

# Chapter 6

A cognitive behavioral treatment improves lifestyle in patients with type 2 diabetes when added to managed care; a randomized controlled trial

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## **Abstract**

### **Objective**

To investigate the effect of adding a cognitive behavioral treatment (CBT) to managed care on coronary heart disease (CHD) risk.

### **Research design and methods**

For this randomized controlled trial, patients were recruited from selected general practices (n = 14) who are participating in a diabetes management system (DMS). The intervention group (n=76) received managed care and the CBT, which consisted of Problem Solving Treatment. The control group (n=78) received managed care from the DMS only.

Our primary outcome measure was the risk of developing CHD, calculated with the UKPDS risk engine. Other outcome measures were clinical characteristics, lifestyle (physical activity, dietary behavior and smoking status), determinants of behavior change (attitude, social influences and self-efficacy, based on the ASE-model), quality of life, and depression.

Differences between the two groups after 6 and 12 months were analyzed by two way analysis of variance.

### **Results**

The intervention did not result in a significant reduction of CHD risk ( $\Delta$  intervention and control group was [95% CI] -0.32% [-2.27 ; 1.63]). However, the amount of heavy physical activity increased significantly in the intervention group compared with the control group ( $\Delta$  intervention and control group was [95% CI] 20.14 min/day [4.6 ; 35.70]). More patients in the intervention group quit smoking, but not statistically significant. Quality of life and level of depression improved as well. No effects were found on clinical characteristics, dietary behavior and determinants of behavioral change.

### **Conclusion**

Adding CBT to managed care improved physical activity and might be beneficial for CHD risk. Also, quality of life and level of depression improved.

## Introduction

Behavioral interventions focused on lifestyle in patients with type 2 diabetes have shown to be effective in improvements in weight (1) and glycaemic control (2). It is still unclear what kind of intervention is most effective (2), but it is generally acknowledged that a behavioral intervention should be based on a theoretical framework (3-5) and that such interventions should focus on the increase of self-management of the patient (4,6).

In order to improve patients' clinical characteristics and finally the 10-year risk of a coronary heart disease (CHD), we have added a behavioral intervention to the Diabetes Management System (DMS). This system was implemented in a part of the Netherlands in 1997 in order to improve chronic diabetes care. This system was based on the chronic care model (7-10) and was successful in improving and stabilizing patients' characteristics, but more than 70% of the patients was still overweight and 40% had an HbA1c > 7.0% (11).

Our intervention was focused on three behavioral domains: increase physical activity, change eating behavior and/or quit smoking. It is believed that this contributes to a more likely increase in self-management of patients than an intervention focused on one domain, because patients are encouraged to make choices (12).

Problem Solving Treatment (PST), a practical skill building treatment, was used as a tool to guide the intervention (13-15). PST was found to be an effective treatment for patients with depression (16-18), and might be useful for patients with diabetes for several reasons. Firstly, PST is a treatment that attempts to provide solutions for specific problems, like changing lifestyle for patients with diabetes. Glasgow et al. have also recognized problem-solving as a key element for successful self-management of diabetes (6,19). Secondly, PST fits into the generally acknowledged patient empowerment approach, which is defined as 'helping patients discover and develop their own ability to gain mastery over their diabetes' (20). Goal setting is one of the main strategies in this approach, and this is also the main element in PST (20-22). Thirdly, PST fits into the theoretical framework of the Attitude, Social influences, and self-Efficacy model (ASE-model) (23-25). We hypothesized that PST might increase patient's attitude, social influences and self-efficacy, which attribute to a patients' intention to change behavior, resulting in improvement of patients' characteristics and in a reduction of CHD risk (26-28).

The present study describes the effects of adding a cognitive behavioral treatment (CBT) aimed at changing lifestyle to managed diabetes care for patients with type 2 diabetes on the estimated risk of developing a CHD event in the next 10 years (29). Effects on lifestyle, patients' clinical characteristics, and

determinants of behavior change were also assessed. In addition, we have compared quality of life, and the level of depression between the intervention and control group.

## Research design and methods

A randomized controlled trial (RCT) was conducted with patients with type 2 diabetes that were included in the DMS. The design of the study has been described in detail previously and will only be described here in brief (30).

This DMS coordinates care between different caregivers, provides feedback to patients and specialist and promotes patient empowerment by providing information and education. General practitioners (GPs) in the region West-Friesland were asked to refer all their patients with diabetes to the DMS, in addition to their care. The care in the DMS is organized in yearly assessments consisting of a measurement visit followed by a visit to a dietician and a diabetes nurse (2-3 weeks after the measurement visit, both for 30 minutes), in order to receive and discuss results of the clinical measurements. A standardized protocol according to the Guidelines of the Dutch College of General Practitioners was used (31).

For the purpose of this study, GPs participating in the DMS who had a practice nurse were recruited. 13 of 21 recruited GPs were willing to participate. Patients were considered eligible for the study based on the following inclusion criteria:  $\leq 75$  years old; able to understand the Dutch language; at high risk of developing cardiovascular disease and diabetes complications ( $\text{HbA1c} \geq 7.0\%$  or body-mass index  $\geq 27.0 \text{ kg/m}^2$  or smoking). All participating patients gave their written informed consent. The Medical Ethics Committee of the VU University Medical Center in Amsterdam approved the study design.

### Study population

Patients were invited for a recruitment visit by means of an invitation letter, including information on the study, from the DMS. This recruitment visit was included in the yearly assessments of the DMS. During the recruitment visit, a research assistant explained the study and patients could decide whether or not to participate. Consequently, we had 1 year to recruit patients, because after this year, the same patients returned to the DMS for their next yearly assessment. If a patient was willing to participate, the results of the yearly assessment were used as baseline measures.

Patients that were interested in participation were randomized into an intervention and a control group by means of block randomization within general practices.

### **Treatment**

The intervention group received 3 - 6 sessions of the CBT. During the first session, the most important behavioral domain was assessed by the diabetes nurse. The intervention was transmitted to a dietician if the component was related to dietary intake. In case of smoking or physical activity, a diabetes nurse continued with the intervention. During all sessions, PST was used to set achievable goals for behavior change. PST consists of several steps including: problem definition, goal setting, generating a solution, implementing the solution, and evaluation of the outcome of the implementation (32).

The dieticians (n=6) and diabetes nurses (n=4) had received a training in the CBT of two days, followed by two instruction days on how to implement the intervention in the DMS. A treatment manual was used during the intervention. In addition, all sessions were tape recorded in order to be able to assess treatment fidelity. Each four weeks, a supervision meeting, guided by a specialized CBT psychologist (PvO), was organized.

The control group received the usual yearly assessments by the DMS in order to discuss results, receive information and education.

### **Measurements**

Outcome measurements were extracted from self-reported questionnaires and physical examinations. The baseline questionnaire was given at the recruitment visit and patients were asked to return the questionnaire by means of a reply envelope. Follow-up questionnaires were sent to the patients by mail and patients were requested to bring the questionnaire to the measurement visits. A blinded research assistant checked if the questionnaires were completed. If not, the patients were asked to complete the questionnaire in the waiting room.

#### *CHD risk*

The 10-year risk of developing a CHD event was calculated at baseline and at 12 months using the UK Prospective Diabetes Study (UKPDS) risk engine (29). Variables included in this algorithm are: age at diagnosis, duration of diabetes, sex, ethnicity, smoking status, systolic blood pressure, HbA<sub>1c</sub>, total and HDL-cholesterol.

*Clinical characteristics*

Measurements were taken at the DMS by research assistants according to a standardized protocol. Weight and height were measured while patients were barefoot and wearing only light clothes. Systolic and diastolic blood pressure were measured after 5 minutes of rest in a seated position using an oscillometric device (Colin Press Mate BP-8800, Komaki City, Japan). HbA<sub>1c</sub> was measured with high performance liquid chromatography. Fasting plasma glucose was measured by means of a hexokinase method (Roche Diagnostics GmbH, Mannheim, Germany). Levels of total cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides were measured using enzymatic techniques (Boehringer-Mannheim, Mannheim, Germany). All measurements were performed at baseline, after 6 and 12 months, except for total and HDL cholesterol and triglycerides which were only measured at baseline and after 12 months.

*Lifestyle: physical activity, eating behavior and smoking*

The SQUASH questionnaire (Short Questionnaire to Assess Health Enhancing Physical Activity) was used to assess physical activity (33). The total amount of minutes per day that a patient was performing light (2-4 MET), moderate (4-6.5 MET), or heavy physical activity ( $\geq 6.5$  MET) was calculated (MET = unit of metabolic equivalent, which is the ratio of the energy cost of a given activity to resting metabolic rate and was derived from published tables (34)).

Eating behavior was assessed by the Dutch Eating Behavior Questionnaire (DEBQ) (35). This questionnaire consists of 33 items and scoring is on a five-point scale (1 = never, 2 = seldom, 3 = sometimes, 4 = often, 5 = very often). This questionnaire assessed whether a patient is a restraint, emotional, or external eater. Classification into one of these three domains was achieved by dividing the sum of the corresponding items for a specific domain by the number of items.

Smoking was assessed by asking if a patient was a smoker or a non-smoker.

*Determinants of behavior change*

Determinants of behavior change were assessed by means of a questionnaire developed according to the ASE model (23-25). There were 3 separate questionnaires for all 3 behavioral domains (increase physical activity, eat healthier, and quit smoking), each containing the same items. There were 5 items concerning attitude, 2 items on self-efficacy, 2 items on social influences and 2 items on intention to change behavior. All items were measured on a 7-point Likert scale.

The mean of the items of each behavioral determinant was taken as a measure for the specific determinant. Social influences were separated into influences from the partner (if the patient had a partner) and from friends. Low scores indicate a positive attitude towards change of behavior, a high self-efficacy to perform the behavior, a positive social influence from the partner and/or friends, and a strong intention to change behavior.

Cronbach's  $\alpha$  were all  $> 0.60$ , indicating sufficient internal consistency. Except for the Cronbach's  $\alpha$  of smoking (between 0.50 and 0.60).

#### *Quality of life*

The EuroQol was used to assess quality of life (36,37). This questionnaire consists of a visual analogue scale on which patients had to indicate their health status (scale 0 - 100) and five questions on different domains, each with a scale of three levels: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. A mean weighted health status was calculated with a range of 0 - 1.

#### *Depression and general health*

An important co-morbidity of patients with diabetes and also an important covariate in intervention studies is depression (38). We used the CES-D (Center for Epidemiological Studies Depression scale) to assess if depression was present (39). This is a 20-item questionnaire with a Likert-type scale ranging from 1 to 4 (0=seldom/never, 1=sometimes, 2=often, 3=mostly/always). An overall score was calculated by summing up all scores, resulting in an overall score between 0 and 60. A patient with a score  $\geq 16$  was considered as a possible depressive case.

#### **Statistical analyses**

Descriptive statistics for both groups are presented as percentages of patients with a given characteristic, means  $\pm$  SD, or median (interquartile range, IQR) in case of a skewed distribution.

Changes between separate time points (0-6 months, 6-12 months and 0-12 months) were calculated for each outcome measure. Two way analyses of variance were used to calculate differences in the changes between the 3 time points between the two groups. General practices were added to the model as a fixed factor, to account for differences between them. Mantel-Haenszel statistic was used to assess differences between the two groups for dichotomous outcome measures. In additional analyses was adjusted for age, gender, and diabetes duration. All analyses were performed according to the intention-to-treat principle.

In addition, we performed subgroup analyses to investigate if there were specific patients that would benefit from the intervention. We assessed the following subgroups: high education level (college/university), per-protocol analysis including patients with  $\geq 3$  CBT sessions, patients without a depression (CES-D score  $< 16$ ).

Missing data were not imputed. P-values below 0.05 were considered statistically significant. All statistical analyses were performed using SPSS for Windows (version 14.0, SPSS Inc., Chicago, IL)

## Results

At baseline, 76 patients were randomized to the intervention group and 78 patients to the control group. A flow chart showing follow-up of patients can be found in figure 1.

More men than women were included in both groups (Table 1). Groups were comparable at baseline, except for the proportion of patients with a score  $\geq 16$  on the CES-D questionnaire, indicating depression (23.4% vs. 17.8% depressive patients in the intervention and control group, respectively). However, this difference was not statistically significant. At baseline, despite the inclusion criteria, mean levels of most clinical characteristics were still quite well for patients with diabetes with a mean HbA1c of 6.8% in both groups.

### Coronary heart disease risk

The risk of developing CHD in the next 10 years decreased from 10.6 to 9.9% in the intervention group and increased from 11.1 to 11.2% in the control group (Table 2); a difference of 0.32% in favour of the intervention group [95% BI: -2.27 ; 1.63] change, although not statistically significantly different.

### Clinical characteristics

Clinical characteristics are shown in Table 2. We only found small differences between the intervention and the control group after both 6 and 12 months of follow-up, but not of clinical importance.

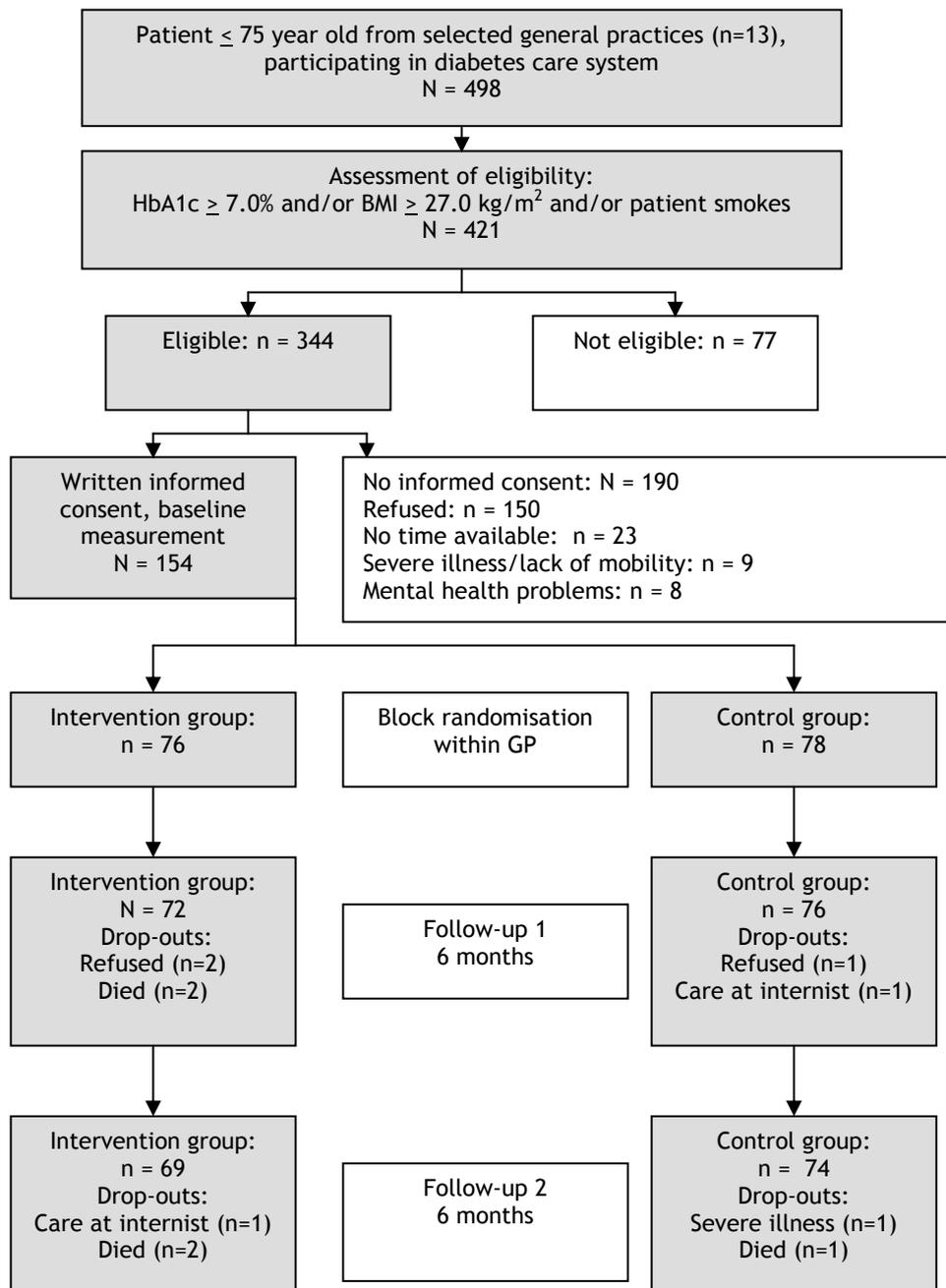


Figure 1. Design of the randomized controlled trial

**Table 1. Baseline characteristics**

	Intervention group (n = 76)	Control group (n = 78)
Age (years)	60.5 ± 9.4	61.2 ± 8.8
Gender (% male)	59.5	64.2
Ethnicity (% Caucasian)	97.3	94.9
Marital/cohabiting status (% with partner)	84.8	83.3
Work status (% employed)	30.3	38.2
Level of education (%)		
Primary	50	42.9
Secondary	34.8	44.2
College/university	15.2	12.9
Smoking (% smokers)	28.3	23.3
Diabetes duration (years)	7.6 ± 5.0	7.8 ± 6.1
Body-mass index (kg/m <sup>2</sup> )	31.6 ± 5.7	31.6 ± 5.2
Systolic blood pressure (mmHg)	144.5 ± 20.3	144.6 ± 18.3
Diastolic blood pressure (mmHg)	77.8 ± 7.9	77.0 ± 9.0
HbA1c (%)	6.8 ± 1.0	6.7 ± 1.0
Fasting blood glucose (mmol/l)	7.8 ± 2.2	7.7 ± 1.5
Total cholesterol (mmol/l)	4.4 ± 1.0	4.4 ± 1.0
HDL cholesterol (mmol/l)	1.2 ± 0.3	1.2 ± 0.3
Triglycerides (mmol/l)	2.0 ± 1.1	1.9 ± 0.9
Risk for CHD (%)	10.6 ± 7.2	11.1 ± 8.8
PHQ score depression (% patients)		
no depression (score = 0)	19.7	24.2
minimal (1-4)	36.1	39.4
mild (5-9)	36.1	31.8
moderate (10-14)	4.9	1.5
moderately severe (15-19)	3.3	1.5
severe (20-27)	0	1.5
CES-D score ≥ 16 (% depressive patients)	23.4	17.8

Data are means ± SD, or % of patients. CHD + coronary heart disease

**Table 2. Differences in CHD risk and clinical characteristics between patients in the intervention group and the control group at baseline, after 6 and 12 months.**

	Baseline (CBT n = 76) (Control n = 78)	6 months (CBT n = 54) (Control n = 72)	12 months (CBT n = 69) (Control n = 74)	Δ 0-6 months (95% BI) P value	Δ 6-12 months (95% BI) P value	Δ 0-12 months (95% BI) P value
CHD risk (%; UKPDS risk engine) † CBT CONTROL	10.6 ± 7.2 11.1 ± 8.8	NA NA	9.9 ± 5.9 11.2 ± 7.0	NA	NA	-0.32 (-2.27;1.63) P = 0.75
Weight (kg) † CBT CONTROL	94.4 ± 19.8 95.8 ± 17.0	95.3 ± 20.8 96.0 ± 17.2	94.1 ± 22.1 95.8 ± 16.6	0.15 (-0.90;1.19) P = 0.78	-0.18 (-1.14;0.77) P = 0.70	-0.20 (-1.33;0.93) P = 0.73
Body-mass index † (kg/m <sup>2</sup> ) CBT CONTROL	31.6 ± 5.7 31.6 ± 5.2	31.8 ± 6.0 31.6 ± 5.3	31.5 ± 6.1 31.8 ± 5.2	0.06 (-0.29;0.40) P = 0.75	-0.04 (-0.44;0.36) P = 0.86	-0.07 (-0.50;0.37) P = 0.77
Systolic blood pressure (mmHg) † CBT CONTROL	144.5 ± 20.3 144.6 ± 18.3	143.3 ± 21.3 145.1 ± 19.3	143.7 ± 19.9 142.4 ± 18.0	-1.70 (-7.08;3.69) P = 0.53	0.51 (-4.94;5.95) P = 0.85	-0.67 (-5.89;4.58) P = 0.80
Diastolic blood pressure (mmHg) † CBT CONTROL	77.8 ± 7.9 77.0 ± 9.0	75.4 ± 8.2 77.0 ± 8.3	76.4 ± 9.1 77.0 ± 8.3	-2.60 (-5.50;0.31) P = 0.08	1.16 (-1.90;4.23) P = 0.45	-1.63 (-4.22;0.96) P = 0.22
HbA1c (%) † CBT CONTROL	6.8 ± 1.0 6.7 ± 1.0	6.7 ± 1.1 6.7 ± 0.9	6.8 ± 1.1 6.8 ± 0.9	-0.07 (-0.39;0.24) P = 0.65	0.04 (-0.17;0.24) P = 0.73	-0.05 (-0.33;0.22) P = 0.71
Fasting blood glucose (mmol/l) † CBT CONTROL	7.8 ± 2.2 7.7 ± 1.5	7.9 ± 2.6 7.7 ± 1.5	8.1 ± 2.2 7.6 ± 1.8	0.41 (-0.29;1.11) P = 0.25	0.01 (-0.65;0.66) P = 0.98	0.30 (-0.36;0.97) P = 0.37
Total cholesterol (mmol/l) † CBT CONTROL	4.4 ± 1.0 4.4 ± 1.0	NA NA	4.1 ± 0.7 4.3 ± 0.9	NA	NA	-0.17 (-0.46;0.11) P = 0.24
HDL cholesterol (mmol/l) † CBT CONTROL	1.2 ± 0.3 1.2 ± 0.3	NA NA	1.1 ± 0.3 1.2 ± 0.3	NA	NA	-0.02 (-0.07;0.03) P = 0.49
Triglycerides (mmol/l) † CBT CONTROL	2.0 ± 1.1 1.9 ± 0.9	NA NA	1.9 ± 1.3 2.0 ± 1.1	NA	NA	-0.11 (-0.45;0.24) P = 0.55
LDL cholesterol (mmol/l) † CBT CONTROL	2.3 ± 0.9 2.3 ± 0.9	NA NA	2.1 ± 0.7 2.2 ± 0.9	NA	NA	-0.03 (-0.30;0.24) P = 0.84

Data are means ± SD, CBT = cognitive behavioral treatment, CHD = coronary heart disease, \* P < 0.05, † two way analysis of variance, adjusted for general practice

### **Lifestyle: physical activity, eating behavior and smoking**

We found statistically significant differences (Table 3) on the highest level of physical activity: patients in the intervention group increased their amount of physical activity per day significantly compared with patients in the control group between 0 and 6 months (mean difference [95% CI] was: 20.14 min/day [4.6 ; 35.70]).

There were no important differences between the three time points on eating behavior. Patients in both groups had higher scores on the restraint scale than on the emotional and external scales, indicating that they were trying to lose weight.

The percentage of smokers decreased from 25 to 18.3% in the intervention group, compared with an increase from 22.4 to 22.9% in the control group. It therefore seems that the intervention had effects on smoking cessation, although differences were not statistically significant.

### **Determinants of behavior**

We found no statistically significant differences between the two groups on the components of the ASE-model (data not shown). Attitudes concerning all 3 behaviors improved somewhat in both groups between 0 and 6 months. The highest attitude was found concerning changing physical activity. Self-efficacy to change behavior was neither high nor low, in both groups at all time points. The lowest self-efficacy was found for quitting smoking. Social influences from the partner seemed of higher importance than those of friends. Patients did not have a strong intention to change behavior, and neither a weak one.

**Table 3. Differences in physical activity, eating behaviour and smoking between patients in the intervention and control group at baseline, after 6 and 12 months.**

	Baseline (CBT n = 68) (Control n = 76)	6 months (CBT n = 62) (Control n = 73)	12 months (CBT n = 64) (Control n = 71)	Δ 0-6 months (95% BI) P value	Δ 6-12 months (95% BI) P value	Δ 0-12 months (95% BI) P value
<b>Physical activity SQUASH (min/day) †</b>						
CBT (2-4 MET)	146.2 ± 16.3	136.6 ± 16.2	197.3 ± 28.8	1.41 (-40.63;43.45)	35.20 (-25.81;96.21)	36.65 (-29.85;103.15)
CONTROL (2-4 MET)	173.4 ± 20.8	161.6 ± 18.2	198.9 ± 22.5	P = 0.95	P = 0.26	P = 0.28
CBT (4-6.5 MET)	85.3 ± 11.7	68.1 ± 9.5	87.4 ± 12.6	-9.80 (-36.62;17.03)	9.8 (-33.10;52.73)	-0.70 (-42.84;41.45)
CONTROL (4-6.5 MET)	68.1 ± 9.5	72.3 ± 12.9	97.1 ± 14.6	P = 0.47	P = 0.65	P = 0.97
CBT (≥ 6.5 MET)	30.1 ± 4.8	41.0 ± 7.4	60.1 ± 11.7	20.14 (4.6;35.70)	-6.46 (-35.80;22.88)	11.68 (-14.73;36.08)
CONTROL (≥ 6.5 MET)	39.5 ± 6.4	27.9 ± 4.3	55.2 ± 11.2	P = 0.01 *	P = 0.66	P = 0.38
<b>Eating behaviour DEBQ †</b>						
<i>Emotional</i>						
CBT	1.87 ± 0.90	1.84 ± 0.87	1.82 ± 0.80	0.05 (-0.14;0.24)	-0.00 (-0.15;0.15)	0.11 (-0.05;0.67)
CONTROL	1.82 ± 0.75	1.74 ± 0.81	1.66 ± 0.72	P = 0.61	P = 0.97	P = 0.17
<i>External</i>						
CBT	2.28 ± 0.59	2.19 ± 0.63	2.16 ± 0.64	-0.01 (-0.15;0.13)	-0.06 (-0.20;0.08)	-0.10 (-0.27;0.06)
CONTROL	2.30 ± 0.58	2.23 ± 0.63	2.22 ± 0.64	P = 0.87	P = 0.40	P = 0.21
<i>Restraint</i>						
CBT	2.87 ± 0.81	2.94 ± 0.81	2.83 ± 0.80	0.06 (-0.15;0.26)	-0.14 (-0.35;0.06)	-0.12 (-0.33;0.09)
CONTROL	2.94 ± 0.82	2.95 ± 0.85	2.92 ± 0.83	P = 0.59	P = 0.17	P = 0.25
<b>Smoking (%) #</b>						
CBT	17/68 (25%)	11/60 (18.3%)	9/62 (14.5%)	P = 0.94	P = 0.74	P = 0.96
CONTROL	17/76 (22.4%)	16/70 (22.9%)	14/69 (20.3%)			

Data are means ± SD, CBT = cognitive behavioral treatment, \* P < 0.05, † two way analysis of variance, adjusted for general practice, # Mantel-Haenszel statistic, adjusted for general practice

### Quality of life

Quality of life, as measured by the EuroQoL questions, improved little in both groups (Table 4). The intervention group showed a statistically significant increase in quality of life between baseline and 6 months on the VAS scale, whereas the control group showed a decrease.

### Depression and general health

Between baseline and 6 months of follow-up, we found a statistically significant difference ( $P=0.01$ ) between the intervention group, in which patients became less depressive, and the control group, in which patients' level of depression increased (Table 4).

**Table 4. Differences in quality of life and depression between patients in the intervention and control group at baseline, after 6 and 12 months.**

	Baseline CBT n = 68 Control n = 76	6 months CBT n = 62 Control n = 73	12 months CBT n = 64 Control n = 71	$\Delta$ 0-6 months (95% BI) P value	$\Delta$ 6-12 months (95% BI) P value	$\Delta$ 0-12 months (95% BI) P value
<b>Quality of life:</b>						
<i>Score EuroQoL</i> †						
CBT	0.71 ± 0.28	0.73 ± 0.27	0.73 ± 0.25	0.03 (-0.05 ; 0.10)	0.03 (-0.04 ; 0.10)	0.03 (-0.04 ; 0.10)
CONTROL	0.76 ± 0.24	0.77 ± 0.19	0.74 ± 0.25	P = 0.45	P = 0.34	P = 0.40
<i>VAS scale EuroQoL</i> †						
CBT	65.2 ± 18.2	68.4 ± 17.5	65.1 ± 20.5	5.81 (0.54 ; 11.08)	-1.05 (-6.53 ; 4.43)	1.73 (-4.65 ; 8.12)
CONTROL	65.6 ± 18.4	63.6 ± 17.2	61.5 ± 19.2	P = 0.03 *	P = 0.71	P = 0.59
<b>Depression: CES-D</b>						
<i>Score CES-D</i> †						
CBT	11.1 ± 8.1	9.9 ± 7.7	11.3 ± 9.9	-2.77 (-4.70 ; -0.81)	1.35 (-0.94 ; 3.63)	-0.39 (-2.38 ; 1.60)
CONTROL	9.6 ± 8.2	10.3 ± 8.6	11.0 ± 9.4	P = 0.01 *	P = 0.25	P = 0.70
<b>Depressive patients (%)</b> †#						
CBT	23.4	21.7	26.2	P = 0.63	P = 0.85	P = 0.90
CONTROL	17.8	14.9	17.9			

Data are means ± SD or median (interquartile range) in case of a skewed distribution.

VAS = Visual Analogue Scale EuroQoL (0 - 100), CBT = cognitive behavioural treatment

† Depressive = score of  $\geq 16$  on the CES-D

\*  $P < 0.05$

† two way analysis of variance, adjusted for general practice

# Mantel-Haenszel statistic, adjusted for general practice

### **Covariates and subgroups**

Age, gender, diabetes duration and baseline values did not influence the results (data not shown). We investigated if certain subgroups would have more benefit from the intervention but we were not able to find any. Subgroups with either a high education, or more than 3 CBT sessions, or no depression did not have better improvements in all outcome measures than patients who did not fulfill any of these criteria.

### **Conclusions**

In the present study, we found that a cognitive behavioral treatment did not significantly improve CHD risk, when adding to managed care for patients with type 2 diabetes. We found no significant effects on clinical characteristics. However, the amount of physical activity increased significantly in the intervention group compared with the control group and more patients were able to quit smoking in the intervention group, although this was not significant. No significant differences between the two groups were found on eating behavior. Quality of life improved as a result of the intervention, and the level of depression decreased. The statistically significant effects all occurred between 0 and 6 months and disappeared between 6 and 12 months, indicating that the intervention was not effective on the long term.

Although the differences between the intervention group and control group were small, we do want to address some interesting findings of this study. We found effects on physical activity as a result of the intervention, which might indicate that the techniques of PST, including goal setting is an effective strategy to achieve behavior change, when adding to managed care. The decrease in CHD risk was probably caused by the decrease in the number of smokers in the intervention group. The increase in physical activity is not visible in patients outcomes because this is not part of the algorithm of the CHD risk (29).

This study was an effectiveness study, which is related to the question whether an intervention works in routine clinical care, like the DMS. The performance of an effectiveness trial is more sophisticated than of an efficacy trial. It is likely that the DMS had provided adequate care, including strict medication treatment and education on lifestyle, with the consequence that a behavioral intervention is not of additional value to improve clinical characteristics. Other intervention studies started with baseline HbA<sub>1c</sub> values of about 8.5%, compared to 6.8% in our study (40-42). With regard to the CHD risk, our baseline levels were 10.6% and 11.1% in the CBT and control group,

respectively, while in another Dutch study population, with newly diagnosed patients, levels of 13.3% for men and 18.6% for women were found (43).

We found two other similar intervention studies, theoretically driven and based on techniques like problem solving and goal setting, which were expected to increase self-management of the patient. Steed et al. found that a self-management intervention of five 2.5 hour sessions by diabetes nurses and dieticians, focused on several topics like diet, exercise, and self-monitoring of blood glucose, resulted in an improvement in exercise behavior and quality of life. The control group received no education at all. Also in their intervention, clinical characteristics did not change after 3 months of follow-up (40). Thoolen et al. (42) investigated the effectiveness of a self-management program and showed that cardiovascular risk and BMI improved, apart from intensive medical treatment. However, a combination of the lifestyle intervention and medical treatment was the most effective. This was also found in an earlier multifactorial intervention study by Gaede et al. (41,44). Several other lifestyle intervention studies have shown improvements in weight, cardiovascular disease risk and self-management (12,45-48). These studies do highlight the idea that we have to continue developing lifestyle interventions, however, the lack of a theory in most of these studies and a detailed description of the contents of the intervention makes it difficult to determine which were the successful elements in these studies. Our study design was theory-based and the key element was problem solving treatment, a useable technique to achieve behavioral change. In addition, we not only measured many outcome measures guided by our theoretical framework, but also the level of depression, which was lacking in many earlier interventions (40).

The strengths of the intervention were that it is theoretically driven by the ASE-model. It was also carefully implemented and controlled by means of a training for the diabetes nurses and dieticians, and a treatment manual, which encouraged diabetes nurses and dieticians to give a standardized intervention. Supervision meetings and tape recordings consolidated this.

This study also had some methodological limitations that we have to address. Firstly, it is known that people have the tendency to overestimate physical activity. This might have happened in both groups but it is likely that patients in the intervention group, who are encouraged to change, overestimate physical activity more than patient in the control group. In this case, this might have influenced our results. Secondly, we were not able to find a validated questionnaire to assess determinants of behavior. A questionnaire was developed by using several questionnaires of colleagues in the field but we are not able to say that results were valid. Thirdly, we aimed for 68 patients in each group to

find a minimally clinically relevant difference in the risk of developing cardiovascular disease between the two groups. We were able to include 76 and 78 patients in the intervention and control group, respectively. This means that we reached our aim but we had little opportunities to find suitable subgroups that are likely to benefit from the intervention, due to a relative small group of patients. We could not extend the inclusion period because we recruited patients in yearly assessments of the DMS and after 1 year, all patients were invited.

We also have to admit that in our original design (30), the intervention started with a motivational phase with techniques of Motivational Interviewing (49,50), but in practice we were not able to implement this due to the complexity of PST only. Therefore, we considered that it was more reasonable to focus on PST.

This study has several implications for research and clinical practice. We have provided an extensively described study design that might encourage other researchers to continue performing lifestyle interventions. We also showed that diabetes nurses and dieticians were able to learn and use a CBT, which implicates that such interventions can be implemented in clinical practice.

In conclusion, this study showed that adding a cognitive behavioral treatment to managed care seems to have beneficial effects on cardiovascular risk profile and was able to increase physical activity. Further theoretical driven intervention studies are needed in larger groups to investigate if self-management of patients with type 2 diabetes can be achieved with beneficial effects on clinical outcomes and which specific subgroups could have benefit from behavioral interventions.

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