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Chapter 2 - Uncovering the Effects of Patients' Emotional Status on Self-care Activities and Glycemic Control in People with Type 2 Diabetes using Structural Equation Modelling.

Submitted for publication

M van Vugt, Y Roelofsen, M de Wit, HJG Bilo, FJ Snoek. Uncovering the Effects of Patients' Emotional Status on Self-care Activities and Glycemic Control in People with Type 2 Diabetes using Structural Equation Modelling.

Abstract

Objective

The role and impact of diabetes patients' emotional status on self-care activities and glycemic control is still poorly understood. Therefore, we aimed to test a hypothetical model where emotional well-being and diabetes-related distress exert a direct influence on glycemic control as well as an indirect effect via self-care behaviors.

Methods

We used cross-sectional data of 880 Dutch type 2 diabetes patients treated in routine primary care. Structural equation modeling (SEM) was applied for testing the proposed model. Outcome measures were emotional well-being (WHO-5), diabetes-related distress (PAID-5), diabetes self-care activities (SDSCA) and glycemic control (HbA1c).

Results

We found a direct association between diabetes-related distress and worse glycemic control, and between 30 minutes of daily exercise and better glycemic control. We further found a significant indirect effect of emotional well-being on glycemic control, via self-care behaviors, and partial mediation effect by self-care behaviors for the association between diabetes-related distress and glycemic control. Post-hoc analyses revealed a direct association between emotional well-being and glycemic control for women only.

Conclusion

Our findings indicate an explanatory role for diabetes-related distress and emotional well-being in linking patients' self-care with glycemic control, with apparent differential effects for men and women. Longitudinal research in diverse patient samples with suboptimal glycemic control is warranted to further test the proposed model.

Key-words

glycemic control; self-care; diabetes-related distress; emotional well-being; type 2 diabetes.

Introduction

In type 2 diabetes, self-management is the cornerstone of treatment, with the most recognized self-care tasks relating to diet, exercise, and medication adherence.⁴¹ Improvements of these self-care behaviors within people with type 2 diabetes demonstrates subsequent improvements in the most important diabetes outcome measure; glycemic control (lower HbA1c).^{26,27,42-44} The influence of self-care behaviors on medical outcomes is recognized by social cognitive models and theories, which also emphasize the role of cognitions (i.e. attitudes and beliefs) in explaining behavior change.^{26,27,32} For instance, the recently proposed Information-Motivation-Behavioral skills model of diabetes self-care (IMB) predicts medication adherence information, personal motivation, and social support, to have a direct effect on glycemic control, and an indirect effect through self-care behaviors.⁴⁵ However, these models and theories, give little attention to the patients' emotional status and its influence on behavioral and medical outcomes. Like cognitions, patients' emotions, such as depressive mood and diabetes-related distress, are likely to impact self-care behaviors and subsequent glycemic outcomes.⁴⁶⁻⁴⁹

Depressed mood is common among people with type 2 diabetes, characterized by indifference and negative feelings about one's self and the treatment, low self-efficacy beliefs, and is associated with poorer diabetes self-care.^{17,20,21,50,51} Moreover, diabetes-related distress, which is characterized by having concerns about diabetes outcomes, and feeling overwhelmed and defeated by the disease, has also been found to associate with poor glycemic outcomes, although the underlying mechanism is unknown.^{22,52} Low mood, i.e. poor emotional well-being, and diabetes-related distress are inter-related constructs but not interchangeable and therefore both deserve to be included in studies linking patients' emotional status with self-care and glycemic outcomes.^{23,53} The indirect effect of emotional status on glycemic control, via self-care behaviors remain poorly understood. Research into the complex interacting relationships between emotional well-being, diabetes-related distress, diabetes self-care behaviors, and glycemic control, can help to enhance our understanding of the underlying pathways and can inform the development of tailored diabetes self-management education programs for people with type 2 diabetes. Therefore, we hypothesize a model in which low emotional well-being and high diabetes-related distress, both negatively impact diabetes self-care behaviors and subsequent glycemic control. See Figure 1 for the proposed model. Based on research to date, diabetes-related distress is expected to exert a predominantly direct effect on glycemic control, while emotional well-being is expected to have predominantly indirect effect on glycemic control via poorer self-care.^{48,49,54}

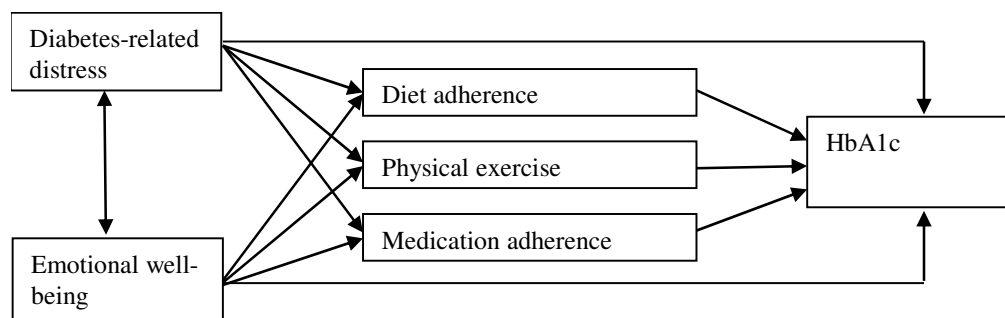


Figure 1. Hypothesized model of the relationship between emotional status, self-care and glycemic control.

Research Design and Methods

To test the proposed model we used cross-sectional data from a large prospective cohort study performed in 43 primary health care practices in the north-eastern region of the Netherlands.⁵⁵ Between January 2012 and December 2013, 3726 type 2 diabetes patients were invited by their treating physician to participate in the study and fill in a questionnaire. Inclusion criteria were: physician diagnosis of type 2 diabetes and treated by a general practitioner, aged ≥ 18 years. Exclusion criteria were: Mental retardation, schizophrenia, organic mental disorder or bipolar disorder currently or in the past, insufficient knowledge of the Dutch language, life expectancy < 1 year due to malignancies or other terminal illnesses, and cognitive impairment including dementia. Eventually, the data of 1179 patients was available for this study. All participants gave informed consent prior to the study. The study was approved by the Medical Ethics Committee of Isala, Zwolle, the Netherlands, and the Medical Ethics Committee of the VU University Medical Center, the Netherlands.

Measurements

Emotional well-being was assessed using the World Health Organization Wellbeing Index 5 items questionnaire (WHO-5) with a 6 point Likert scale (5 'all the time' to 0 'at no time'), which covers positive mood, vitality and general interests over the past 2 weeks. The WHO-5 has good psychometric properties ($\alpha = .93$) and has clinical use as depression screener.^{56,57} The sum score ranges from 0 to 100, where higher scores represent better emotional well-being with scores below 50 indicating depressed mood.

Diabetes-related distress was assessed using the Problem Areas in Diabetes 5 items questionnaire (PAID-5) with a 5 point Likert scale (0 'not a problem' to 4 'serious problem') ($\alpha = .86$). The sum score ranges from 0 to 20, where higher scores represent more distress. A score higher than 8 is regarded indicative of high diabetes distress.⁵⁸

Diabetes self-care activities were measured across 3 domains (average diet adherence, 30 minutes of daily exercise, and medication adherence) derived from the widely-used Summary of Diabetes Self-Care Activities questionnaire (SDSCA). The SDSCA, measures frequency of the mentioned behaviors pertaining to the past week on an 8 point Likert scale (0 '0 days a week' to 7 '7 days a week').^{59,60} The SDSCA allows for measuring of non-coherent domains of self-care activities with moderate internal consistency ($\alpha = .20 - .52$), indicating relative independence of different self-care domains.

Demographic and clinical diabetes-related variables (treatment regimen, glycosylated hemoglobin (HbA1c), and diabetes duration) were extracted from patients' health care records. HbA1c provides an indication of glycemic control that covers the previous 6-8 weeks period and most recent data were used at the time of questionnaire self-administration.

Statistical analysis

Data are presented as mean, standard deviations and percentages (if applicable). Effects are presented as regression coefficients (β), standardized regression coefficients (Beta), and standardized error (SE). For testing the proposed theoretical model, we used structural equation modelling (SEM) using SPSS AMOS 21 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.). SEM analysis allows for testing a hypothetical association model as a whole, rather than testing association paths individually, thereby minimizing risk of

type 1 errors.⁶¹ We used maximum-likelihood estimation for the model's parameters. The SEM analyses were corrected for correlating variables: age, gender, and diabetes duration. Model fit is tested with Chi² ($p \geq 0.05$), the comparative fit index (CFI) ($p \geq .95$), and the root mean square error of approximation (RMSEA) ($p \leq .08$, CI = .00-.08).⁶¹

Prior to the SEM analyses, the data were checked on linearity and normality. The distributions of SDSCA scores on 'average diet adherence', 'medication adherence' and the PAID-5 (diabetes-related distress) were skewed (skewness: -1.864, -5.172, 1.586 respectively), however the maximum likelihood estimation of SEM tends to be robust against skewed distributions.⁶² Single missing items within an outcome variable were treated by mean substitution, and cases with extreme outliers (n=40) were removed from the dataset. Additionally, during the SEM analysis cases were checked on multivariate outliers with the Mahalanobis distance. However, deleting additional cases based on the Mahalanobis distance did not improve the model and the outcomes, and was therefore not continued.

To allow SPSS AMOS to uncover the significance of the indirect and total effects we used bootstrapping methods with 5000 samples. For conducting the bootstrapping analysis, cases with multiple missing variables needed to be deleted from the dataset (n=259).

Results

Baseline characteristics of the used study sample (n = 880) are presented in Table 1. Mean age of the participants was 64.5 (± 10.0) and 43.6% were female. Participants were mainly Caucasian (99%). Over 80% of the patients were prescribed oral blood glucose lowering medication and 14.5% were taking insulin injections. Reported mean medication adherence was high (6.75 on an 8-point scale, with 7 as highest possible answer). Mean HbA1c indicated 29.2% of the participants had suboptimal HbA1c values (defined as HbA1c > 7% or 55 mmol/mol).

Structural Equation Model

The structural relations between emotional well-being and diabetes-related distress and their associations with diabetes self-care behaviors and glycemic control are displayed in Figure 2. The SEM analysis showed the following model fit statistics: Chi²(3) = 11.481 $p = .009$, CFI = 0.977, RMSEA = 0.057 CI [.025-.093]. The statistical results of the direct effects, indirect effects and total effects of the model can be found in Table 2. For the model, we found a statistically significant association between 30 minutes of daily exercise and better glycemic control (Beta = -.068, $p = .042$), and an association between higher diabetes-related distress and worse glycemic control (Beta = .136, $p < .001$). Furthermore we found that emotional well-being was positively associated with 30 minutes of daily exercise (Beta = .113, $p = .002$) and with diet adherence (Beta = .111, $p = .002$). We also found a negative association between diabetes-related distress and 30 minutes of daily exercise (Beta = -.105, $p = .004$). Additionally we found a significant correlation between emotional well-being and diabetes-related distress ($r = -.37$, $p < .001$).

Bootstrapping analyses of the indirect paths showed a significant indirect effect of emotional well-being on glycemic control, via self-care behaviors (Beta = -.011, $p = .025$). With the bootstrapping analyses we also found a partial mediation effect by self-care behaviors for the association between diabetes-related distress and glycemic control (Beta = .008, $p = .043$). No other significant associations were found.

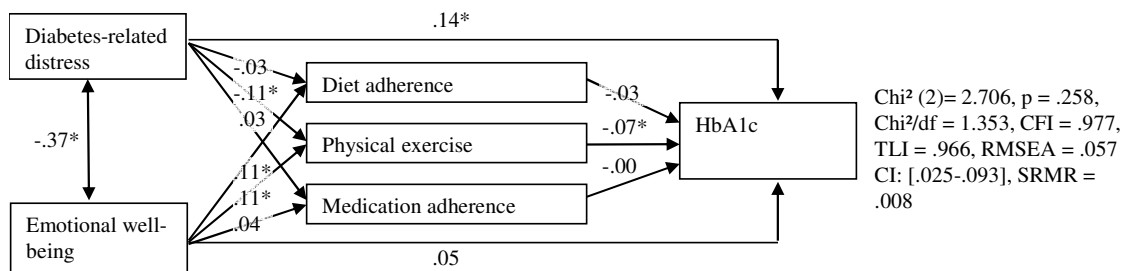


Figure 2. Standardized effects of emotional well-being and diabetes-related distress, on diabetes self-care behaviors and glycemic control ($*p < 0.05\%$).

Post hoc analyses

The data showed that women reported significantly lower emotional well-being ($M = 74.3$ versus $M = 68.9, p < 0.001$) and higher diabetes-related distress compared to men ($M = 2.13$ versus $M = 2.53, p = 0.034$). Additionally, literature shows that women are more susceptible to low mood and high distress.⁶³ Therefore, post-hoc analyses were performed, testing the model with the SEM procedure separately for men and for women (again corrected for age and diabetes duration). A visual representation of the standardized effects of the post-hoc analyses for men and women is shown in Figure 3 a and b. The statistical results of the direct effects, indirect effects and total effects of the model for men and women separately can be found in Table 2. The fit statistics of the post-hoc subgroup analyses for both men and women was $\chi^2(6) = 13.193, p = 0.040, CFI = 0.980, RMSEA = 0.037, CI [.007-.064]$. The association between emotional well-being and diabetes-related distress was stronger in men ($r = -.41, p < .001$), compared to the main model and the model for women ($r = -.33, p < .001$). The results for the men-only model showed a statistically significant positive association between diabetes-related distress and worse glycemic control (Beta = $.115, p = .018$). In addition we found that emotional well-being (Beta = $.124, p = .011$) and diabetes-related distress (Beta = $-.131, p = .007$) were both significantly associated with 30 minutes of daily exercise. No other associations were found for men only. The results for the women-only model showed statistically significant associations between higher diabetes-distress and worse glycemic control (Beta = $.151, p = .004$), and an association between higher emotional well-being and worse glycemic control (Beta = $.122, p = .024$). Furthermore we found that higher emotional well-being was positively associated with average diet adherence (Beta = $.172, p = .001$). No other associations were found for the post-hoc analyses.

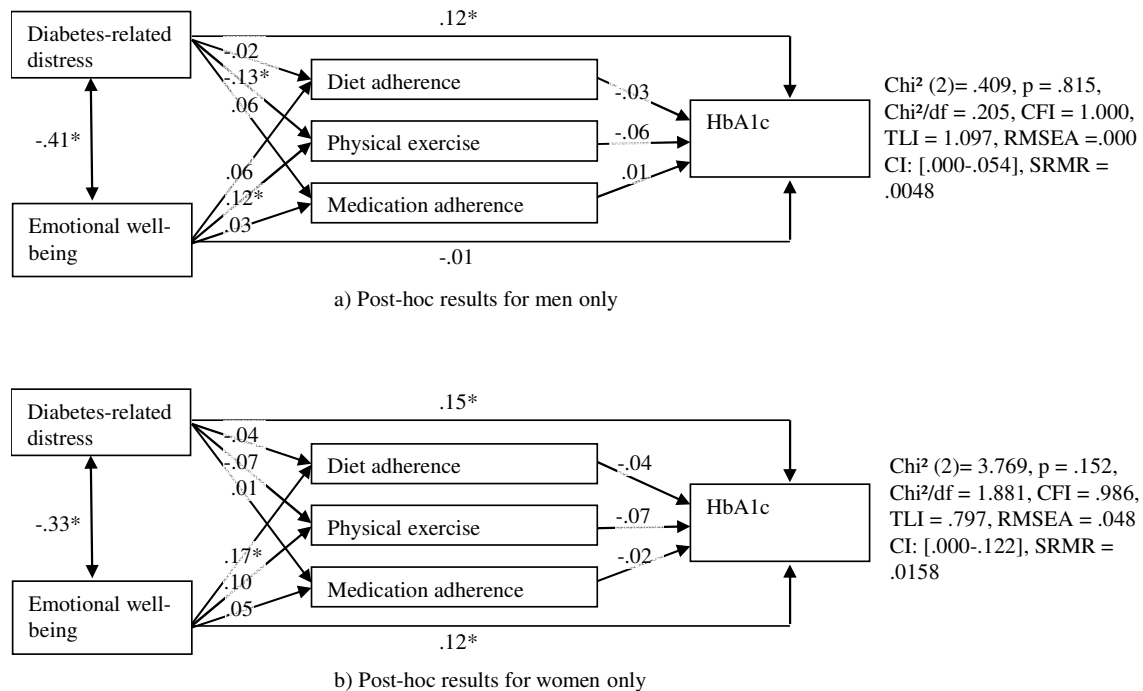


Figure 3. Post-hoc analysis for men and woman of the standardized effects of emotional well-being and diabetes-related distress, on diabetes self-care behaviors and glycemic control (* $p < 0.05\%$).

Conclusions

Discussion

To the best of our knowledge, we are among the first to test the effects of emotional status on self-care behaviors and glycemic control in one model, using SEM. By doing so we derive at a better understanding of how these constructs interact with each other. Outcomes of the SEM analyses showed that the proposed explanatory model fits the data, making it an acceptable model from a statistical perspective. Results indicate that emotional well-being and diabetes-related distress both play a role in influencing self-care behaviors and subsequent glycemic control. Higher diabetes-related distress associates with higher HbA1c levels, which is in concert with previous studies.^{48,49} In the current study this relationship is partly mediated by 30 minutes of daily exercise, while showing a direct relationship as well. The direct effect of diabetes-related distress on HbA1c could be due to a stress response, where a prolonged release of glucocortisol results in hyperglycemia and thus higher HbA1c values.⁶⁴ In addition to the direct physiological effects of stress, higher diabetes-related distress may hamper adequate and sufficient execution of daily self-care behaviors, particularly physical activity, resulting in increased insulin resistance and thereby worsening of glycemic control. This would underline the importance of addressing diabetes-related distress in the treatment of people with type 2 diabetes.

The relationship between emotional well-being and glycemic control appears more complex. In the model, a direct effect of emotional well-being was absent, but an indirect lowering effect on HbA1c via self-care was present. The data confirm our expectation that emotional well-being has a more prominent indirect effect on diabetes outcomes via self-care than diabetes-related distress. ‘Thirty minutes of daily exercise’ was positively associated with emotional well-being, and negatively associated with diabetes-related distress. Due to the cross-sectional nature of the

data we cannot infer causal relationships, but the interpretation that poorer emotional functioning has a negative effect on daily exercise (and vice versa), is highly plausible and in line with well-being literature.⁶⁵ Our data underscore the importance of taking patient's emotional status into account when aiming to improve their physical activity level. Of the three diabetes self-care activities that were included in the model, only frequency of daily exercise behavior was found to be associated with glycemic control. The lack of association between diet adherence and glycemic control in this study could be due to the fact that the majority of subjects were effectively treated with oral medication and showed satisfactory glycemic control. This is further indicated in this study, by the SDSCA item 'medication adherence' which showed a ceiling effect and very little variance, with the vast majority of people reporting to be highly consistent with the recommended frequency of medication taking (7 days a week), which may also have contributed by the lack of association between medication adherence and glycemic control.

In our sample, women reported significantly lower emotional well-being and higher diabetes-related distress compared to men, which seems in line with known literature.⁶⁶ This could indicate that women might also be more impacted by the influence of emotional status on glycemic control than men. Surprisingly, the post-hoc analyses showed a significant direct effect of emotional well-being on glycemic control for women, with *better* emotional well-being being associated with higher HbA1c values. This is in contrast with the literature that shows that depressive symptoms are associated with worse glycemic control^{67,68}, especially in woman with type 2 diabetes.⁶³ Post-hoc analyses also showed that the effect was reversely mediated by diabetes-related distress, where the association between emotional well-being and glycaemia control disappeared when diabetes-related distress was removed from the model. This could indicate that for women, having some concerns about diabetes may actually positively influence emotional well-being, but in itself has a negative influence on glycaemia control. Furthermore, the post-hoc analyses showed that for men, higher diabetes-related distress associated with a lower frequency of 30 minutes of daily exercise, where in women we did not find this association. For women, however, higher emotional well-being was associated with better diet behavior, which was not seen for men. This could indicate that diabetes-related distress might be more influential for men, and emotional well-being more influential for women with regard to diabetes control. Interestingly, we also found a lower correlation between diabetes-related distress and emotional well-being for women compared to men. This finding is difficult to explain and may hint at gender differences in experiencing low mood and distress.⁶⁹ These post-hoc results are indicative of different interactions between gender, emotional functioning and diabetes outcomes, which deserve further study.

Limitations

This study used data from a cross-sectional study, therefore we cannot infer causal relationship. However, the dataset suffices to be used for association analyses.⁷⁰ As to the external validity, we should acknowledge the fact that we included mainly Caucasian patients and a majority (70.8%) showed good glycemic control. Testing the model in more diverse populations is therefore recommended. Self-care behavior was measured by self-report and therefore should be interpreted with caution.⁷¹ The use of unobtrusive, objective measures of adherence (e.g. pill counts, use of pedometers) should help to verify the level of daily diabetes self-management. Finally,

it is known that the chi-squared is highly influenced by large sample sizes and can therefore lose its usability as fit-statistic.^{61,72} However, the other fit-statistics showed satisfactory results.⁶¹

Conclusion

Based on our findings, we can propose an explanatory model as a first step towards developing a validated psychological framework that considers the interactions between patients' emotional status, their diabetes self-care activities, and glycemic control. Considering and testing these constructs in one model rather than considering and testing them separately, can help us to better understand the complex interaction and mediating effects. From a clinical point of view, our findings corroborate the notion that addressing patients' emotional problems in diabetes care, is not only important to improve mental health but may also contribute to achieving satisfactory glycemic control. In this context, differences between men and women warrant further study. The proposed model could additionally be expanded with elements from the IMB model such as information, motivation, and social support, adding further to the explanatory power of the model.

Chapter 2 – Structural Equation Modelling

Table 1.
Baseline characteristics.

	Total Sample (n=880)		Men (n=496)		Women (n=384)		p
	M or n	% or SD	M or n	% or SD	M or n	% or SD	
Gender							
Female	384	43.6%					
Male	496	56.4%					
Ethnicity ¹							.329
Caucasian	730	99.0%	418	84.3%	312	81.3%	
Non- Caucasian	8	1.0%	4	.8%	4	1.0%	
Age group (years)	64.46	±10.0	64.64	±9.32	63.37	±10.52	.382
<40	8	.9%	3	.6%	5	1.3%	
40-49	65	7.4%	32	6.5%	33	8.6%	
50-59	192	21.8%	101	20.4%	91	23.7%	
60-69	361	41.0%	214	43.1%	147	38.3%	
70-79	204	23.2%	119	24.0%	85	22.1%	
80>	50	5.7%	27	5.4%	23	6.0%	
Education ²							<.001*
No education	8	.9%	4	.8%	4	1.0%	
School level qualifications	490	55.7%	242	48.8%	248	64.6%	
Professional or vocational	237	26.9%	145	29.2%	92	24.0%	
Bachelor's degree or higher	140	15.9%	101	20.4%	39	10.2%	
Employed ³	253	28.8%	155	31.3%	98	25.5%	<.001*
Diabetes treatment ⁴							
Insulin	128	14.5%	67	13.5%	61	15.9%	.335
Tablets	759	87.0%	430	86.7%	329	85.7%	.761
Combination Insulin and Tablets	114	12.9%	59	11.9%	55	14.3%	.311
Diabetes related outcomes							
Diabetes duration in years	6.95	±5.39	6.84	±5.40	7.09	5.38	.502
Retinopathy	40	4.5%	23	4.6%	17	4.4%	
Nephropathy	2	0.2%	2	.4%	69	18.0%	
Cardiovascular	119	15.9%	95	19.2%	24	6.3%	
Neuropathy	198	22.5%	119	24.0%	79	20.6%	
Medical outcome measures							
HbA1c [%]	6.73	±.77	6.72	±.78	6.74	±.76	
HbA1c [mmol/mol]	50.11	±8.46	50.03	±8.57	50.21	±8.33	.751
HbA1c > 7% or 55 mmol/mol	257	29.2%	144	29.0%	113	29.4%	.469
Systolic blood pressure [mm Hg]	136.07	±15.32	136.63	±15.26	135.35	±15.39	.220
Diastolic blood pressure [mm Hg]	77.39	±9.02	77.66	±9.38	77.05	±8.52	.325
Cholesterol [mmol/L]	4.38	±0.94	4.25	±.91	4.55	±.95	<.001*
Emotional well-being	71.9	±16.5	74.3	±14.6	68.9	±18.2	<.001*
Depressive mood (WHO-5 < 50)	93	10.6%	38	7.7%	55	14.3%	
Diabetes distress	2.30	±2.83	2.13	±2.67	2.53	±3.01	<.034*
Elevated distress (PAID-5 > 8)	31	3.5%	14	2.8%	17	4.4%	
Diabetes self-care behaviors							
average diet adherence	5.64	±1.76	5.52	±1.87	5.79	±1.59	.025*
30 min of daily exercise	4.92	±2.09	4.99	±2.11	4.84	±2.05	.300
Medication adherence	6.75	±1.04	6.77	±1.04	6.72	±1.04	.509

Note. ¹n=142 missing information; ²n=5 missing information; ³n=2 missing information; ⁴n=8 missing information; M mean; SD standard deviation; p probability value; WHO-5 World Health Organization Wellbeing Index 5 items questionnaire; PAID-5 Problem Areas in Diabetes 5 items questionnaire.

Table 2.
Results of the structural equation modelling analyses and post-hoc analyses for both men and women.

	Main model				Post-hoc analysis for Men				Post-hoc analysis for Women				
	β	Beta	SE	p	β	Beta	SE	p	β	Beta	SE	p	
Direct effect													
Emotional Well-being	.012	.111	.004	.002 *	.008	.062	.006	.203	.015	.172	.005	.001 *	
Emotional Well-being	.014	.113	.005	.002 *	.018	.124	.007	.011 *	.011	.102	.006	.056	
Emotional Well-being	.003	.040	.002	.275	.002	.026	.004	.596	.003	.053	.003	.714	
Emotional Well-being	.027	.053	.018	.143	-.007	-.012	.028	.798	.056	.122	.024	.021 *	
Diabetes-related Distress	→ Diet adherence	-.018	-.030	.022	.411	-.015	-.021	.034	.666	-.023	-.043	.028	.416
Diabetes-related Distress	→ 30 minutes of daily exercise	-.078	-.105	.027	.004 *	-.104	-.131	.038	.007 *	-.048	-.069	.037	.198
Diabetes-related Distress	→ Medication adherence	.009	.026	.014	.485	.023	.059	.019	.240	-.005	-.014	.019	.793
Diabetes-related Distress	→ Glycemic control (HbA1c)	.405	.136	.107	<.001 *	.367	.115	.155	.018 *	.417	.151	.146	.004 *
Diet adherence	→ Glycemic control (HbA1c)	-.163	-.034	.161	.311	-.141	-.031	.201	.483	-.220	-.042	.264	.404
30 minutes of daily exercise	→ Glycemic control (HbA1c)	-.273	-.067	.135	.043 *	-.241	-.059	.181	.183	-.284	-.070	.202	.159
Medication adherence	→ Glycemic control (HbA1c)	-.011	-.001	.264	.968	.071	.009	.355	.842	-.144	-.018	.393	.714
Indirect effect													
Emotional Well-being	→ Glycemic control (HbA1c)	-.006	-.011	.003	.025 *	-.005	-.009	.004	.121	-.007	-.015	.005	.125
Diabetes-related Distress	→ Glycemic control (HbA1c)	.024	.008	.015	.043 *	.029	.009	.025	.145	.019	.007	.024	.259
Total effect													
Emotional Well-being	→ Glycemic control (HbA1c)	.021	.041	.019	.253	-.013	-.021	.028	.633	.049	.107	.025	.035 *
Diabetes-related Distress	→ Glycemic control (HbA1c)	.429	.144	.105	<.001 *	.395	.123	.154	.005 *	.437	.158	.144	.002 *

Note. *p < 0.05%; HbA1c Blood glucose levels; β regression coefficient; Beta standardized regression coefficient; SE standard error; p probability value.

