown). Taking into account that outcomes may fluctuate in a nonlinear fashion over time, we included both a linear (time) and quadratic function of time (time^2). Variances in BMI, A1C, and BP depended on both the time point of measurement and the individual patient. In contrast, variances in lipid profiles depended on time, indicating that these outcomes did not change (consistently) over time. Variance in total, LDL, and HDL cholesterol depended solely on the individual; these outcomes were analyzed using a one-level model examining mean differences between individuals. Finally, variance in triglycerides was dependent on both the individual and practice, indicating that patients from the same practice showed more similarity with each other than with other patients. Analyses of triglycerides therefore took both the individual and practice into account.

Subsequent analyses followed traditional regression analyses, taking relevant levels into account. For each dependent variable (cardiovascular risk factor), predictors were entered in the regression equation, step by step. First, sex, education, and disease duration were included, given the differences between groups and/or potential for these variables to influence outcomes. Disease duration was included as a dichotomous variable, with 1.5 years as a median split. Next, we examined the effects of the predictors ADDITION (intensive versus usual-care treatment) and Beyond (self-management course versus control) on both mean levels and changes in outcomes over time, also including two- and three-way interactions between ADDITION, Beyond, and time.

For interpretative purposes, day of measurement was translated into years (e.g., day 365 = 1). As such, regression coefficients related to time are indicative of relative changes over 1 year, allowing us to predict beginning and end points and mean changes over 1 year in each group of patients, from the start of the course to 9-month follow-up, differentiated by their allocation to the medical treatment and self-management intervention.

RESULTS — The results of the multilevel regression analyses for each outcome are depicted in Table 2 and described in the text below. To maintain legibility, the table only includes the regression coefficient when significant. To indicate the relative effect of different combinations of treatments, the lower part of the table indicates estimated starting and end points and absolute mean change in outcome over 1 year depending on patients' allocation in ADDITION (intensive versus usual care) and Beyond (course versus control).

BMI

The effect of control variables were examined first. Education and disease duration did not affect BMI, but women showed significantly higher BMI (+2.07 kg/m^2) than men; sex was therefore included in subsequent analysis. The regression analysis indicated that BMI changed over time in a nonlinear fashion, depending on patients' allocation to the self-management intervention (Beyond) (Fig. 1). Intervention participants lost a significant amount of weight during the first months of the course, with weight loss gradually tapering off to a net loss of −0.39 BMI by the 9-month follow-up. In contrast, control patients gained weight at an ever-increasing rate (+0.38 BMI), a difference of 0.77 BMI (or 2.6 kg) at the 9-month follow-up. Medical treatment (ADDITION) had no effect on mean level or changes in BMI over time.

BP

Sociodemographic factors and disease duration had no significant main effects on systolic or diastolic BP, but before the self-management intervention, intensively treated patients already had a significantly lower BP than usual-care patients (−6.7 mmHg systolic and −4.2 mmHg diastolic BP).

With regard to systolic BP, outcomes changed over time in a nonlinear fashion, depending on patients' allocation to the behavioral and medical interventions, indicated by a significant interaction effect of Beyond × time ($B = -6.2$, $P < 0.05$) and a marginal effect of ADDITION × time ($B = -4.6$, $P = 0.06$) (Fig. 1).

Without any additional care, patients' systolic BP gradually increased over 12 months to 4.9 mmHg by the 9-month follow-up. Taken separately, both the intensive medical treatment and the self-management course were effective in reducing BP, but BP tended to revert to baseline levels by the 9-month follow-up. In contrast, patients receiving both intensive medical treatment and the self-management course achieved significant and sustained reductions in their systolic BP: a net decrease of 5.9 mmHg and a difference of 10.8 mmHg with those patients receiving no additional care.

With regard to diastolic BP, there was no main effect of time, and neither ADDITION nor Beyond significantly influenced changes over time.

A1C

Sociodemographic factors and disease duration had no significant main effects on A1C, but patients receiving intensive medical treatment had a significantly lower A1C (−0.27) (ADDITION). A1C

Table 2—*Effectiveness of a self-management intervention (Beyond: course [1] versus control [0]) on top of and next to intensive medical treatment (ADDITION: intensive [1] versus usual-care [0] treatment)*

		BP				Cholesterol		
	BMI	Systolic	Diastolic	Total	A1C	HDL	LDL	Triglycerides
Predictors								
Number of measures	621	597	597	703	385	377	373	375
Mean per patient ± SD	3.2 ± 1.4	3.0 ± 1.6	3.0 ± 1.6	3.6 ± 1.6	2.0 ± 0.8	2.0 ± 0.8	2.0 ± 0.8	2.0 ± 0.8
Constant	29.52	140.0	81.3	6.32	4.55	1.09	2.91	1.53
Sex (male = 1)	2.07†	NS	NS	NS	0.33‡	0.26‡	0.18*	NS
Education	NS	NS	NS	NS	NS	NS	NS	NS
Duration	NS	NS	NS	NS	NS	NS	0.18*	NS
Time	-0.34^{NS}	-7.6^{NS}	NS	−0.55†	—	—	—	—
Time^2	0.72*	12.5†	NS	0.57†	—	—	—	—
ADDITION	NS	−6.7†	−4.2‡	−0.27†	−0.60‡	NS	−0.54‡	NS
ADDITION × time	NS	−4.6§	NS	0.70†	—	—	—	—
ADDITION × time^2	NS	NS	NS	−0.60†	—	—	—	—
Beyond	0.27^{NS}	0.9^{NS}	NS	NS	NS	NS	NS	NS
Beyond × time	−0.77‡	−6.2*	NS	NS	—	—	—	—
Beyond × time^2	NS	NS	NS	NS	—	—	—	—
Mean estimated starting levels differentiated by medical treatment and self-management condition ADDITION × beyond								
Usual care × control	29.52	140	81.3	6.32	4.55	1.09	2.91	1.53
Usual care × course	29.79	140.9	81.3	6.32	4.55	1.09	2.91	1.53
Intensive × control	29.52	133.3	77.1	6.05	3.95	1.09	2.37	1.53
Intensive × course	29.79	134.2	77.1	6.05	3.95	1.09	2.37	1.53
Mean year change in outcomes differentiated by medical treatment and self-management condition ADDITION × beyond								
Usual care × control	+0.38	+4.9	—	+0.02	—	—	—	—
Usual care × course	−0.39	−1.3	—	+0.02	—	—	—	—
Intensive × control	+0.38	+0.3	—	+0.12	—	—	—	—
Intensive × course	−0.39	−5.9	—	+0.12	—	—	—	—
Mean estimated levels at 9-month follow-up differentiated by medical treatment and self-management condition ADDITION × beyond								
Usual care × control	30.00	144.9	81.3	6.34	4.55	1.09	2.91	1.53
Usual care × course	29.40	139.6	81.3	6.34	4.55	1.09	2.91	1.53
Intensive × control	30.00	133.6	77.1	6.17	3.95	1.09	2.37	1.53
Intensive × course	29.40	128.3	77.1	6.17	3.95	1.09	2.37	1.53

A multilevel regression analysis of change in cardiovascular outcomes over 12 months, from the start of the 3-month course to 9-month follow-up, reported in terms of significant *B* values. $*P < 0.05$, $\dagger P < 0.01$, $\ddagger P < 0.001$, $\S P < 0.07$. Two- and three-way interactions between ADDITION and Beyond were not significant. BMI, A1C, and BP were based on two-level models including person and time. HDL, LDL, and total cholesterol were based on the one-level model, including the person. Triglyceride was based on a two-level model including the general practitioner and the person. NS, not significant.

levels varied over time in a nonlinear fashion, depending on patients' medical treatment, with both usual and intensively treated patients showing slight increases in A1C (0.02 and 0.12, respectively). In both groups, however, levels remained in the normal healthy range (6.34 and 6.17, respectively, for the usual and intensively treated group). The self-management intervention (Beyond) had no effects on mean levels or changes in A1C.

Lipid profiles

Preliminary analyses revealed that lipid profiles did not vary significantly over time; hence, analyses were limited to mean differences. Females showed significantly higher total, HDL, and LDL cholesterol than men, and patients with longer disease duration reported a significantly higher LDL. Patients receiving intensive medical treatment had significantly lower total cholesterol (−0.60, $P < 0.001$) and LDL levels (−0.54, $P < 0.001$) than patients receiving usual treatment, but they did not differ with regard to either HDL or triglyceride levels. The self-management intervention (Beyond) had no effects on lipid profiles.

CONCLUSIONS — This study suggests that a self-management intervention can be effective in improving cardiovascular risk in screen-detected patients recently diagnosed with type 2 diabetes, both on top of and apart from intensive medical treatment. The fact that the course achieved these changes in patients who had already experienced considerable improvements in their cardiovascular risk factors further emphasizes the effectiveness of this theory-driven self-management course and the potential for lifestyle interventions in general to make a difference in diabetes care.

The self-management intervention led to significant weight loss and important decreases in systolic BP that were maintained up to 9 months after the intervention ceased. With regard to weight change, we found that, regardless of medical treatment, patients in the control condition gained weight, while patients in the intervention condition lost weight, leading to a difference in BMI of 0.77 kg/m^2 or 2.6 kg in 1 year, a difference that continued to increase. While such differences may appear relatively small, until now, few other interventions have successfully

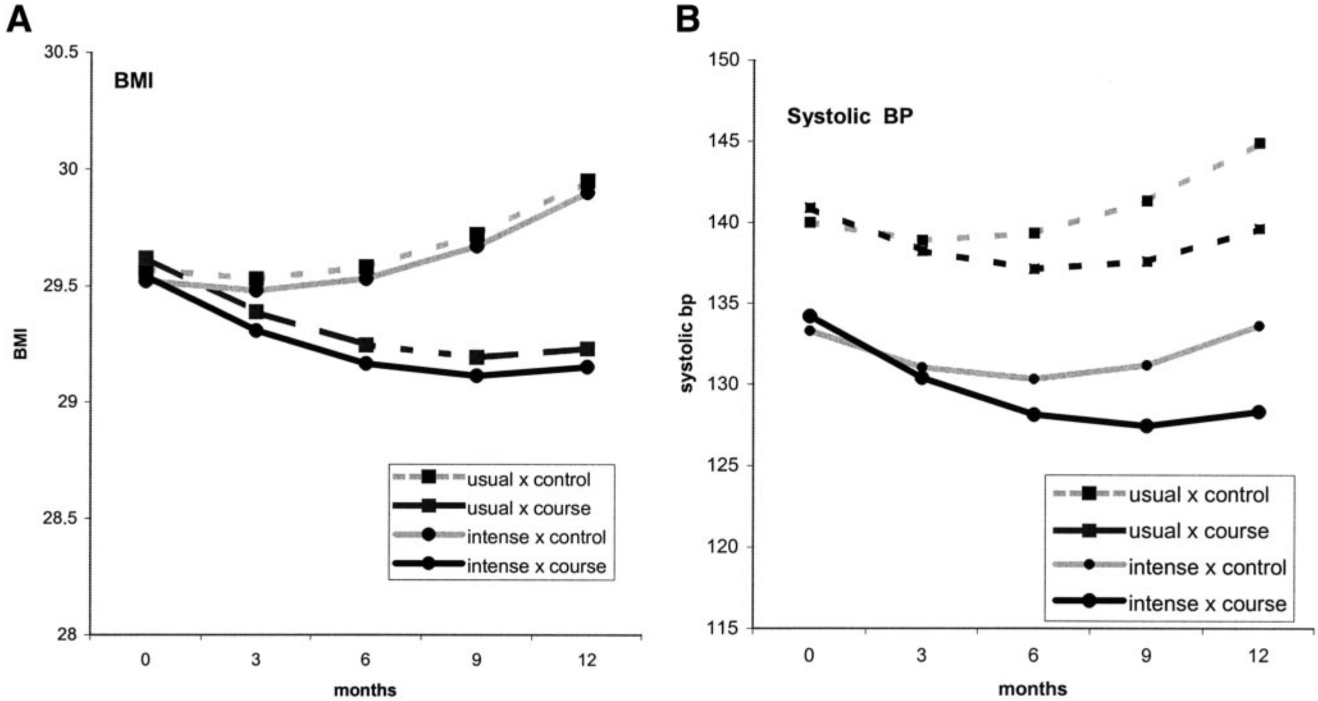

Figure 1—*Changes in BMI and systolic BP by treatment: Beyond (course vs. control) by ADDITION (intense vs. usual).*

been able to make a difference once contact is removed (8,9). Weight loss appears to be one area in which behavioral interventions can be more effective than a medical approach. Furthermore, the self-management intervention was more effective than medical treatment with regard to systolic BP. Despite the initial successes of the intensive medical treatment, systolic BP tended to increase by the end of this study in both usual-care and intensively treated patients. A combination of intensive medical treatment and the self-management course proved to be most effective; patients who received both interventions ultimately had a mean systolic BP of 128.3 mmHg at the 9-month follow-up, compared with 144.9 mmHg for patients receiving only usual care.

These results are even more encouraging when one considers that the course was relatively brief and given by a minimally trained nurse in the patient's local environment. Previous evaluations of the course have indicated that its theoretical underpinnings, notably the combination of goal setting, planning, and anticipation, were very successful in helping patients to initiate and maintain small changes in their self-management behaviors, diet, and exercise in particular (11; B.T., D.D.R., J.B., K.G., G.R., unpublished data). However, those findings were based on patients' self-reports. This study provides some more objective evidence that such a theory-based intervention can indeed help patients to achieve improvements. Recent meta-analyses suggest that self-management interventions relying on goal setting and planning are particularly effective (18). We would suggest that anticipation is another important ingredient. Patients will be more likely to achieve their self-management goals when they recognize barriers to and conditions for goal attainment and consider alternative strategies beforehand and how they will evaluate their progress. The concept of proactive coping has been implemented to help patients with a wide range of conditions to deal with potential problems before they arise (19–21). This study suggests that it can also be effective in diabetes management.

That said, the effectiveness of the self-management intervention with regard to other cardiovascular risk factors was limited. For that matter, other psychological interventions have had only limited effects in improving metabolic control or lipid profiles (8). In this study, the potential for change was limited given the relatively healthy mean levels of cardiovascular outcomes in both medical treatment arms. This, in part, reflects the success of medical treatment that these screen-detected patients received after diagnosis; patients in the intensive arm of ADDITION already showed significantly better outcomes with regard to BP, A1C, and total and LDL cholesterol at baseline, while mean A1C in both medical treatments was <6.5%. Nevertheless, this study suggests that a self-management course can confer additional benefit, independent of medical treatment.

The present study had a number of limitations. First, this study relied on a population who was already taking part in a medical intervention in which half did not participate. A detailed comparison of the recruitment and retention process indicated that nonparticipants and dropouts primarily had practical reasons, while education level was the primary variable differentiating between participants, nonparticipants, and dropouts (16). We controlled for this in our analyses but found that education did not significantly influence cardiovascular risk factors. A second issue was our reliance on patient files with the number and time points of measurements varying considerably and depending on patients' visits to the general practitioner and laboratory. Multilevel techniques helped to overcome these limitations in our data, allowing us to take these variations into account and base our analyses on existing data rather than imputing missing data that can produce considerable errors in estimation (17). Nevertheless, we did not have measurements for all patients in the 3 months in which the intervention took place (potentially the most effective period). As such, our findings give a good indication of net change over 1 year, but improvements that may have been achieved during the intervention are more obscure.

The use of multilevel modeling also allowed us to control for potential influences of patients' general practices on outcomes. We found that patients from the same practice were not more similar to each other with regard to most cardiovascular outcomes. In fact, triglycerides were the only outcome influenced by general practice. In sum, our strict adherence to statistical procedures and our consideration of multiple levels allows us to conclude with a high degree of certainty that the self-management intervention was successful in helping patients to reduce their weight and systolic BP.

From this perspective, this self-management intervention can be a valuable addition to medical treatments no matter how intensive, particularly when it is taken into account that the course also increased patients' awareness, confidence, and self-management behaviors (diet and exercise in particular) (11; B.T., D.D.R., J.B., K.G., G.R., unpublished data). This study suggests that intensive medical treatments may be effective for a while, but gradual relapses in weight, BP, and A1C suggest that additional support may be needed to help patients maintain and achieve further improvements. This study supports a growing body of evidence that self-management interventions can be effective when they have a sound theoretical basis.

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