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ORIGINAL ARTICLE

The impact of communicating cardiovascular risk in type 2 diabetics on patient risk perception, diabetes self-care, glycosylated hemoglobin, and cardiovascular risk

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Abstract
Aim This study aims to investigate the effect of a cardiovascular risk (CVR) communication intervention on the accuracy of CVR perception, diabetes self-care (DSC), glycosylated hemoglobin percent (HbA1c%), and CVR in patients with type 2 diabetes mellitus (T2DM).
Subject and methods A randomized controlled trial was performed in T2DM patients attending the family medicine outpatient clinic in Suez Canal University Hospital, Ismailia. The intervention group ($n = 107$) received a comprehensive CVR communication. Control subjects ($n = 107$) received the standard usual care. The outcome measures were: accuracy of risk perception, DSC, HbA1c%, and CVR scores. Patients were investigated at baseline and 3 months after the intervention. Differences between arms were assessed using chi-square and Student's t-test, and within-group differences were assessed using the paired t-test and McNemar's test.
Results After the intervention, the accuracy rate of risk perception was significantly improved (from 44.9 % to 89.7 %) in the intervention group with excellent improvement in agreement between perceived and objective risk (kappa ± SE 83.7 ± 4.4 %, $p < 0.000$). Diabetes self-care sum scale scores and HbA1c% showed statistically significant improvements for within-intervention group comparisons and between groups after the intervention ($p < 0.000$). Cardiovascular risk scores showed minimal, not statistically significant improvement in both groups.
Conclusion Our intervention significantly improved CVR perception, DSC, and HbA1c% in patients with T2DM. Further research is needed to investigate the effectiveness of applying more complex and longer lifestyle interventions and to confirm the credibility and sustainability of improvement.

Keywords Cardiovascular risk · Risk perception · Diabetes self care · Communicating risk · Glycosylated hemoglobin

Introduction

Diabetes represents a major health care problem in Egypt. In 2013, the International Diabetes Federation estimated that 15.4 % of the Egyptian population (20 years of age and older) has diabetes and that this prevalence will rise to 18.6 by 2035 (International Diabetes 2014). The clinical and economic burden from the disease arises from the fact that people with diabetes have a two- to four-fold increased risk of the life-threatening complication of cardiovascular disease compared to the general population (Yach et al. 2006). Because of this, guidelines for the management of type 2 diabetes mellitus (T2DM) advocate in particular calculating the cardiovascular disease risk (CVR) to guide the initiation of appropriate treatment (Rydén et al. 2007; British Cardiac Society et al. 2005).

Cardiovascular risk score assessment is based on measuring the absolute risk, which is defined as the percentage risk of a cardiovascular event within the next 5 or 10 years (Ferket et al. 2010). Absolute CVR assessment will help to identify and treat the high-risk population as well as to communicate risk effectively (Lloyd-Jones 2010). According to Leventhal's Self-Regulation Theory (SRT) (Leventhal et al. 1997) and

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Theory of Planned Behavior (TPB) (Ajzen 1991), communicating understandable risk information may change the illness perceptions, which in turn may change the attitude concerning the importance of behavior change and intention to change (Edwards 2009). Because more than 95 % of day-to-day care in diabetes is done by the patient (Shrivastava et al. 2013), successful diabetes clinical management relies mainly on proper patient self-care (Lai et al. 2007).

Based on the previous two behavioral theories, comprehensive CVR communication with T2DM patients is expected to improve patient CVR perception, resulting in better diabetes self-care (DSC) and glycemic control, which will further improve the CVR scores in these patients. This study aims to investigate the effect of a CVR communication intervention on the accuracy of CVR perception, DSC, glycemic control, and CVR scores in patients with T2DM.

Methods

Study design, setting, and time

Our study is a randomized controlled trial. The study was conducted in the family medicine outpatient clinic at Suez Canal University Hospital, Ismailia, from the start of May to the end of September 2015. The clinic was chosen for its ability to achieve the recruitment rate and for the presence of established diabetes care services.

Study population

Recruitment

Patients who were diagnosed with T2DM for 1 year or more and who were between 40 and 79 years old were included (Fig. 1 displays a flowchart of participants).

Screening for eligibility

Patients who were already using a medication chart similar to the one used in the intervention, patients participating in any other clinical research studies in the preceding 6 months, patients who had severe or terminal health conditions, and patients who had a behavioral health issue that could make it difficult to understand the communication were excluded.

Consent process and enrollment

Patients were informed about the aim of the study: "to improve DSC and glycemic control and to decrease the CVR in patients with T2DM," and the study procedure was explained. Informed consent was obtained from all individual participants included in the study. Participants were enrolled, and demographic data (age, gender, duration of illness, education, family history, and comorbidity) that could affect a patient's intention to participate for both accepted and non-accepted patients were investigated to test for sampling bias.

Randomization

Patients who agreed to participate were randomly allocated to an intervention group receiving comprehensive CVR communication and a control group receiving usual diabetes care.

Concealed allocation

The allocated assignments were concealed from patients and the research coordinator (outcome assessor) from the start of the study until it was concluded.

Blinding

Patient blindness was ensured by informing patients in both groups about the study aim without giving them knowledge about their group allocation. The research coordinator collected and analyzed the outcome measures blindingly to the patient allocation group.

Withdrawal criteria

Those who did not attend any one of the scheduled visits and those who refused to provide blood samples or complete the questionnaires were considered to be noncompliant with the study requirements.

Sample size

A sample size of 90 patients in each group was estimated as sufficient to detect a clinically important difference of 0.5 in glycosylated hemoglobin% (HbA1c%), assuming a standard deviation of 1.2 (based on a pilot study with 20 patients who are not included in the study sample). The calculation was based on the difference between means with a power of 80 % and a significance level of 95 %, assuming that HbA1c% was normally distributed. This number was increased to 120 per group to allow for an expected drop out from treatment of around one third.

Outcome measurement

a *Cardiovascular risk perception and accuracy:* Participant perception of CVR was measured at baseline and after 3 months by asking them about their perceived percentage risk of developing heart disease in the next 10 years. Answers were classified as less than 10 %, 10–<20 %, 20–<30 %, 30–<40 %, and ≥40 %. Accuracy was

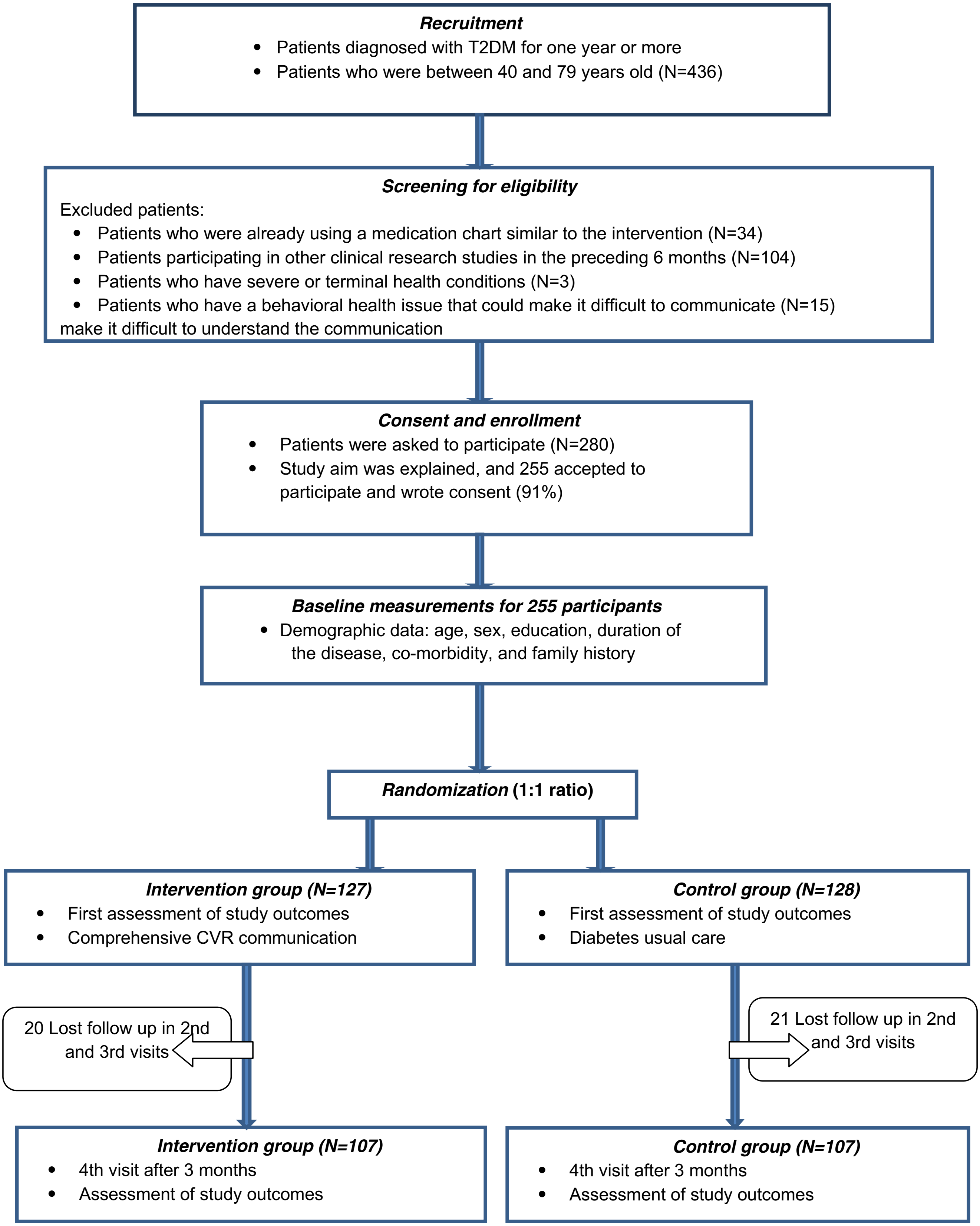


Fig. 1 Flowchart of participants

measured by determining whether participants' calculated CVR scores fell into the category they indicated.

b *Patient DSC:* The Diabetes Self-Management Questionnaire (Schmitt et al. 2013), a previously developed and evaluated valid and reliable questionnaire, was used for the assessment of DSC behaviors and activities associated with glycemic control in our participants. It has 16 items categorized in four subscales: glucose management, dietary control, physical activity, and health-care use, and one scale for self-assessment, as well as a sum scale as a global measure of self-care. The author's permission was obtained for using the questionnaire. The questionnaire was translated into the Arabic language and transformed to an interview questionnaire considering the literacy and cultural status of most of our patients.

c *Smoking status, clinical and laboratory outcomes:* Smokers were classified into smokers and occasional smokers according to their daily basis smoking. Blood samples were collected by laboratory staff, and the analysis was performed at the Suez Canal University Hospital reference laboratory. Total cholesterol was measured using the enzymatic colorimetric method. Patient HbA1c% was measured by the turbidimetric inhibition immunoassay technique. Blood pressure was measured twice, at least 2 min apart, using a sphygmomanometer in the left arm after the patient had been sitting for at least 5 min.

d *Predicted CVR scores:* This was measured using the World Health Organization/ International Society of Hypertension (WHO/ISH) risk prediction chart for Eastern Mediterranean Sub-region D version for diabetics with cholesterol methodology (WHO 2007a).

Study procedure

Before implementation, the treating physicians received training consisting of an introduction to the importance of providing information to the patients on CVR including the definition of risk, an explanation of absolute and relative risks, methods of risk communication, the SRT, and the TPB. In addition, they received a demonstration on how to use the WHO/ISH CVR prediction chart and on how to discuss CVR with patients. Discussing CVR was based on the risk of having a heart attack. This included:

- *The introduction of the risk communication:* This step includes a general explanation about the health risks associated with T2DM by providing a simple and clear message on the causes and consequences of the risk of developing cardiovascular disease and on what actions can possibly prevent it. This step is focused on the dimension "*cause and consequences*" from the SRT (Leventhal et al. 1997).
- *Visual presentation of risk:* After determining the CVR interval for each patient, the absolute risk score (determined as the mid-range), the relative risk (risk of developing cardiovascular disease in a diabetic person with similar age and sex but without other contributing factors), as well as the seriousness of the risk in the form of low, intermediate and high risk were explained in frequency and percentage formats and demonstrated to the patients.
- *Positive framing:* Physicians explained to patients how to change their CVR based on the guidelines of the WHO/ ISH for cardiovascular diseases (WHO 2007b). This step is based on the dimension "*controllability*" of the SRT (Leventhal et al. 1997) and was focused on the attitude and intention concerning behavioral changes as stipulated in the TPB (Ajzen 1991).

In the first visit, treating physicians measured patient study outcomes (risk accuracy, DSC, HbA1c%, and CVR scores) and provided comprehensive communication and management of CVR to those assigned to the intervention group according to the WHO/ISH guidelines (WHO 2007b). Regarding the control group, the treating physicians measured the patient study outcomes without disclosing the CVR scores and provided standard usual care based on the guidelines of the American Diabetes (American Diabetes Association 2014). Patients were given three follow-up appointments for the purpose of the study (4 weeks from baseline and 4 weeks apart to the end of the trial). In the second and third visits, physicians provided the assigned care for each group, and in the fourth visit (end of the 3rd month since the start of the intervention), physicians measured patient study outcomes.

Statistical analysis

Frequencies and percentages were used for presenting categorical variables, and means ± SD were used for presenting continuous variables. Chi-square and Student *t*-tests were respectively used for testing the significance of differences from the baseline qualitative and quantitative variables: among accepted and refused patients, patients in both study groups, and for pre- and post-intervention comparison of study outcome variables between groups. McNemar and paired t-tests were used for intragroup pre-post differences. The kappa test was used for detecting the degree of agreement between pre- and post-perceived risk with baseline objective risk. In the intervention group, point biserial correlation was used to test for correlation between post-intervention CVR accuracy and DSC scores, Pearson correlation was used to test for correlation between post-intervention DSC sum scale scores and HbA1c%, and Spearman correlation was used to test for correlation between HbA1c% and CVR scores.

Results

Analysis of baseline data after deleting dropouts revealed the persistence of similarity between the two groups (107/each

Table 1 Descriptive statistics of included subjects

Characteristic	Intervention group ($N=107$)	Control group ($N=107$)	p-value
Age (x ± SD)	56.3 ± 8.4	55.1 ± 8.3	0.291
Gender males n (%)	52 (48.6)	48 (44.9)	0.584
Education n (%)			
• Illiterate	42 (39.2)	38 (35.5)	0.783
• Read and write	16 (15)	19 (17.8)	
• Primary and prep school	15 (14)	20 (18.7)	
• Secondary school	18 (16.8)	18 (16.8)	
• University	16 (15)	12 (11.2)	
Duration of the disease (x ± SD)	8.5 ± 1.2	8.18 ± 1.5	0.091
Family history n (%)			
• No history	34 (31.8)	38 (35.5)	0.915
• Diabetes	41 (38.3)	41 (38.3)	
• Hypertension	19 (17.8)	16 (15)	
• Diabetes and hypertension	13 (12.1)	12 (11.2)	
Comorbidity n (%)			
• None	31 (29)	34 (31.8)	0.645
• Hypertension	48 (44.9)	49 (45.8)	
• Liver disease	20 (18.6)	17 (15.9)	
• Other	3 (2.8)	4 (3.7)	
• More than one comorbidity	5 (4.7)	3 (2.8)	

group) with the absence of a statistically significant difference among them regarding the examined variables (Table 1). At baseline, about 70 % of patients in both groups (75 in the intervention group and 76 in the control group) perceived their risk as intermediate/high compared to 47 (34 %) and 78 (73 %), respectively, after the intervention. Kappa analysis showed low agreement between perceived and objective risk before the intervention in both groups (kappa ± SE =27.1 ± 5.2 % and 8.8 ± 4.5 %, respectively). After the intervention, the rate of accuracy significantly increased in the intervention group from 44.9 % to 89.7 %, which was reflected in the increased agreement between the perceived and objective risk in this group (kappa ± SE 83.7 ± 4.4 %, $p<0.000$). In the control group, the rate of accuracy showed little improvement from 30.8 % to 31.7 %, with little improvement in agreement (kappa ± SE 10.5 ± 4.6 %, $p>0.05$). Before the intervention, 55.1 % of the intervention group and 69.2 % of the control group were inaccurate in their perception ($p>0.05$), with a greater rate of overestimation (41.1 %, and 45.8 % in the intervention and control group, respectively) than of underestimation (14 % and 23.4 % respectively); this rate was reduced to 1.9 % and 45 % in both groups, respectively (Table 2).

At baseline, 36.5 % of patients in both groups were smokers (regular and occasional smokers). Total proportions did not change by the end of the intervention, but subgroup change occurred among smokers in both groups with increasing occasional smokers among the intervention group from 7.5 % to 10.3 % at the end of the intervention. Within- and between-group differences were found to be statistically non-significant ($p>0.05$). Regarding the DSC scores, the mean subscale scores (except for DSC/physical activity) increased in the intervention group compared to the control group by the end of the intervention ($p<0.000$) (Table 3).

Mean HbA1c% in both groups was nearly equal at baseline (8.13 ± 1.4 and 8.15 ± 1.2). By the end of the intervention, the between-group difference in mean HbA1c% (0.62 %) as well as within-intervention group difference (0.63 %) was found to be statistically significant ($p<0.000$). After the intervention, more patients in the intervention group showed a controlled HbA1c% (cutoff point of ≤7) compared to the control group (12.1 % and 6.5 %, respectively) with statistical significance for the within-intervention group difference ($p=0.015$). Total cholesterol was nearly equal between both groups at baseline (6.5 ± 1.8 and 6.28 ± 1.6, respectively). By the end of the study, minimal improvement occurred in both groups without statistical significance in the difference for the between- and within-group comparisons. Mean systolic and diastolic blood pressure values were nearly equal at the start of the intervention in both groups, with minimal improvement in the intervention group (−2.8 and −1.4 mmHg in systole and diastole, respectively) by the end of the study, with statistical significance in differences for the within-intervention group comparison ($p<0.000$; Table 4).

At baseline both groups had nearly equal proportions (57.9 % and 57 %, respectively) of patients with low CVR. Both groups showed minimal change by the end of the intervention without showing statistical significance for either the between- or within-group comparison ($p>0.05$) (Table 5). Correlation among the key study elements showed significant

Table 2 Agreement of perceived CVR scores in both groups with pre-intervention objective CVR scores

Perceived CVR scores		Pre-intervention objective WHO/ISH CVR scores[a] n(%)									
		Intervention group (N = 107)					Control group (N = 107)				
Pre-intervention		<10 %	10 %-	20 %-	30 %-	≥40 %	<10 %	10 %-	20 %-	30 %-	≥40 %
	<10 %	31 (50)	0	1 (9.1)	0	0	26 (42.6)	3 (27.3)	2 (11.1)	0	0
	10 %-	24 (38.7)	4 (40)	1 (9.1)	0	1 (7.6)	35 (57.4)	2 (18.2)	8 (44.5)	0	0
	20 %-	7 (11.3)	6 (60)	6 (54.5)	2 (18.2)	5 (38.5)	0	6 (54.5)	2 (11.1)	3 (37.5)	2 (22.2)
	30 %-	0	0	2 (18.2)	5 (45.5)	5 (38.5)	0	0	6 (33.3)	3 (37.5)	7 (77.8)
	≥40 %	0	0	1 (9.1)	4 (36.3)	2 (15.4)	0	0	0	2 (25)	0
	Kappa ± SE p-value	27.1 ± 5.2 % 0.000					8.8 ± 4.5 % 0.052				
	Accuracy rate	48 (44.9 %)					33 (30.8 %)				
Post-intervention	<10 %	60 (96.8)	0	0	0	0	25 (41)	4 (36.4)	0	0	0
	10 %-	2 (3.2)	10 (100)	1 (9.1)	0	0	29 (47.5)	3 (27.3)	9 (50)	0	0
	20 %-	0	0	10 (90.9)	2 (18.2)	0	7 (11.5)	3 (27.3)	4 (22.2)	4 (50)	2 (22.2)
	30 %-	0	0	0	9 (81.8)	6 (46.2)	0	1 (9)	5 (27.8)	1 (12.5)	6 (66.7)
	≥40 %	0	0	0	0	7 (53.8)	0	0	0	3 (37.5)	1 (11.1)
	Kappa ± SE p-value	83.7 ± 4.4 % 0.000					10.5 ± 4.6 0.022				
	Accuracy rate	96 (89.7 %)					34 (31.8 %)				
Risk accuracy		Pre-intervention n (%)		Post-intervention n (%)			Pre-intervention n (%)		Post-intervention n (%)		
	Accurate	48 (44.9)		96 (89.7)			33 (30.8)		34 (31.8)		
	Underestimated	15 (14)		9 (8.4)			25 (23.4)		25 (23.4)		
	Overestimated	44(41.1)		2 (1.9)			49 (45.8)		48 (44.8)		
	Within group p- value	0.000					0.938				
	Between groups pre and post p- value	0.072[b] 0.000[c]									

[a] WHO/ISH CVR scores: low = <10 %, intermediate = 10–< 30 %, high = ≥30 %

[b] Pre-intervention in between-group comparison p-value; [c] post- intervention in between-group comparison p-value

Table 3 Pre- and post-intervention comparison of behavioral characteristics in both groups

Characteristics/between groups *p*-value	Pre-intervention		Post-intervention		Pre-post within group *p*-value	
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Smoking status n (%)						
Non-smoker	68 (63.5)	73 (68.2)	68 (63.5)	73 (68.2)	0.257	0.572
Smoker	31(29)	25(23.4)	28(26.2)	26(24.3)		
Occasional smoker	8(7.5)	9(8.4)	11(10.3)	8(7.5)		
	0.644		0.696			
Diabetes self-care/subscale (maximum sum of items) (x ± SD)						
DSC/glucose management (15)	10.56 ± 1.9 0.101	10.95 ± 1.6	12.73 ± 2.3 0.000	11.15 ± 2.7	0.000	0.064
DSC/dietary control (12)	8.64 ± 1.5 0.187	8.93 ± 1.7	10.1 ± 1.6 0.000	8.87 ± 0.5	0.000	0.607
DSC/physical activity (9)	7.07 ± 1.4 0.290	7.32 ± 2	7.2 ± 0.9 0.479	7.3 ± 1.1	.789	0.998
DSC/health-care use (9)	5.44 ± 1 0.398	5.55 ± 0.9	6.74 ± 1 0.000	5.58 ± 0.7	0.000	0.072
DSC/self-assessment (3)	2.2 ± 0.6 0.186	2.3 ± 0.5	2.66 ± 0.5 0.000	2.3 ± 0.8	0.000	0.463
DSC/sum scale (48)	33.91 ± 6.7 0.256	35.05 ± 7.9	39.43 ± 7.2 0.000	35.12 ± 9.8	0.000	0.705

results ($p < 0.000$) (between CVR accuracy and DSC/sum scale scores, r = 0.242; between DSC/sum scale scores and HbA1c%, r = −0.835; between the HbA1c% and CVR scores, r = 0.613) (Fig. 2a–c).

Discussion

To our knowledge, no studies have been conducted to examine the effects of CVR communication on health outcomes of diabetic patients in Egypt. Furthermore, results from previous studies in other countries (Asimakopoulou et al. 2008a; Benner et al. 2008; Koelewijn-van Loon et al. 2008), despite showing promising results on risk perception, were lacking a theoretical base and implications for self-management (Asimakopoulou et al. 2008a; Benner et al. 2008), which makes it difficult to prove the role of risk perception on diabetes self-management (Asimakopoulou et al. 2008a).

The absence of statistically significant differences between the two study groups regarding their demographic characteristics, duration of the disease, family history, and comorbidity at baseline provided evidence of the appropriateness of the

Table 4 Pre- and post-intervention comparison of the clinical characteristics in both groups

Clinical characteristics/between groups *p*-value	Pre-intervention		Post-intervention		Pre-post within group *p*-value	
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
HbA1c% (x ± SD)	8.13 ± 1.4 0.934	8.15 ± 1.2	7.5 ± 0.8 0.000	8.12 ± 0.9	0.000	0.455
• Controlled n (%)	22 (20.6)	25 (23.4)	35 (32.7)	32 (29.9)	0.015	0.337
• Non-controlled n (%)	85 (79.4)	82 (76.6)	72 (67.3)	75 (70.1)		
	0.620		0.658			
Total cholesterol (mmol/l) (x ± SD)	6.5 ± 1.8 0.345	6.28 ± 1.6	6.45 ± 1.2 0.140	6.21 ± 1.2	0.883	0.737
Systolic blood pressure (mmHg) (x ± SD)	145.8 ± 12 0.065	143 ± 10	143 ± 8 0.563	144 ± 16	0.000	0.089
Diastolic blood pressure (mmHg) (x ± SD)	87.9 ± 8 0.099	86.3 ± 6	86.5 ± 6.7 0.667	87 ± 10	0.000	0.074

Table 5 Pre- and post-intervention comparison of CVR scores in both groups

WHO/ISH CVR scores	Pre-intervention		Post-intervention		Pre-post within group *P*-value	
	Intervention group *n* (%)	Control group *n* (%)	Intervention group *n* (%)	Control group *n* (%)	Intervention group	Control group
<10 %	62 (57.9)	61 (57)	65 (60.7)	60 (56)	0.087	0.277
10 %-	10 (9.3)	11 (10.3)	11 (10.3)	13 (12.2)		
20 %-	11 (10.3)	18 (16.8)	13 (12.2)	24 (22.4)		
30 %-	11 (10.3)	8 (7.5)	10 (9.3)	5 (4.7)		
≥40 %	13 (12.2)	9 (8.4)	8 (7.5)	5 (4.7)		
Between groups *p*-value	0.567		0.199			

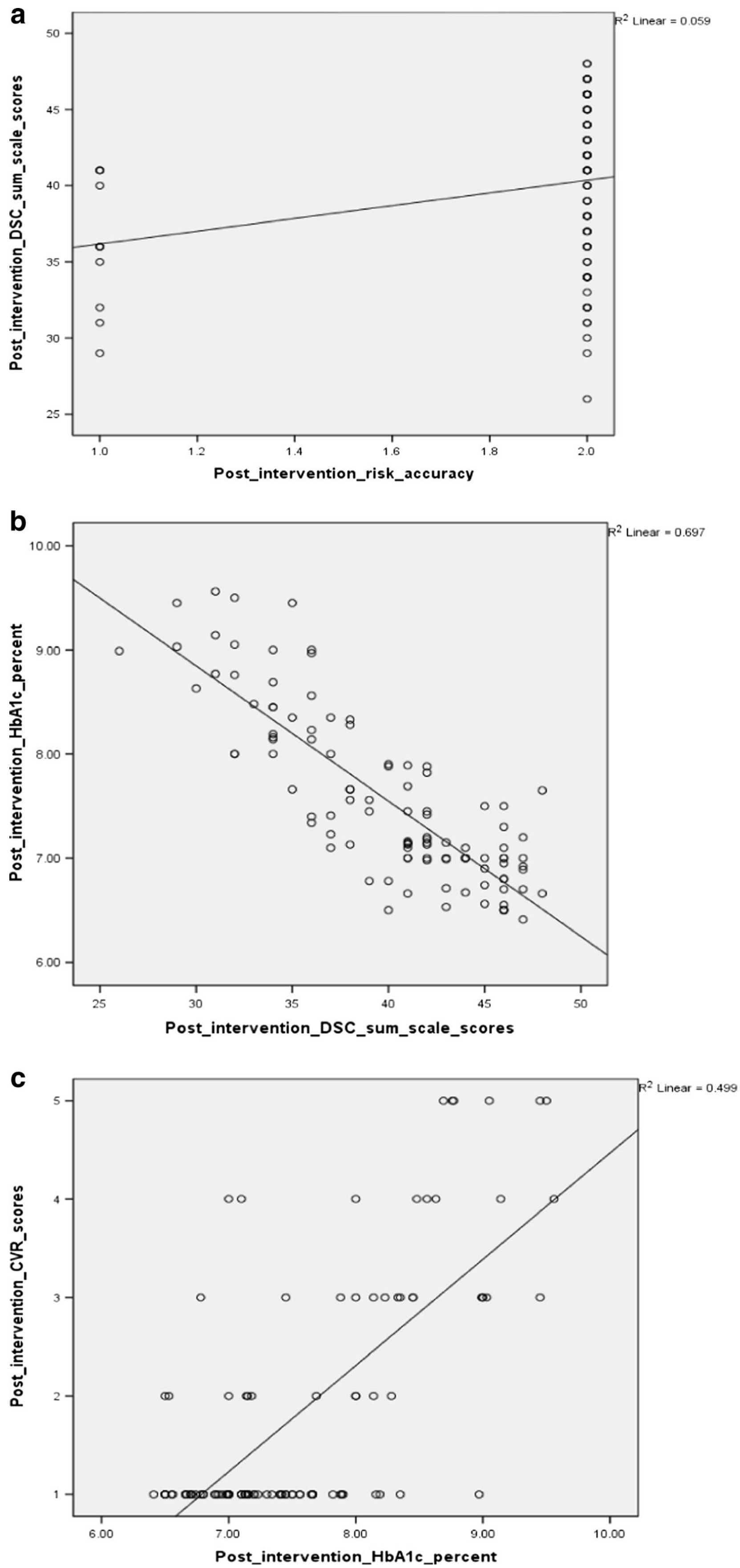
randomization technique used in this study. The lack of accuracy of baseline CVR perception among participants in our study is consistent with the results of previous studies that demonstrated that diabetic patients either underestimate (Claassen et al. 2010) or overestimate their risk to develop cardiovascular disease (Asimakopoulou et al. 2008b).

In our intervention, the provision of CVR communication in repeated patient visits was shown to significantly improve the risk accuracy for the within-intervention group and between groups by the end of the intervention. These results confirm the credibility of the application of the key element of the SRT called "*understanding the cause*" (Leventhal et al. 1997) to our patients. A similar study (Welschen et al. 2012) showed that CVR communication intervention improved patient accuracy in the intervention group compared to the control group in the short term, but the effects disappeared after 12 weeks. The authors in that study recommended repeating risk communication to patients in subsequent visits to allow for better recall of their risk.

The trend to reduce smoking is increased in the intervention group compared to the control group, giving promising results, although it did not achieve statistical significance. This was in agreement with the results of a previous trial (van Steenkiste et al. 2007), which was conducted in a lower CVR sample and targeted lifestyle changes that would be appropriate for all patients regardless of their CVR level. However, the methodological differences between the two studies do not allow for appropriate comparison. A similar short-term (12-week) trial showed that CVR assessment and communication based on lifestyle change was significantly associated with an increase in the number of patients in the intervention group reported to have quit smoking at the end of the study compared to the usual care group (Koelewijn-van Loon et al. 2010). Another similar but long-term trial (7 years) that used CVR scores for the primary prevention of cardiovascular disease reported significant differences in smoking cessation between the intervention and control arms (Multiple Risk Factor Intervention Trial Research Group 1982). The use of decisional aids for CVR presentation and communication in the first intervention, despite the short-term period, and the longevity of the second intervention could explain the statistical significance in the difference between smokers and non-smokers in these trials.

In our study, the results of self-care activities confirm the hypothesized theory in which the patients understood their risk and then adopted behavioral and therapeutic changes. Physical activity was the only behavior that did not show significant improvement. This was in agreement with a previous study conducted in our country and concluded that the exercise regimen showed the lowest values among all studied items of compliance to management (i.e., taking medications as prescribed, taking medication in time, dietary control, and exercise control) (Ibrahim et al. 2010). The authors explained this low patient compliance with physical activity as being due to the fear of increased risk of trauma and/or the perception that exercise could exacerbate their illness. Provision of comprehensive communication in our study was expected to induce significant improvement among the intervention group by improving patient perception regarding the positive influence of physical activity, but actually we did not provide our patients with "how to" procedures. On the other hand, a short-term (6-week) community-based peer-led intervention trial (Lorig et al. 2009) conducted on diabetic patients to examine the intervention effects on diabetes self-management showed statistically significant but marginal improvement in aerobic exercise in the intervention compared to the control arm. The authors explained their findings to be related to the level of HbA1c%, which was much lower than in similar trials, and they suggested that people with diabetes without elevated HbA1c% can benefit from this community-based, peer-led diabetes program. Other studies concluded no effects of CVR communication on the behavior change

Fig. 2 **a**–**c** Correlations in the intervention group: between post-intervention CVR accuracy and DSC/sum scale scores (**a**), between post-intervention DSC/sum scale scores and HbA1c% (**b**), and between post-intervention HbA1c% and CVR scores (**c**)



of physical activity, and the authors declared that risk communication alone might not be enough and should be the first step of a more complex lifestyle intervention (Price et al. 2011).

Regarding behaviors related to dietary control, our study showed conflicting results compared to those of a previous trial (Welschen et al. 2012). The authors of that study demonstrated no effects of CVR communication on intentions toward dietary control in diabetic patients, and this was explained to be due to the pessimistic view of more than half of the patients, which finally led to the lack of an intervention effect on this health behavior measure. In our study, providing repeated communication with our patients could be responsible for the success in changing their dietary behavior.

The low DSC glucose management scores as well as the high level of HbA1c% at baseline could be explained to be due to the inaccurate risk perception in these patients. Previous studies have demonstrated that both optimistic and pessimistic patients have reluctance about their self-management (Claassen et al. 2010; Asimakopoulou et al. 2008b) with a resultant high HbA1c%. Our intervention has significantly improved self-reported behaviors related to glucose management and health service utilization. Although improvement in HbA1c% is the clear-cut measure of diabetes self-management, previous studies in this area did not focus on this outcome measure (either subjectively, i.e., self-reported; or objectively, i.e., HbA1c%) or have a different research question, which makes comparison difficult (Welschen et al. 2012; Price et al. 2011; Asimakopoulou et al. 2008a; Koelewijn-van Loon et al. 2008).

The positive significant correlation (although weak) between post-intervention risk accuracy and DSC sum scale scores in the intervention group confirms the positive influence of risk accuracy on improving patients' ability to control diabetes. The weak association between these two variables could be due to the floor effect indicated by the high percentage of patients who showed accurate CVR scores at baseline. The significant improvement of post-intervention mean HbA1c% in the intervention group, although it did not reach the recommended levels (American Diabetes Association 2014), supports the influence of our intervention, and the high negative correlation between the DSC sum scale scores and mean HbA1c% further supports the theoretical framework of our study. The unexpected increase in the percentage of controlled diabetics among the control group could be explained by the increase in patient compliance to treatment and lifestyle changes because of their participation in a clinical trial.

In our study, the total cholesterol level showed minimal nonstatistically significant decline for between- or within-group comparison. This is in agreement with results of a previous study that demonstrated that communicating CVR is associated with a small but measurable improvement in the efficacy of lipid therapy (Grover et al. 2007). Greater than expected improvement in the control group in our study could be responsible for not achieving statistical significance. Another explanation is that the trial period was too short to achieve the desired effects. The minimal improvement in systolic and diastolic blood pressure for within intervention group comparison in our study, although statistically significant, is clinically not significant and does not reach the recommended levels. This trend in improvement could achieve more clinical significance in studies with long-term periods of follow-up or in studies with more intensive interventions. A previous study showed that interventions using CVR calculation was associated with lower mean systolic blood pressure at 6 months (Benner et al. 2008) and 12 months (Montgomery et al. 2000) compared to use of no risk calculation. A systematic review of global coronary heart disease risk calculation suggested that improvements in risk and treatment compliance depend on the quality of educational interventions (Sheridan et al. 2010).

We used the WHO/ISH CVR prediction chart for investigating the effect of our intervention on patients' CVR scores. These charts differ from others used in previous studies, and studies that used these charts in their methods are scarce, which makes it difficult for comparison. In a recent study conducted in an Arabic country (Oman) to compare the performance of the WHO/ISH charts versus the Framingham risk scores, the WHO/ISH charts were found to underestimate the number of patients in need of primary prevention of cardiovascular diseases compared with the Framingham risk scores (Al-Lawati et al. 2013). The controversy regarding which model to use becomes irrelevant if the model has a high discriminative ability and focuses on relative risk rather than absolute risk estimation. The WHO/ISH prediction charts are useful as tools to discriminate those at high total CVR and particularly to motivate patients to change their behavior (WHO 2007c). Our study results showed minimal, not statistically significant improvement in CVR scores after providing repeated CVR communication. Previous studies showed mixed effects of CVR information on the predicted CVR, which seemed to be related to the intensity of the intervention provided. Studies that showed repeated presentation of risk with a modicum of education (Grover et al. 2007) and repeated doses of counseling (Wister et al. 2007) also concluded small but statistically significant reductions in the 10-year global coronary heart disease risk. One point in time intervention showed negligible to small effects (Krones et al. 2008).

Further studies implementing continued CVR communication to our patients might induce a significant reduction on their CVR. Lack of significance in our study could be due to the floor effect as indicated by the high proportion (more than 50 %) of patients who had low CVR scores at baseline. This floor effect could be considered a “true floor effect,” i.e., a high proportion of diabetics have low CVR scores, or a “false floor effect,” i.e., inherent underestimation of CVR due to the inability of the chart to factor in family history, history of cardiovascular disease events, and history of any treatment being received to control CVR factors in diabetics (Liew et al. 2011). Whether true or false, the floor effect could be responsible for diluting the influence of our intervention by creating a smaller treatment gap with no options for CVR reduction among these patients. However, despite the lack of statistical significance in our study, the trend toward improved CVR scores can be considered a success at some level. The strong positive correlation between HbA1c% and CVR scores further confirms the credibility of the application of the key element “*behavioral change*” in the TPB (Ajzen 1991) to our patients.

Limitations of the study

This study has some limitations. First, the WHO/ISH CVR prediction charts have not been validated for routine use in clinical practice in the African continent. Second, applying a mid-range score instead of the risk range provided by these charts could not help to demonstrate the expected relative risk reduction for those who were determined to have an open class interval (i.e., CVR scores ≥40). Third, these charts do not factor in either the history of cardiovascular disease events or treatments received to control CVR factors. Fourth, this was a short-term study with only 3 months of follow-up, and we did not measure the impact of our trial after stopping the intervention.

Conclusion and recommendations

In conclusion, our intervention significantly improved risk perception, self-reported DSC activities (except physical activity), and HbA1c% in diabetic patients compared with those who received usual care. The CVR scores showed minimal nonsignificant improvement. Correlation results confirm the credibility of applying the key elements of the hypothesized theories to our patients. Further research is needed to investigate the effectiveness of applying more complex and longer lifestyle interventions on self-reported DSC activities and CVR scores in T2DM patients. The utilization of different CVR prediction models and performance of future follow-up after stopping the intervention would help to confirm the credibility of improvement and would provide proof of the sustainability of the positive impact on health.

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Compliance with ethical standards All procedures were in accordance with the ethical standards of the Research Ethics Committee of Suez Canal University in Ismailia, Egypt (approval number: 2356), and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Conflict of interest The authors declare that they have no conflict of interest.

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