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Differences, predictors, and moderators of therapeutic adherence in patients recently diagnosed with type 2 diabetes

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Abstract

This study analyzed the differences over time in newly diagnosed type 2 diabetes patients on reported adherence. A longitudinal design with two assessment moments was used with 268 patients who were assessed on adherence to self-care behaviors and medication, beliefs about medicines, psychological distress, trust in the physician, and satisfaction with care. HbA1c and general beliefs about medicines decreased from T1 to T2 while adherence to foot care, the needs of medicines, and psychological distress increased. Beliefs about medicines, satisfaction with communication/information, and trust in physician predicted adherence. Intervention should consider these variables when promoting adherence.

Keywords

adherence, longitudinal study, Portugal, self-care behaviors, type 2 diabetes

Introduction

Nowadays, diabetes mellitus (DM) affects 422 million people worldwide (World Health Organization (WHO), 2016). In Portugal, the Annual Report of the Diabetes' National Observatory (Portuguese Society of Diabetology (PSD), 2016) revealed that, in 2015, 13.3 percent of the population had DM and 27.4 percent pre-diabetes. Type 2 diabetes mellitus (T2DM) is the most common type of diabetes worldwide, comprising the majority of the cases (WHO, 2016).

Adherence to T2DM treatment is complex, since patients have to plan and integrate, in their routine, several self-care behaviors, such as taking medication, adopt a healthy eating plan, practice moderate exercise, monitor blood glucose level, and adopt specific foot care (Delamater, 2006). In fact, non-adherence is a problem in T2DM (Ciechanowski et al., 2000; DeBerardis et al., 2005; Delamater, 2006; Geulayov et al., 2010; Lin et al., 2004) resulting in poor glycemic control and in short- and long-term complications that dimensions impact multiple organ systems (American Diabetes Association (ADA), 2017). Indeed, WHO

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(2016) highlights DM as the primary cause of blindness, kidney failure, and amputation.

Individual and family self-management theory

The individual and family self-management theory (IFSMT) (Ryan and Sawin, 2009) provides a theoretical framework to understand the factors that influence adherence to self-care behaviors. According to this theory, self-management comprises three dimensions—context, process, and outcomes. The context dimension includes factors regarding the specific condition, the physical and social environment, and the individual and family characteristics. The process dimension includes knowledge and beliefs, self-regulation skills and abilities, and social facilitation. Both context and process dimensions impact the outcomes that include proximal outcomes comprising the actual engagement in self-care behaviors and health care use; or distal outcomes, such as health status, quality of life, and health costs.

Contextual variables: individual characteristics

Depression and anxiety (psychological distress) affect adherence to self-care behaviors in DM. Indeed, psychological distress has been associated with decreased health and quality of life over time (Khuwaja et al., 2010), poor glycemic control (Li et al., 2008), hyperglycemia, decreased adherence to oral medications (Ciechanowski et al., 2000; Kalsekar et al., 2006; Lin et al., 2004) and to diet (Pandit et al., 2014), and an increase in the number of DM complications (Lloyd et al., 2000; Papelbaum et al., 2011).

Contextual variables: physical and social environment

Several studies have shown a relationship between trust in the physician and adherence to medication in DM (Parchman et al., 2010; Pereira et al., 2013a). Furthermore, patients with DM who present higher trust in their physician show better mental and physical health, engage in healthy behaviors, and show lower HbA1c levels (Alazri and Neal, 2003; Egede and Michel, 2006; Parchman et al., 2010). Also, patients' satisfaction with health care has been associated with better adherence to self-care behaviors in DM (Alazri and Neal, 2003; Doubova et al., 2009). Patients who received DM education report more satisfaction with health care delivery (Doubova et al., 2009).

Process variables: knowledge and beliefs

Beliefs about medicines are considered an important factor in therapeutic adherence (Horne, 1997; Horne and Weinman, 1999). Adherence to medication has been associated with stronger beliefs about the need of medicines and weaker beliefs about concerns with medicines and its harmful effects in general, in T2DM patients (Polonsky and Henry, 2016; Sweileh et al., 2014). In addition to patients' self-report adherence, glycemic control, which is assessed by HbA1c level, is associated with self-monitoring of glucose (Schütt et al., 2006), as well as better adherence to diet (Savoca et al., 2004).

Outcome variables: proximal outcome

In this study, adherence to T2DM self-care behaviors will be considered the proximal outcome. Knowing which variables predict adherence to self-care behaviors and medication would allow to develop data-driven models to help understand the phenomena. Also, the knowledge of these variables may help to understand and adjust the health education interventions, earlier on, to decrease non-adherence, in T2DM, helping to prevent later DM micro- and macrovascular complications.

This study

This study analyzed the differences between T1 (diagnosed no longer than a year prior to the assessment) and the following patient's routine

appointment (4 months after the educational session) regarding adherence to self-care behaviors and medication, taking into account psychological variables related to the patient and the health care system, as well as to analyze the predictors and moderators of adherence. It was expected that (H1) general beliefs about harmful effects of medication would decrease over time; adherence to self-care behaviors, beliefs about needs of medicines, as well as the concerns about the side effects and dependence of medicines, psychological distress, trust in physician, and satisfaction with health care services would increase over time; (H2) lower psychological distress; stronger beliefs about the needs of medicines, and weaker concerns with the prescribed medicines, and beliefs about the medicines in general; higher trust in physician; and greater satisfaction with health care services, at T1, would predict adherence to self-care behaviors and medication at T2.

Methods

Participants

This study comprised 387 patients recently diagnosed with T2DM. The inclusion criteria were as follows: being diagnosed with T2DM no longer than a year prior to the assessment, taking only oral medications for T2DM, and being 18 or more years old. Data were collected in 40 health care units in the northern region of Portugal.

Procedure

The study was approved by the Ethics Committee of North Regional Health Association, in Portugal. Health professionals (physicians and nurses) from 40 health units in the North of Portugal identified patients who met the inclusion criteria and the family physician invited patients to participate in the study. All participants were knowledgeable of the purpose of the study, agreed to participate, and signed an informed consent. Participation was voluntary. Patients answered the questionnaires individually in a room provided by the health care unit for that purpose, in the presence of one of the researchers. Data were collected between 2010 and 2013.

The design used was longitudinal, assessing patients in a first moment (T1: after T2DM diagnosis) and 4 months later (T2), since the purpose was to assess adherence early on. In order to control for education regarding DM, two groups of patients were taken into consideration according to inclusion criteria: those diagnosed in the previous 5 months (received 1/2 education consultations) and those diagnosed between 6 and 12 months (received 3/4 education consultations). The educational consultations are part of the clinical standard protocol for diabetes patients in primary health care with no psychological intervention. The consultations include information about healthy diet, physical activity, foot care behaviors, glucose monitoring, and oral medication. Besides the information, patients are helped to identify and overcome barriers to adherence to these self-care behaviors. In these sessions, health professionals also assess blood pressure, weight, and patient's feet. Laboratory analysis and adherence to medication (dose frequency, other medicines intake) are also checked. T2 included, for all patients, one more educational consultation after the first assessment.

Instruments

Revised Summary of Diabetes Self-Care Activities Measure (RSDSCA). This scale has 11 items and assesses levels of self-care and management of the different components of the DM regimen, namely, diet, physical activity, monitoring of blood glucose, foot care, and smoking. Higher scores indicate better adherence to self-care behaviors (Pereira et al., 2008).

Medication Adherence Report Scale (MARS). The adapted version for the Portuguese population consists of five items, assessing adherence to oral medication, including the frequency with which individuals omit or change the medication dose prescribed by their physician. Highest scores indicate higher levels of adherence (Pereira et al., 2012).

Patient Satisfaction Questionnaire (PSQ). The questionnaire assesses patient satisfaction with health care services. In this study, only the 26 items of the subscales communication/information and interpersonal relationships were administered, since the other dimensions were of no interest regarding the study aims (McIntyre et al., 1999b). High scores indicate higher satisfaction in the respective dimension.

Trust in Physician Scale (TPS). The adapted version of Trust in Physician Scale for Portuguese population consists of 11 items that assess the degree of trust in the patient's regular physician. Higher results indicate stronger trust in the physician (Pereira et al., 2013a).

Beliefs about Medicines Questionnaire (BMQ). Beliefs about Medicines Questionnaire assesses the cognitive representations individuals have in relation to medicines, namely, general beliefs regarding the harmful and addictive effects of medication as well as their over prescription by physicians; and specific needs and specific concerns regarding the medication prescribed by the physician (Pereira et al., 2013b). Higher scores indicate stronger beliefs regarding the negative effects of medicines, in the respective dimension.

Hospital Anxiety and Depression Scale (HADS). Evaluate depression and anxiety in a 14-item scale, with 7 items for each subscale. The total scale assesses psychological distress. Higher scores indicate higher levels of psychological distress or anxiety and depression when the subscales are used separately (McIntyre et al., 1999a).

Data analysis

Data analysis was performed in two phases. In the first phase, a mixed model to compare repeated measures was used and in the second phase, a path analysis to predict adherence was performed. The mixed models provide a flexible approach to correlate data over time, allowing a variety of pattern correlation (or variance-covariance structures) explicitly modeled. Univariate models were used for each variable under consideration, controlling for gender and time of diagnosis, when differences were found.

To find the predictors of adherence, a multivariate linear regression model for patients was performed for the adherence variables at Time 2 (dependent variables) and psychological variables at Time 1 (independent variables). In the initial model, dependent variables were patient's adherence to medication (MARS), diet, physical activity, glucose monitoring, and foot care (four subscales of RSDSCA). The independent variables were beliefs regarding medicines (BMQ: general beliefs, needs, and concerns), trust in the physician (TPS), psychological distress (HADS), and patient satisfaction (PSQ: communication/information and interpersonal relationships). Adequate fit was defined as chi-square p-value over .05, goodness-of-fit index (GFI) over .95, root mean square error approximation (RMSEA) below .07, and standardized root mean square residual (SRMR) below .08 (Hooper et al., 2008).

Then, a multiple-group analysis was used to test differences in time since diagnosis (below 6 months and between 6 and 12 months). The following steps were conducted: first, unconstrained multiple-group model across time of diagnosis, in which the same pattern of structural paths was tested without constraints across groups; second, constrained multiple-group model, where structural paths were constrained to be equal across groups. The comparison between the two nested models was tested by the significance of the difference in the chi-square value.

The use of the square Mahalanobis distance and the verification of normality of the variables through the asymmetry coefficients and kurtosis univariate and multivariate allowed the elimination of the cases that generated the violation of assumptions. In the final sample, no variable showed values of asymmetry and kurtosis indicators of violation of the normal distribution, and there were no Mahalanobis distance indicators of the existence of outliers and also

there were no strong correlations between the exogenous variables, indicators of multicollinearity. Standardized beta coefficients (β) were derived for each explanatory variable in order to allow comparing and estimating the relative importance of each measure.

All standard statistical analyses were done using the IBM SPSS Statistics 22 while path analyses were done in IBM SPSS Amos 22.

Results

Sample characterization

At T1, 387 patients participated in the study. The final sample that participated, both at T1 and T2, included 268 patients recently diagnosed with T2DM. Differences were found between dropouts and participants regarding only trust in physician and beliefs about concerns with prescribed medicines, i.e., participants showed higher levels of trust in physician and stronger concerns with the prescribed medicines than dropouts. No differences in the other clinical and psychological characteristics were found between participants and dropouts.

Of the total sample, 48.1 percent had T2DM no longer than 6 months and the remaining between 6 and 12 months. Patients showed a mean age of 59.1 years (standard deviation (SD) = 10.2) and 57.1 percent of the patients were male. Regarding education, 4.9 percent had no education, 67.5 percent had only 4 years of education, and the remaining had at least 6 years. The majority of the sample was married/cohabitant (99.3%) and the mean duration of the marriage was 32 years (SD = 12.8). Since the inclusion criteria required being in the first year of diagnosis, in the first assessment (T1), the average metabolic control for the entire sample was 7.00 percent, ranging between 4.60 and 14.60 percent and, at T2, was 6.73, ranging between 4.50 and 13.60.

Preliminary analyses

Regarding internal consistency, the alpha for the RSDSCA diet subscale was .68 (the scale includes four items); for physical activity .69 (the scale includes two items); for monitoring of blood glucose .98; and for foot care .76. Cronbach's alpha for the MARS scale was .74; for total TPS .82; for satisfaction with communication/information .87; and for interpersonal relationships .91. The adapted version of BMQ, for the Portuguese population, yielded only three scales and, in this sample, Cronbach's alpha was .76 for the general beliefs; .69 for concerns (the scale includes 5 items); and .77 for needs (Pereira et al., 2013b). Finally, Cronbach's alpha for the anxiety scale was .78 and for the depression scale was .77, although only the total scale (psychological distress) was used, with a Cronbach's alpha of .85.

Table 1 shows the associations between the variables at T1 and adherence at T2.

Differences between T1 and T2

The results of the mixed models between the two moments revealed that HbA1c value ($t = -3.88$, $p < .001$) and general beliefs about medicines ($t = -3.58$, $p < .001$) decreased from T1 to T2. Adherence to foot care ($t = 3.63$, $p < .001$), beliefs about the need to take the prescribed medication ($t = 4.98$, $p < 0.001$), and psychological distress ($t = 2.95$, $p < .003$) increased from T1 to T2. When gender and duration of diagnosis were controlled, the estimates did not range significantly, but differences according to duration of diagnosis on foot care adherence were found, indicating that patients with less duration of disease, that is, up to 6 months of diagnosis reported higher adherence (estimate = 1.427; standard error (SE) = .630; $p < .05$). Differences according to gender on psychological distress were also found and distress was higher in men (estimate = −2.594; $SE = .897$; $p < .01$).

Predictors and moderators of adherence at T2

The multivariate linear regression model showed a good global adjustment: $\chi^2(24) = 44.43$, $p = .007$; RMSEA = .057; GFI = .964; SRMR = .058. The regression coefficients between trust in the physician and medication adherence ($\beta = .21$, $p < .001$) and

Table 1. Pearson's correlation coefficients between variables at study.

	1	2	3	4	5	6	7	8	9	10	11	12	13
1. RSDSCA_diet (T2)	–												
2. RSDSCA_physical activity (T2)	.246***	–											
3. RSDSCA_glucose monitoring (T2)	.132*	−.008	–										
4. RSDSCA_foot care (T2)	.133*	.205***	.068	–									
5. MARS_medication (T2)	.179**	−.011	−.018	.067	–								
6. HbA1c (T1)	−.081	−.039	.195***	−.115	−.005	–							
7. BMQ_general beliefs (T1)	−.111	−.106	.099	.139*	−.075	.062	–						
8. BMQ_needs (T1)	.080	.110	.115	.147*	.077	.036	.015	–					
9. BMQ_concerns (T1)	−.038	.044	.051	.055	−.017	.064	.464***	.046	–				
10. TPS_trust in physician (T1)	.119	.043	−.061	.106	.214***	.067	−.173**	.372***	−.175**	–			
11. PSQ_communication/information (T1)	.044	−.018	.248***	.082	−.016	−.001	−.148*	.108	−.192**	.194**	–		
12. PSQ_interpersonal relationships (T1)	.083	.004	.222***	.038	.066	−.039	−.189**	.156*	−.235***	.249***	.776***	–	
13. HADS_psychological distress (T1)	−.010	.080	.041	−.071	−.075	−.074	.099	.241***	.253***	−.010	−.097	−.074	–

HbA1c: metabolic control; RSDSCA: Revised Summary of Diabetes Self-Care Activities Measure; MARS: Medication Adherence Report Scale; BMQ: Beliefs about Medicines Questionnaire; TPS: Trust in Physician Scale; PSQ: Patient Satisfaction Questionnaire; HADS: Hospital Anxiety and Depression Scale.
*$p < .05$; **$p < .01$; ***$p < .001$.

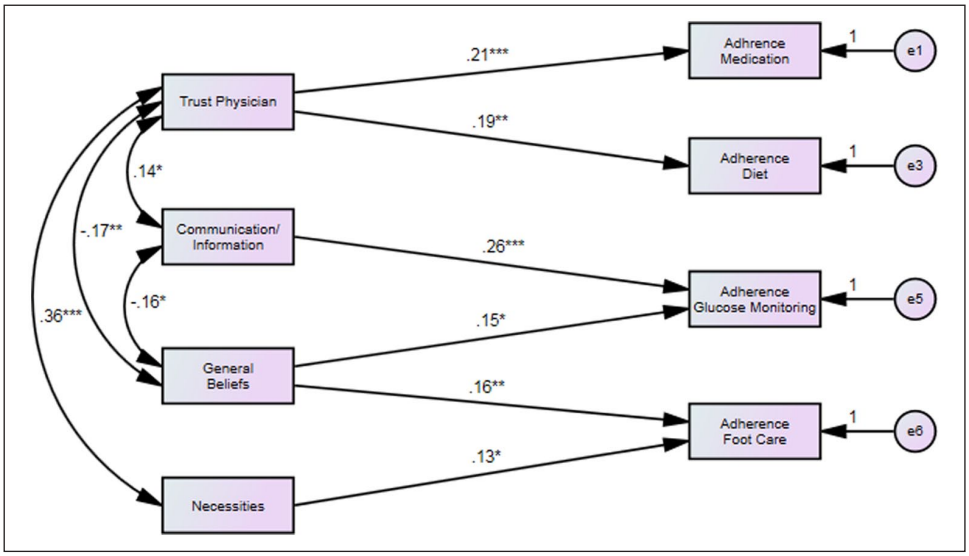

Figure 1. Multivariate linear regression for patients (with standardized estimates).
***$p < .001$; **$p < .01$; *$p < .05$.
$\chi^2_{(24)} = 44.434$; $p = .007$; RMSEA = .057; P[RMSEA ⩽ 0.05] = .304; SRMR = .058; GFI = .964.

adherence to diet ($\beta = .19$, $p < .01$) were statistically significant, which means that higher levels of trust in the physician at T1 predicted higher levels of medication adherence and adherence to diet at T2. Also in this model, the regression coefficients between general beliefs about medicines and glucose monitoring ($\beta = .15$, $p < .05$) and adherence to foot care ($\beta = .16$, $p < .01$) were statistically significant, which means that stronger general beliefs about medicines at T1 predicted higher levels of glucose monitoring and adherence to foot care at T2. Also, the regression coefficients between satisfaction with care regarding communication/information and glucose monitoring ($\beta = .26$, $p < .001$) and with beliefs about the need to take the prescribed medication and adherence to foot care ($\beta = .13$, $p < .05$) were statistically significant, which means that higher levels of satisfaction with care regarding communication/information at T1 predicted higher levels of glucose monitoring at T2 and stronger beliefs about the need to take the prescribed medication at T1 predicted higher levels of adherence to foot care at T2. However, the path between needs and foot care was present for patients diagnosed between 6 and 12 months and not for those diagnosed between 1 and 5 months.

Finally, not all exogenous variables showed significant correlations between them: patients with higher levels of trust in the physician showed higher satisfaction with care regarding communication/information ($R = .14$; $p < .05$), stronger beliefs about the need to take the prescribed medication ($R = .36$; $p < .001$) and weaker general beliefs about medicines ($R = -.17$; $p < .01$) and patients with higher levels of satisfaction with care regarding communication/information ($R = -.16$; $p < .05$) showed weaker general beliefs ($R = -.16$; $p < .05$; Figure 1).

In the multiple-group analysis, the chi-square difference between the unconstrained and full constrained model was significant, $\Delta\chi^2(6) = 26.17$, $p = .012$, suggesting that one or more structural path is different across time since diagnosis. Looking at the loadings with the largest unstandardized difference, the beta from the variable adherence to foot care was released. The chi-square difference between the unconstrained and the partial constrained model was not significant, $\Delta\chi^2(7) = 10.69$, $p = .153$. So,

duration of diagnosis only moderated the relationship between the needs of medication and adherence to foot care, and the effect was observed in patients with longer duration of diagnosis, that is, patients diagnosed between 6 and 12 months.

Discussion

According to the results, glycemic control (HbA1c) decreased from T1 to T2 and was associated with adherence to self-monitoring of blood glucose, at T2. Foot care adherence and psychological distress increased from T1 to T2, as well as beliefs about the need to take the prescribed medication. In turn, general beliefs about the harmful and addictive effects of medication and over prescription decreased from T1 to T2. Regarding the predictors of adherence, results showed that adherence to medication and to diet were predicted by higher levels of trust in the physician, at T1. Adherence to glucose monitoring, at T2, was predicted by higher satisfaction with communication/information and stronger general beliefs about medicines, at T1. Foot care adherence was predicted by stronger general beliefs about medicines and the need to take the prescribed medication, also at T1.

Glycemic control (HbA1c) decreased from T1 to T2 and was associated with adherence to self-monitoring of blood glucose. This result makes intuitive sense and is in accordance with the literature (Barnett et al., 2008; Schütt et al., 2006). Foot care adherence increased from T1 to T2, although the literature suggests that this is one of the more neglected self-care behaviors of T2DM patients (Chiwanga and Njelekela, 2015; DeBerardis et al., 2005). Since diabetic foot ulcers (DFU) are the major cause of amputation (International Working Group on the Diabetic Foot, 2015), this is an important result. Interestingly, patients who perform foot care behaviors, at T2, were those with a shorter duration of diagnosis, emphasizing risk awareness and the efficacy of the educational consultations.

Results showed that general beliefs about the harmful and addictive effects of medication and over prescription decreased from T1 to T2, which is an important result, because literature suggests that these beliefs are a barrier to adherence (Pereira et al., 2013b; Sweileh et al., 2014). Beliefs about the need to take the prescribed medication increased from T1 to T2, as expected, since they facilitate medication adherence (Pereira et al., 2013b).

Finally, psychological distress increased from T1 to T2, which would be expected, since studies report that psychological distress is a usual patient's reaction to T2DM's diagnosis (Lin et al., 2004; Lloyd et al., 2000). In fact, this is an interesting finding, since as psychological distress increased so did glycemic control and adherence, probably because psychological distress may become adaptive, motivating patients to control their sugar levels, in this initial phase of the disease. Future studies need to pursue this hypothesis. However, an unexpected finding was the increase in psychological distress in men. Depression is more prevalent in women than in men (Khuwaja et al., 2010; Roupa et al., 2009) because men tend to adapt more easily to DM, with less depression and anxiety (Mosaku et al., 2008). Therefore, future studies should clarify this issue in different samples.

Regarding the predictors of adherence at T2, results highlight the influence of trust in physician, satisfaction with communication/information in health care, and beliefs about the need of medicines as well as general beliefs about medicines at T1, to the adherence to prescribed medication, diet, foot care, and glucose monitoring, at T2. In other studies, trust in physician has been shown to predict adherence to self-care behaviors (Pereira et al., 2013a) and, in this study, was significant toward adherence to diet and medication. In turn, higher satisfaction with communication/information received by health professionals and stronger general beliefs about medicines, at T1, predicted adherence to glucose monitoring, at T2. If patients are satisfied with the communication and information received by health professionals, it would be expected that they would feel well informed about the DM treatment in general, and the importance of glucose monitoring, in particular, in order to control

their DM, thus promoting adherence to this self-care behavior (Alazri and Neal, 2003; Doubova et al., 2009). Also, if patients have stronger general beliefs about medicines and show more adherence to glucose monitoring, one may assume that patients perceive this self-care behavior as a way to control DM and avoid medication intake (e.g. insulin), later on.

Stronger general beliefs about medicines and stronger beliefs about the need to take the prescribed medication, at T1, predicted foot care adherence, at T2. However, the latter only took place in the group of patients diagnosed between 6 and 12 months. One may hypothesize that patients, between T1 and T2, became more aware of the importance of foot care, and it makes intuitive sense that those who have been learning more about the disease consequences may believe more on the needs of medication in order to prevent serious complications, such as amputations (ADA, 2017; PSD, 2016). Interestingly, unlike what was expected, general beliefs about medicines contributed to foot care behavior. Currently, several studies showed that these beliefs are a barrier to adherence (Pereira et al., 2013b; Sweileh et al., 2014). So, one may assume that patients adhere to foot care, hoping to maintain their current health and avoid or decrease the need of medicine intake, in the future. Future studies should pursue this hypothesis.

Intervention in clinical practice aiming to promote adherence to self-care behaviors to T2DM should focus on contextual variables, such as trust in the physician and the patient-physician relationship, and satisfaction with health care services (context dimension), given the direct influence on the proximal outcomes, such as adherence to medicines, diet, and glucose monitoring. Also, process variables, like beliefs about the need to take the prescribed medication, should be a target to be considered in patients with shorter duration of diagnosis, regarding foot care adherence. A screening instrument to assess psychological distress over time is also important since, in the early phase of the disease, it seems to have a protective role but should be monitored over time when patients face new demands.

Limitations

This study has limitations that need to be addressed. First, the sample included only T2DM patients diagnosed no longer than a year and the period between T1 and T2 (4 months) is a short period. Therefore, future research should focus on patients with longer disease duration, in order to understand and compare the impact of psychological variables on adherence to self-care behaviors with patients recently diagnosed, particularly regarding psychological distress. The nurse-patient relationship, in particular, should also be assessed in future studies. Finally, this study used exclusively self-report measures. Future studies should consider using electronic devices to measure adherence to medication and physical activity, for instance.

Conclusion

This study provides knowledge about reported adherence to T2DM self-care behaviors in newly diagnosed patients. The results corroborate the IFSMT (Ryan and Sawin, 2009), once contextual variables, such as trust in the physician and satisfaction with health care services, and process variables, like beliefs about medicines, showed a direct influence on the proximal outcomes, such as adherence to T2DM self-care behaviors. Interestingly, in this study, we found that the most cited non-adherent self-care behavior, such as foot care, increased from T1 to T2 as well as psychological distress. Also, the results showed the importance of contextual variables such as the patient-physician relationship and satisfaction with communication in therapeutic adherence to diet, glucose monitoring, and medication. Therefore, these variables should be targeted in intervention to promote self-care adherence to T2DM and guide health professionals in daily clinical practice.

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