Effects of Cardiovascular Disease Risk Communication for Patients With Type 2 Diabetes on Risk Perception in a Randomized Controlled Trial

The @RISK Study

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OBJECTIVE—Patients with type 2 diabetes mellitus (T2DM) underestimate their risk of developing severe complications, and they do not always understand the risk communication by their caregivers. The aim of this study was to investigate the effects of an intervention focused on the communication of the absolute 10-year risk of developing cardiovascular disease (CVD) in patients with T2DM.

RESEARCH DESIGN AND METHODS—A randomized controlled trial was performed in T2DM patients newly referred to the Diabetes Care System (DCS) West-Friesland, a managed-care system in the Netherlands. The intervention group (n = 131) received a six-step CVD risk communication. Control subjects (n = 130) received standard managed care. The primary outcome measure was appropriateness of risk perception (difference between actual CVD risk calculated by the UK Prospective Diabetes Study risk engine and risk perception). Secondary outcome measures were illness perceptions, attitude and intention to change behavior, satisfaction with the communication, and anxiety and worry about CVD risk. Patients completed questionnaires at baseline, at 2 weeks (immediately after the intervention), and at 12 weeks.

RESULTS—Appropriateness of risk perception improved between the intervention and control groups at 2 weeks. This effect disappeared at 12 weeks. No effects were found on illness perceptions, attitude and intention to change behavior, or anxiety and worry about CVD risk. Patients in the intervention group were significantly more satisfied with the communication.

CONCLUSIONS— This risk communication method improved patients' risk perception at 2 weeks but not at 12 weeks. Negative effects were not found, as patients did not become anxious or worried after the CVD risk communication.

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Care for patients with type 2 diabetes mellitus (T2DM) is focused on optimal control of the disease and the prevention of the development of severe complications, in particular cardiovascular disease (CVD) (1). Increasing evidence suggests that patients who take a more active role in their care achieve better health outcomes (2), and appropriate risk communication may facilitate this process (3). Although studies have shown that general risk communication is helpful for patients with T2DM, studies incorporating patients' individual risk are scarce, and, in particular, the effects on the intention to perform self-management activities are unclear (4–7).

In the current study, a cardiovascular risk communication intervention was developed for T2DM patients incorporating the individual risk for CVD. Three principles that have been shown to be important in risk communication were used in the development of this intervention. The first principle was to provide a simple and clear message on the causes and consequences of the risk of developing CVD and on what actions can possibly prevent CVD (3,8). The second was to use a simple format, such as visual presentations of the risk rather than percentages, which patients might be able to better understand, although evidence is mixed (5,9–14). Third, communication of the benefits of change in a so-called positive frame, rather than a negative presentation—for example, in terms of loss of healthy years—has been shown to increase patients' motivation (4,13,15). The rationale for this study was based on Leventhal's self-regulation theory and the Theory of Planned Behavior (TPB). According to the self-regulation theory, patients have perceptions concerning their disease that are either correct or incorrect (16,17). These perceptions determine how patients cope with their disease and manage their risks of developing complications (18). It is hypothesized that providing understandable risk information may change the illness perceptions, which in turn may change the attitude concerning importance of behavior change and intention to change—as laid down in the TPB (19).

The aim of the current study was to investigate the effects of a CVD risk communication intervention on appropriateness of risk perception in patients with T2DM. Secondary objectives were to investigate the effects on illness perceptions, attitude, and intention to change behavior. In addition, patients' general satisfaction with the communication and

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anxiety and worry about CVD risk were assessed to check for adverse effects of risk communication.

RESEARCH DESIGN AND METHODS

—A randomized controlled trial was conducted within the Diabetes Care System (DCS) West-Friesland, a managed care system that was implemented in the Netherlands in 1997. The design of the study has previously been described in detail (20), as have been the objectives and function of the DCS (21). Briefly, the DCS coordinates care between different caregivers in the region West-Friesland, provides feedback to patients and specialists, and promotes patient empowerment by providing information and education—in addition to the 3-monthly care of the general practitioners.

Newly referred patients were invited to participate in the study. Inclusion criteria were as follows: maximum age of 75 years, ability to fill in questionnaires in the Dutch language, and not having experienced a cerebrovascular accident or transient ischemic attack because of possible communication problems. All participating patients gave written informed consent and were randomized into an intervention and a control group by means of a list drawn up by a computerized randomization program (version 1.0.0; Random Allocation Software). The Medical Ethical Committee of the VU University Medical Center in Amsterdam approved the study protocol.

Control group

The control group received usual care provided by the diabetes nurses and dietitians of the DCS. This consisted of the annual measurement visit for physical examination, including weight and blood pressure, and collection of blood samples to assess HbA_{1c} and cholesterol levels. Two weeks later, patients visited a diabetes nurse and dietitian (both for 30 min) for general information about having diabetes and the risk of developing diabetes-related complications. Moreover, simple education was given about treatment options and lifestyle changes. Care was provided according to the guidelines of the Dutch College of General Practitioners (22).

Intervention group

The intervention group received a risk communication intervention in addition to the usual care described above. The diabetes nurses and dietitians received a training of two half-days in performing the intervention. For further training, a pilot study (coaching on the job) was performed with a coach who gave feedback immediately after the visit. The intervention was standardized by means of a treatment manual.

The risk communication intervention started with the diabetes nurse and consisted of six steps. *1*) The introduction of the risk communication: a general explanation about health-related risks related to T2DM, including the cause and consequences of the CVD risk. *2*) Communication of the absolute risk according to the UK Prospective Diabetes Study (UKPDS) risk engine: the absolute risk of developing CVD in the next 10 years was explained in the format of natural frequencies. The risk of developing CVD was estimated with the UKPDS risk engine (23). The following sentence was used: "Your risk to develop CVD in the next 10 years is X%. This means that of the 100 men/women of your age and with the same lab results and who also smoke/do not smoke, X will develop CVD in the next 10 years." *3*) Visual communication by means of a risk card: the risk was explained again with the help of a population diagram. This diagram showed 100 people, and the diabetes nurse indicated which people will develop CVD in the next 10 years. While it is still unclear whether and under which circumstances visual presentation is most effective in risk communication (4,5), we chose to present a reference class of 100 people, since some evidence was available for this (13,24). *4*) Positive framing ("message framing"), i.e., explanation that lifestyle changes can help to reduce the risk: translating the risk estimation into a positive message by explaining that the patient is able to change the risk. In addition, the message included the ways to change the risk. It is estimated that the risk of developing CVD in the next 10 years can be reduced by 30% by changing lifestyle habits, such as increasing physical activity, eating a healthier diet, and quitting smoking. For example, a risk of 30% can be reduced to 21% over a period of several years (7). This means that the absolute health gain is 9%. The diabetes nurses showed this on the risk card by indicating the people who will no longer be at risk of developing CVD. In this example, nine people were indicated. *5*) Communication with the patient for a reaction: after finishing the explanation of the risk, the diabetes nurse asked the patient to give a reaction to the information that was given using open questions. *6*) Thinking aloud; patient has to explain the risk him/herself: the patient was encouraged to "think aloud" about the risk and the meaning of the risk. It is believed that active participation will enable the patient to remember the information more easily (25).

Steps 1 and 2 are focused on the dimensions "cause" and "consequences," and step 4 was based on the dimension "controllability" of the self-regulation theory (17). Step 4 was focused on the attitude and intention concerning behavioral changes as laid down in the TPB.

The duration of the risk communication part of the consultation by the diabetes nurse was approximately 5 min. Subsequently, the patient visited the dietitian, who started with step 6 of the intervention to see whether the patient was able to explain what he/she had learned about his/her CVD risk from the diabetes nurse. Depending on the ability of the patient to explain the CVD risk and possibilities of changing the risk, the dietitian either continued with standard managed care of the DCS or repeated the intervention starting at step 2.

Measurements

Systolic blood pressure was measured after 5 min of rest in a seated position by Collon Press mate (BP-8800). HbA_{1c} was measured by high-performance liquid chromatography, and total cholesterol and HDL cholesterol were measured by means of enzymatic techniques (Boehringer Mannheim, Mannheim, Germany). Age, duration of diabetes, sex, ethnicity, level of education, marital or cohabiting status, employment status, family history of T2DM and CVD, and smoking status were included in self-report questionnaires. Smoking status was distinguished as nonsmoker, ex-smoker, or current smoker including number of cigarettes per day. Outcome measurements were assessed by means of self-reported questionnaires at baseline, 2 weeks (directly after the intervention or control visit), and 12 weeks.

Primary outcome measure—Appropriateness of risk perception. Risk perception was measured with a question from a previously developed questionnaire. This question was, "If the mean risk of developing CVD in the next 10 years for men with diabetes is 20 of 100 men and for women 15 of 100 women, how would you rate your risk of developing CVD in the next 10 years?" Appropriateness of

risk perception was assessed by calculating the agreement between the UKPDS score (estimation of risk of developing CVD including nine variables: age at diagnosis, duration of diabetes, sex, ethnicity, smoking status, systolic blood pressure, HbA1c, total cholesterol, and HDL cholesterol) (23) of the patient and the patient's risk perception.

Secondary outcome measures—Anxiety and worry. For assessment of whether patients became anxious or worried about their CVD risk after receiving risk information, two questions were included in the questionnaire, measured on a 7-point Likert scale. These questions were used in an earlier study by Claassen et al. (26).

The Short Form Spielberger State Anxiety Inventory (SF-STAI) (27) was used to investigate general anxiety. It assesses the extent to which patients felt "calm," "tense," "upset," "relaxed," "content," and "worried" on a 4-point scale. Sum scores were calculated and ranged between 20 and 80, with higher scores indicating a higher level of anxiety.

Secondary outcome measures—Illness perceptions. Illness perceptions (i.e., causes and consequences of disease) were assessed by the Brief Illness Perception Questionnaire (Brief-IPQ) (28) consisting of eight items on the seriousness and impact of diabetes on various aspects of life, measured on a 10-point Likert scale. Scores on the eight items were calculated separately and summarized to an overall score (range 0–80). A higher score indicates a more threatening view of having diabetes.

Secondary outcome measures—Determinants of behavior change: attitude and intention. Attitude and intention to change behavior according to the TPB (19) were measured by the validated Determinants of Lifestyle Behavior Questionnaire (29,30). The questionnaire consists of three parts, namely on the attitude and intention to change *1*) dietary intake, *2*) physical activity and *3*) smoking behavior. The six attitude items have a 7-point scale and consisted of three affective and three cognitive attitudes. Affective attitudes are based on emotions toward a behavior (e.g., unpleasant/pleasant); cognitive attitudes are based on previous knowledge, opinions, and beliefs about the advantages and disadvantages associated with a behavior (e.g., unimportant/important) (31). Examples of attitude items are as follows: "I consider eating healthier/increasing physical activity/quitting smoking good-bad, difficult-easy, frustrating-satisfactory." The three intention-to-change behavior items have a 5-point Likert scale. An example is, "I intend to eat healthier/increase physical activity/stop smoking within two months." Mean scores were calculated.

Secondary outcome measures—Satisfaction with the communication. Parts of the COMRADE scale (32) were used to investigate the satisfaction of the patients concerning the general communication by the diabetes nurses. This scale consists of 10 questions on a 5-point scale. The mean score of the 10 questions was calculated. Examples of questions are as follows: "The diabetes nurse gave me information on the advantages of treating or not treating my risk to develop cardiovascular disease" and "The information provided by the diabetes nurse was easy to understand." These questions were only included in the second questionnaire, which was given at 2 weeks just after the visit to the diabetes nurse and dietitian.

Analyses

Descriptive statistics for both groups are presented as *n* (%) patients, means ± SD, or median (interquartile range) in case of a skewed distribution. In order to assess the effect of the intervention, we studied the agreement between perceived risk and UKPDS risk at three time points: baseline, after 2 weeks, and after 12 weeks. We graphically presented the data in scatter plots of UKPDS risk against risk perception, with regression lines. In case of perfect agreement, one would expect the regression lines to coincide with the diagonal (risk perception = UKPDS risk). In order to detect differences between the slopes of the regression lines of the intervention and control groups, we performed multiple linear regression with a product term (group × UKPDS) to test for interaction and adjusted for work status, as this was different between the groups at baseline.

In addition, to measure the random variation of the risk perceptions in both groups we chose the SD of the residuals of the regression, i.e., the vertical spread of the individual perceived risks around the regression line (small SDs are desirable). In order to detect differences between the intervention and the control group, we compared residual SDs with an *F* test (variance ratio test). Finally, we investigated the influence of outliers, i.e., risk perceptions ≥0.80, by performing a sensitivity analysis without these outliers.

Differences in changes between the intervention and the control group were measured with 95% CIs at 2 and 12 weeks for secondary outcomes by means of linear regression analyses. Assumptions for linear regression were met. In case of relevant differences between the groups at baseline, data were adjusted for these factors. Between-group differences on satisfaction with the communication were investigated using independent *t* test. *P* values <0.05 were considered statistically significant. All analyses were performed using SPSS for Windows (version 15.0; SPSS, Chicago, IL).

RESULTS—At baseline, 130 patients were randomized into the control group and 132 patients to the intervention group. A flowchart representing follow-up of patients can be found in Fig. 1.

More men than women were included in both groups (Table 1 [baseline characteristics]). Groups were comparable at baseline, except for a difference in work status; in the control group, significantly more patients were employed ($P = 0.005$).

Primary outcome measure

Appropriateness of risk perception. Results of the primary outcome measure are shown in Table 2*A* and Fig. 2. At baseline, the slope of the regression lines (*B*) was −0.18 for the intervention group and −0.02 for the control group. No relation between UKPDS risk and risk perception was present in either group (Fig. 2*A*). After 2 weeks, the intervention group did statistically significantly better than the control group (Fig. 2*B* and Table 2). The estimated difference between the slopes of the regression lines was 0.48 ($P = 0.04$). After 12 weeks, both groups performed about equally well (Fig. 2*C* and Table 2). The sensitivity analyses (i.e., analysis without outliers: risk perceptions ≥0.80, data not shown) did not change the results.

As for random variation, results of the variance ratio tests were predominantly in favor of the intervention group. At baseline, no difference between groups could be detected ($P = 0.4$) (no outliers). After 2 weeks, no difference was detected ($P = 0.75$); however, after exclusion of outliers ($n = 3$ in the intervention group and $n = 4$ in the control group) a significant difference in favor of the intervention group emerged ($P = 0.006$). After 12 weeks, a significant difference in favor of the intervention group was found ($P < 0.001$), which, however, disappeared after

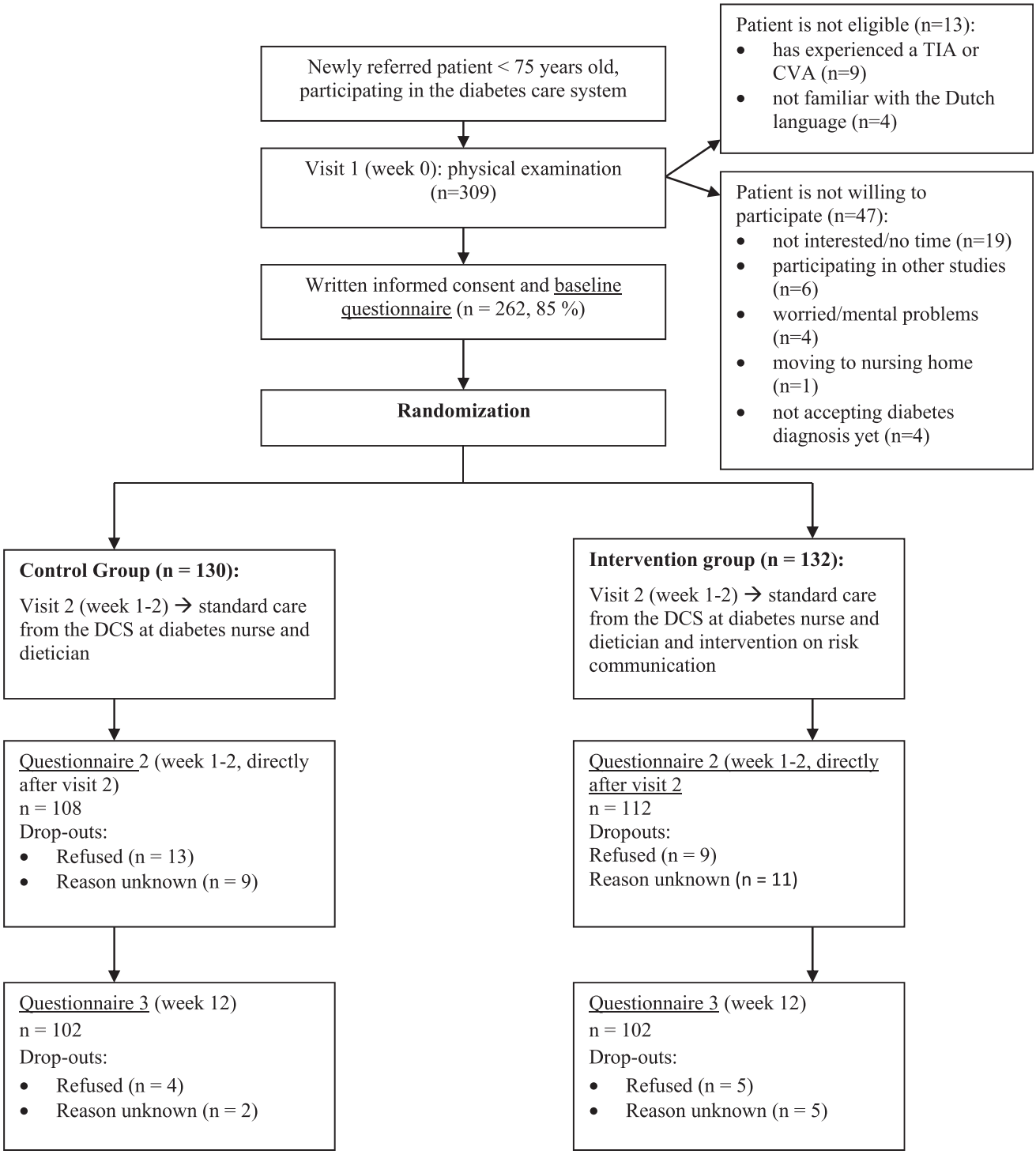

Figure 1—*Design of the randomized controlled trial on the effects of risk communication in patients with T2DM.*

exclusion of outliers (n = 2 in the control group) (P = 0.22, data not shown).

Secondary outcome measures

Results of the secondary outcomes are shown in Table 2*B*. We found no statistically significant differences between the intervention and control group on anxiety or worries about their risk of developing CVD or on general anxiety.

For illness perceptions, an overall score indicating the experienced burden of having diabetes was calculated by summarizing scores on the eight items, as for the individual items no changes were found (data not shown). At baseline, scores were 31.7 ± 12.0 and 31.9 ± 11.2 in the intervention and control group, respectively, and no changes were found 2 and 12 weeks after the intervention (Table 2).

We found that the affective attitude to stop smoking did statistically significantly change in the intervention group between

Table 1—*Baseline characteristics*

	Intervention group	Control group
n	132	130
Age (years)	58.9 ± 10.4	58.2 ± 9.9
Sex (male)	70 (53)	78 (60)
Marital/cohabiting status (with partner)	90 (71)	92 (79)
Work status (employed)#	53 (42)	71 (60)
Family history		
Diabetes	72 (56)	70 (55)
CVD	73 (57)	65 (51)
Level of education		
Primary	42 (33)	40 (34)
Secondary	68 (54)	58 (50)
College/university	16 (13)	19 (16)
Smoking (smokers)	33 (25)	30 (24)
Diabetes duration (years)	0.3 (0.1–1.0)	0.3 (0.1–1.6)
BMI (kg/m^2)	31.5 ± 5.4	31.4 ± 6.6
Systolic blood pressure (mmHg)	142.0 ± 18.6	141.4 ± 19.7
Diastolic blood pressure (mmHg)	78.2 ± 9.2	78.1 ± 10.1
HbA_{1c} (%)	6.7 ± 1.1	6.6 ± 1,2
Fasting blood glucose (mmol/L)	8.0 ± 2.1	7.9 ± 2.5
Total cholesterol (mmol/L)	4.8 ± 1.0	5.0 ± 1.1
HDL cholesterol (mmol/L)	1.2 ± 0.3	1.21 ± 0.3
Risk perception (%)$	17.7 ± 15.5	17.0 ± 15.8
Risk for CVD (%)*	14.7 ± 11.2	15.4 ± 11.3

Data are means ± SD, *n* (%), or median (interquartile range) in case of a skewed distribution. Missing values were low, with the largest found in level of education in the control group (8%). #Significant difference between the intervention and control group, $P = 0.005$, based on χ^2 test. $Measured via the question, "If the mean risk of developing CVD in the next 10 years for men with diabetes is 20 of 100 men and for women 15 of 100 women, how would you rate your risk of developing CVD in the next 10 years?" *Calculated by means of the UKPDS risk engine (Stevens et al., 2001; ref. 23).

baseline and 12 weeks from 4.5 ± 2.0 to 5.3 ± 1.8 compared with the control group, which showed a change from 3.4 ± 2.2 to 4.1 ± 2.1, but no differences were found between baseline and 2 weeks. No other between-group differences were found on the attitude and intention to become more physically active, to adopt a healthier dietary intake, or to stop smoking. We found that patients in the intervention group were statistically significantly more satisfied with the communication (4.0 ± 0.8 on a 5-point scale) compared with patients in the control group (3.6 ± 1.0).

CONCLUSIONS—In the current study, we investigated the effects of a CVD risk communication intervention for T2DM patients. Patients in the intervention group were able to estimate their risk of developing CVD more accurately than patients in the control group in the short term, but the effects disappeared after 12 weeks. No effects were found for worry and anxiety about CVD risk and overall anxiety, indicating that the risk communication did not induce negative feelings. Based on our theoretical framework, we expected that providing risk information would change illness perceptions, attitude, and intention to change physical activity, dietary intake, and smoking behavior, but our results did not confirm this hypothesis. We did find a statistically significant difference between the intervention and control group on satisfaction with the communication in favor of the intervention group.

Earlier studies in patients with T2DM on this topic were mostly qualitative or focused on a different research question, namely, which risk presentation format works best for patients, such as the study of Edwards et al. (33). In our previously published article (20), we highlighted the results of Benner et al. (34), Asimakopoulou et al. (35), and Koelewijn-van Loon et al. (36), who all showed promising results on risk perception but were either lacking a theoretical base and implications on intention for self-management (34,35) or were part of a larger lifestyle intervention (24), which makes it difficult to untangle the effects of risk communication only. A study by Pijl et al. (7) on communicating familiar risk of diabetes showed an increase in personal control and no negative effects on well-being. To our knowledge, since the start of our study, only one additional trial about individual risk communication has been published (by Price et al. [37,38]). The aim of the study was to investigate whether a personalized 10-year CVD risk estimate could increase physical activity in adults at high risk of CVD (19% of whom had diabetes). Their risk presentation, showing the patient's current risk and achievable risk based on targets for clinical outcomes, did not increase physical activity (38).

We could only find an effect of the risk communication on risk perception at 2 weeks—not at 12 weeks. Presumably, patients recall their risk until a few weeks after the intervention but are not able to recall their risk after a few months. The risk communication should therefore be repeated in subsequent visits. An explanation of the lack of effects on illness perceptions, attitude, and intention to change behavior might be that the intervention was too short to achieve this. Risk communication only might not be enough and should be the first step of a more complex lifestyle intervention—which, however, was not our goal. Many participants (55% in the intervention group and 59% in the control group) had a pessimistic view of their risk; i.e., their self-estimated risk was actually higher than their calculated UKPSD risk, which might also explain the lack of an effect on secondary outcome measures. The intervention may be more effective in patients with an optimistic risk perception at baseline compared with patients with a pessimistic risk perception, especially for intention to change behavior. However, analyses did not show any differences in secondary outcomes between these groups (data not shown).

The development of the risk communication intervention was theoretically driven, which is one of the strengths of this study. Behavioral theories are believed to improve interventions by the development of research questions and selection of outcome measures and methods. Another strength is the selection of our population, which consisted of patients all newly referred to the DCS with a recent (<1 year) diagnosis of diabetes.

Much attention was paid to the skills of the diabetes nurses and dietitians in performing the intervention appropriately by means of a standardized treatment manual, a training program, and

Table 2—*Differences in outcome measures between the intervention and control groups at baseline and at 2 and 12 weeks*

	Baseline	Follow-up 1 (2 weeks)	Follow-up 2 (12 weeks)	β of between-group differences at 2 weeks (95% CI)	β of between-group differences at 12 weeks (95% CI)
Appropriateness of risk perception#					
Intervention	−0.18	0.33	0.28	0.48 (0.02–0.95)*	−0.03 (−0.43 to 0.37)
Control	−0.02	−0.10	0.31		
Anxiety about CVD (scale 1–7)§					
Intervention	2.9 ± 1.9	2.8 ± 1.9	2.9 ± 1.7	−0.09 (−0.52 to 0.34)	0.09 (−0.38 to 0.55)
Control	3.0 ± 1.7	3.0 ± 1.8	3.0 ± 1.6		
Worry about CVD (scale 1–7)§					
Intervention	3.5 ± 2.1	0.2 ± 2.0	0.4 ± 1.9	−0.09 (−0.55 to 0.37)	−0.05 (−0.50 to 0.39)
Control	3.5 ± 1.8	3.4 ± 1.8	3.5 ± 1.6		
Illness perceptions (Brief-IPQ; scale 0–80)§					
Intervention	31.7 ± 12.0	31.1 ± 11.4	30.6 ± 11.6	0.51 (−2.98 to 1.97)	0.80 (−3.44 to 1.85)
Control	31.9 ± 11.2	32.2 ± 12.5	32.0 ± 12.3		
Anxiety (SF-STAI; scale 20–80)§					
Intervention	35.0 ± 10.7	32.4 ± 11.4	34.1 ± 11.2	−1.13 (−3.8 to 1.5)	−0.09 (−3.1 to 2.9)
Control	34.8 ± 10.2	34.7 ± 10.9	33.9 ± 11.7		
Satisfaction with communication (scale 1–5)$					
Intervention		4.0 ± 0.8		(−0.65 to −0.14)**	
Control		3.6 ± 1.0			
TPB: smoking§					
Affective attitude (scale 1–7)					
Intervention (*n* = 32)	4.5 ± 2.0	4.7 ± 2.1	5.3 ± 1.8	0.23 (−0.97 to 1.43)	1.92 (0.79 to 3.06)**
Control (*n* = 30)	3.4 ± 2.2	4.3 ± 2.0	4.1 ± 2.1		
Cognitive attitude (scale 1–7)					
Intervention (*n* = 32)	5.5 ± 1.1	5.5 ± 1.2	5.7 ± 1.0	0.39 (−0.12 to 0.90)	0.60 (−0.07 to 1.26)
Control (*n* = 30)	5.0 ± 1.2	5.6 ± 1.0	5.2 ± 1.0		
Intention (scale 1–5)					
Intervention (*n* = 32)	3.4 ± 1.2	3.5 ± 1.1	3.3 ± 1.2	0.02 (−0.43 to 0.48)	0.10 (−0.50 to 0.70)
Control (*n* = 30)	3.3 ± 1.2	3.4 ± 1.1	3.4 ± 1.2		
TPB: physical activity§					
Affective attitude (scale 1–7)					
Intervention	5.5 ± 1.5	5.4 ± 1.5	5.3 ± 1.5	−0.12 (−0.42 to 0.19)	−0.10 (−0.44 to 0.24)
Control	5.5 ± 1.4	5.5 ± 1.4	5.4 ± 1.3		
Cognitive attitude (scale 1–7)					
Intervention	5.9 ± 0.9	5.9 ± 0.8	5.8 ± 0.8	0.02 (−0.19 to 0.22)	0.00 (−0.24 to 0.24)
Control	5.9 ± 0.9	5.8 ± 0.8	5.8 ± 0.8		
Intention (scale 1–5)					
Intervention	3.4 ± 1.0	3.3 ± 1.2	3.3 ± 0.9	−0.09 (−0.35 to 0.17)	−0.25 (−0.52 to 0.02)
Control	3.6 ± 1.0	3.5 ± 1.0	3.5 ± 1.0		
TPB: dietary intake§					
Affective attitude (scale 1–7)					
Intervention	6.0 ± 1.0	6.1 ± 1.0	5.9 ± 1.1	0.25 (−0.04 to 0.53)	0.10 (−0.23 to 0.44)
Control	5.7 ± 1.2	5.6 ± 1.3	5.6 ± 1.1		
Cognitive attitude (scale 1–7)					
Intervention	6.2 ± 0.8	5.2 ± 0.7	6.1 ± 0.9	0.10 (−0.10 to 0.31)	−0.04 (−0.31 to 0.23)
Control	6.0 ± 0.8	6.1 ± 0.8	6.1 ± 0.7		
Intention (scale 1–5)					
Intervention	3.5 ± 1.0	3.5 ± 1.0	3.4 ± 0.8	0.01 (−0.26 to 0.28)	−0.10 (−0.34 to 0.15)
Control	3.6 ± 0.9	3.5 ± 0.9	3.6 ± 0.9		

Data for secondary outcome measures are means ± SD. Higher scores indicate the following: more anxious and worried (anxiety and worry about CVD), more threatening view of diabetes (Brief-IPQ), more anxious (SF-STAI), more satisfied (satisfaction with the communication), and more positive attitude concerning behavior change and higher intention to change behavior (TPB). #$B_{intervention}$, $B_{control}$, and $B_{difference}$ represent the slope of the regression lines of the intervention group and control group and difference between the two groups, respectively. The regression lines are shown in Fig. 2. *$P \leq 0.05$. **$P \leq 0.01$. §Linear regression analysis, adjusted for work status. Positive β, in favor of the intervention group. $Independent *t* test.

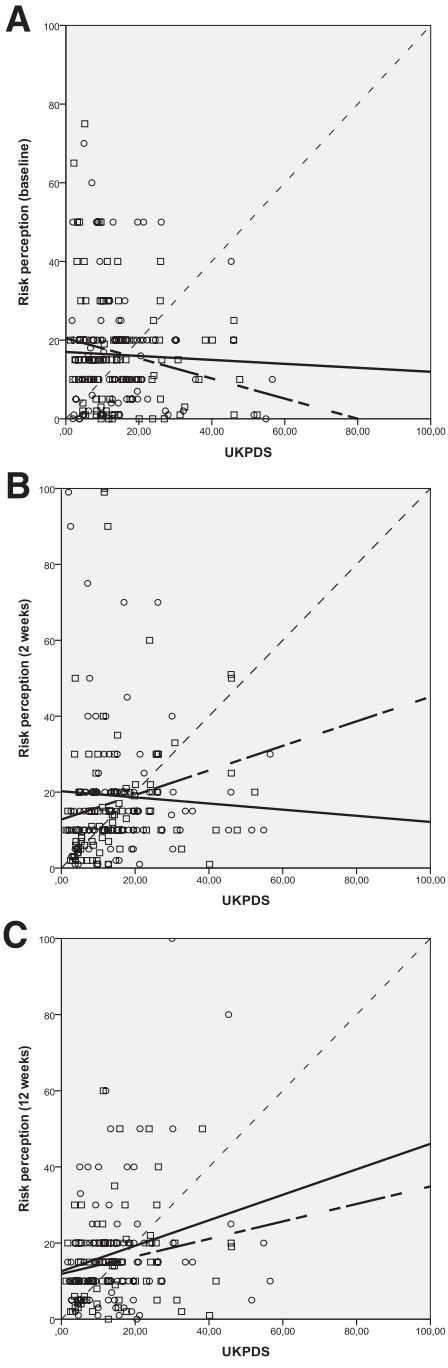

Figure 2—A–C: *Agreement between the UKPDS* (x-*axis*) *and risk perception* (y-*axis*) *(measured by means of the question, "If the mean risk of developing CVD in the next 10 years for men with diabetes is 20 of 100 men and for women 15 of 100 women, how would you rate your risk of developing CVD in the next 10 years?") at baseline* (A)*, 2 weeks* (B)*, and 12 weeks* (C)*, respectively. Each dot represents one patient.* ○*, control group;* □*, intervention group; – — –, linear regression line for the intervention group;*———*, linear regression line control group; - - - - - diagonal line, ideal situation wherein UKPDS = risk perception.*

coaching on the job by a communication coach in a pilot study, which has been found to be very helpful in psychological interventions because of the immediate personalized feedback that is given (39).

The current study has some limitations that should be addressed. First, for practical reasons we were not able to randomize the diabetes nurses and dietitians. In order to limit possible contamination of the intervention into the control group and increase treatment fidelity, we developed both an intervention and a control group protocol that caregivers had to use. In addition, we randomly made tape recordings of ten intervention and ten control sessions and analyzed these (data not shown). We found that the elements of the intervention were not used in the control sessions. In addition, both the intervention and control sessions were composed according to the protocols. Secondly, the Determinants of Lifestyle Behavior Questionnaire (30) to assess determinants of behavior change might not have been sensitive enough to detect changes between different time points, which could cause a lack of room for improvement at follow-up. This might have influenced the results of our secondary outcomes. Also, questions on anxiety and worry about CVD risk were not validated, which might have contributed to a lack of changes found in these outcomes.

This study has several implications for practice and research. We showed that diabetes nurses and dietitians were able to use a simple risk communication tool, indicating that the intervention was easy to implement in daily practice. We did not show that risk communication besides an improved risk perception will motivate patients to adopt a healthier lifestyle by means of self-management. This needs to be addressed in further studies, including risk communication as a first step in a broader lifestyle intervention. In addition, more research is needed to discover which visual risk presentation (i.e., using bar charts, population diagrams, survival curves, etc). is most understandable for patients and useful in clinical practice, while this remains unclear (40).

To conclude, this study showed that a simple risk communication intervention improved appropriateness of risk perception among T2DM patients in the short term without inducing anxious or worried feelings. Our hypothesis that risk information would change illness perceptions, resulting in a change of attitude concerning importance of behavior change and intention to change, was not supported by our data. Improved understanding of risks is important in the shared decision-making approach, as a better understanding of patients' risk of developing CVD might enable them to participate in the treatment process. However, as the final goal is empowered patients performing self-management activities, further research on this topic is needed.

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L.M.C.W. collected the data, performed analyses, and wrote the manuscript. S.D.M.B. contributed to the development of the design of the study, performed analyses, and reviewed, edited, and approved the final manuscript. P.J.K. performed data analyses and reviewed, edited, and approved the final manuscript. J.M.D., D.R.M.T., and T.v.d.W. contributed to the development of the design of the study and reviewed, edited, and approved the final manuscript. G.N. contributed to the development of the design of the study, performed analyses, and reviewed, edited, and approved the final manuscript. G.N. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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