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# Cognitive behavioral treatment to improve psychological adjustment in people recently diagnosed with type 2 diabetes

# Psychological treatment in type 2 diabetes

Héctor Velázquez-Jurado <sup>a,b</sup>, Athena Flores-Torres <sup>b</sup>, Liliana Pérez-Peralta <sup>a</sup>, Edgar Salinas-Rivera <sup>© c</sup>, Marianne Daniela Valle-Nava <sup>© a,b</sup>, Denise Arcila-Martinez <sup>© a</sup>, Sergio Hernández-Jiménez <sup>1</sup><sup>o</sup> and for the CAIPaDi Study Group<sup>a</sup>

<sup>a</sup>Centre for the Comprehensive Care of the Patient with Diabetes, National Institute of Medical Sciences and Nutrition Salvador Zubirán, Mexico City, Mexico; <sup>b</sup>Postgraduate Studies Division, National Autonomous University of Mexico (UNAM), Mexico City, Mexico; <sup>c</sup>Department of Educational Psychology, National Pedagogic University (UPN), Mexico City, Mexico

#### ABSTRACT

Type 2 diabetes mellitus (T2DM) is a chronic disease that affects a person's general well-being. Current evidence sets an association between psychological well-being and controlled metabolic parameters. People newly diagnosed with T2DM show higher prevalence of depression and anxiety symptoms. Cognitive behavioral therapy (CBT) has effectively improved psychological adjustment, but most studies do not specifically address recently diagnosed people nor usually include long-term follow-up measures.

**Objective:** We sought to assess changes in psychological variables in people with newly diagnosed diabetes who received a cognitivebehavioral intervention, within a comprehensive care program.

Method: 1208 adults with T2DM (≤5 years) who attended a national health institute in Mexico received a cognitivebehavioral intervention aimed at improving quality of life and reducing emotional distress that often interferes with diabetes control, as well as evaluating cognitive and emotional resources and social support. Measures of quality of life, diabetes-related distress, anxiety and depression questionnaires were compared at pre-test, post-test and follow up using Friedman's ANOVAs. Multiple logistic regression models evaluated glycosylated hemoglobin (HbA1c) and triglycerides control at post-test and follow up.

**Results:** Questionnaire measures and metabolic variables significantly decreased symptomatology at post-test and these changes maintained at follow-up. Significant associations were

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CONTACT Héctor Velázquez-Jurado 🖾 hector.velazquezj@incmnsz.mx 💽 Centre for the Comprehensive Care of the Patient with Diabetes, National Institute of Medical Sciences and Nutrition Salvador Zubirán, Mexico City, Mexico; National Autonomous University of Mexico, Mexico City, Mexico; Av. Vasco de Quiroga #15, Col. Belisario Dominguez, Sección XVI, Alc. Tlalpan, C.P. 14080, Ciudad de Mexico

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found between quality-of-life scores and HbA1c and triglycerides levels in post-test and follow-up. Diabetes-related distress scores increased the odds of having adequate HbA1c control at post-test.

**Conclusion:** This study contributes to the evidence on the importance of considering psychological factors as part of comprehensive diabetes care to improve quality of life and emotional burden and facilitate the achievement of metabolic goals.

Type 2 diabetes mellitus (T2DM) is a chronic disease that affects a person's general wellbeing, including mental health (Chaturvedi et al., 2019; Farooqi et al., 2022; Jenkinson et al., 2022). Usual management procedures consist of a variety of changes in lifestyle, which can be perceived as stressful, costly, and time-consuming (Helgeson et al., 2020). People may feel overwhelmed by the demands of the self-management or may worry and ruminate about existing or future complications, increasing diabetes-related distress (DRD) (Hernandez et al., 2019; Ngan et al., 2020; Perrin et al., 2017; Schmitt et al., 2021).

DRD is associated with a significant psychological burden, lower self-efficacy, poor self-care, less medication adherence, and poor glycemic control (Berry et al., 2017; Dennick et al., 2016; Helgeson et al., 2020; Perrin et al., 2017).

T2DM is also associated with depression and anxiety, people living with T2DM are twice as likely to suffer from anxious-depressive symptoms compared to the general population (Darwish et al., 2018; González et al., 2020; Naicker et al., 2017; Xie & Deng, 2017). Worries related to disease management and psychosocial problems (Conti et al., 2017; Nicolucci et al., 2013), along with depression symptoms increase chances of having poor glycemic control, physical inactivity, and experience poor quality of life (Conti et al., 2017; Darwish et al., 2018; González et al., 2020; Naicker et al., 2020; Naicker et al., 2017; Nicolucci et al., 2013; Owens-Gary et al., 2018; Uchendu & Blake, 2016).

A multidisciplinary approach becomes then essential from the first clinical evaluation toward the whole treatment plan, and even through follow-up. Such approach allows setting realistic and individualized clinical goals considering both psychological and social aspects of diabetes management (McBain et al., 2016; Ovideo-Gómez & Reidl-Martínez, 2007). Psychological treatments including CBT, have sought to improve therapeutic adherence, develop adequate coping strategies, promote emotional regulation, and reduce disease-related distress (Anguiano–Serrano, 2014), usually based on goal setting and problem solving (Fredrix et al., 2018; McSharry et al., 2020). Motivational interviewing (MI) has been included as part of various CBT intervention protocols to increase participants' engagement in medical treatment (Cornely et al., 2022) and to improving their perception on the importance of behavior change (Li et al., 2020).

All these changes in psychological variables, also known as psychological adjustment, have been associated with better control of glycosylated hemoglobin levels, achieving reduction percentages between 0.7 and 1.2 (Anguiano–Serrano, 2014; Gonzalez et al., 2010; Lawn et al., 2009; van Bastelaar et al., 2011; Xie & Deng, 2017). Regarding T2DM, MI manages to produce behavioral changes by increasing adherence to nutritional and pharmacological treatment and increase physical activity (Selçuk-Tosun & Zincir, 2019) therefore, achieving better metabolic control by reducing HbA1c levels and blood pressure (Steffen et al., 2021). In addition, current evidence points out an association between psychological well-being and levels of LDL cholesterol, triglycerides, and HbA1c, in the way that a lack of psychological wellbeing could promote the maintenance of uncontrolled metabolic parameters (Chew et al., 2014).

However, within the limitations of the reviewed studies, it is observed that some of them do not specify the time since diagnosis (González et al., 2020; Wroe et al., 2018); others include participants who have lived with T2DM for six years or more (Berry et al., 2017; Cornely et al., 2022; Li et al., 2020; Martino et al., 2020; Steffen et al., 2021; Theodoropoulou et al., 2019; van Bastelaar et al., 2011) or exclude newly diagnosed people (Xu et al., 2020). It has been reported that people newly diagnosed with T2DM show high rates of depression and anxiety (Ryu et al., 2021), which can affect blood glucose levels (Chai et al., 2018). Usually, the cohorts analyzed are those with more years of diagnosis, mainly because they have a higher prevalence of complications (Klein et al., 1998), however, it has been reported that up to 15% of people with less than five years of diagnosis already present some complication of the disease (Hernández-Jiménez et al., 2014).

In addition, not all studies include a follow-up stage (Berry et al., 2017; González et al., 2020; Soriano et al., 2020), and those who do, report follow-up periods up to three months (Cornely et al., 2022; Lawn et al., 2009; Li et al., 2020), which can result insufficient to detect clear effects (Berhe et al., 2020). Few studies have included longer follow-up periods, from which only two have reported measures up to six months; still, authors report high rate of withdrawal or a limited number of participants in their studies (Selçuk-Tosun & Zincir, 2019; Steffen et al., 2021).

The purpose of the study is twofold: (1) we sought to assess changes in quality of life, diabetes-related distress, anxiety, and depression in persons with Diabetes (PwD) with recent diagnosis who received a cognitive–behavioral intervention as part of a comprehensive care program in Mexico, and (2) we aimed to determine the extent to which metabolic changes can be predicted by psychological adjustment.

#### Method

## **Participants**

We included adults recently diagnosed with type 2 diabetes (5 years or less) attending the Centre for the Comprehensive Care of the Patient with Diabetes (CAIPaDi Program), in a tertiary care hospital, the National Institute of Medical Sciences and Nutrition, Salvador Zubirán in Mexico City. All were non-smokers with no diabetes-related chronic complications.

The cohort consisted of 1208 participants from which 56.8% were women, with a mean age of  $53 \pm 9.5$  years. Regarding marital status, 57.8% were either married or living in free union, 17.2% were single, and 7.8% were either divorced or widowed, 18.2% did not answer. As for education, 8.7% had completed elementary school, 13.3% junior high, 25.1% high school, 42.5% university and 9.1% postgraduate. Only 0.4% reported not having received formal education.

#### Patient reported outcomes (PRO)

The Hospital Anxiety and Depression Scale (HADS). This measure assesses symptoms of anxiety and depression through 14 items. Responses fluctuate on a Likert-type scale that ranges from 0 to 3, where 0 means the symptom is absent, and 3 that it is experienced intensely. The maximum score for any symptom is 21. If a person scores from 0 to 7 on depression, the symptom's intensity is considered low, while scores above 8 are considered severe. For the anxiety subscale, the first cut-off-point was set to 8 according to Salín-Pascual et al. (2002). For this study, Cronbach's alpha and McDonald's omega coefficients were obtained for the global scale ( $\alpha = .89$ ,  $\omega = .90$ ), whereas both subscales, HAD-a and HAD-d showed alpha and omega coefficients of reliability of  $\alpha = .87$  and  $\omega = .87$  for anxiety and  $\alpha = .80$  and  $\omega = .80$  for depression (N = 345).

The Diabetes Quality of Life scale (DQoL). The scale assesses the construct through dimensions related to the perceived satisfaction (time invested in treatment, life in general) and treatment impact (frequency of hypoglycemia, interference in daily activities), as well as concerns about future complications of the disease. This scale has been validated in the Mexican population, showing an internal consistency of 0.86. It is composed of 45 items that evaluate the amount of deterioration in perceived quality of life. The scores range from 1 (symptom never occurs, or the PwD are very satisfied) to 5 (symptom occurs all the time or the PwD are very unsatisfied). Therefore, according to Robles et al. (2003) the cut-off-point to consider deterioration in the quality of life is DQoL is above 75 points. The scale showed Cronbach's  $\alpha$  of .91 and McDonald's  $\omega$  of .91 for this study (N = 557).

The Problematic Areas in Diabetes scale (PAID). It consists of 20 items that evaluate emotional distress associated with diabetes, that is, the degree to which the management of the disease is problematic and generates an emotional burden. Its Castilian Spanish version was used, which showed an adequate reliability level and Cronbach's alpha and McDonald's omega coefficients of 0.95 for this study's sample (N = 658). The answers are on a Likert scale ranging from 0 to 4, where 0 means the area is not a problem and 4 represents a significant problem, with a cut-off-point for diabetes distress related to  $\geq 40$  (Polonsky et al., 1995).

An *Alert Assessment System* (AAS) was developed and applied in each of the five sessions treatment. It allows assessing the cognitive, emotional and social aspects related to diabetes diagnosis as reported in the scientific literature. Cognitive biases reflect a lack of information and perceived uncertainty caused by treatment (Anguiano–Serrano, 2014; Chew et al., 2014), which tend to increase symptoms of depression and anxiety, while diminishing sense of hope if goals are not achieved (Becerra-Gálvez & Reynoso-Erazo, 2014; Chew et al., 2014, p. 8). In addition, people living with diabetes usually report significant deterioration in interpersonal relationships (Chew et al., 2014), which expresses itself in a lack of motivation and low therapeutic adherence (Becerra-Gálvez & Reynoso-Erazo, 2014).

The AAS is comprised by three dimensions:

1) Cognitive Alert (CA), indicating the psychological impact derived from the PwD's perception regarding diabetes. The main purpose is to identify conscious or easily

accessible verbalizations governed by specific thought patterns. These include statements about the development and prognosis of diabetes, e.g. 'diabetes is caused by emotions such as fear or anger', 'diabetes is curable or temporary', beliefs related to the challenges of living with diabetes such as having unrealistic expectations, the absence of benefits perceived regarding self-care behaviors and low perception of risk and low self-efficacy.

- 2) Emotional Alert (EA), which reflects the emotional burden associated with diabetes. This component seeks to identify feelings and emotions related to specific thoughts such as anger derived by the idea that 'I can't eat what I want', or intense fear due to the use of needles and lancets, and feelings of hopelessness, anxiety and sadness linked to the diagnosis itself.
- 3) Social Support (SS). Since self-care behaviors often take place in social settings, support provided by family and friends will directly affect PwD's adherence. Therefore, social barriers that interfere with self-care are explored; these include for instance social contexts favoring excessive food consumption.

For its interpretation, each dimension is classified into three levels reflecting the perceived impact on self-care behaviors: level 1 suggesting no impact; level 2 indicating moderate impact, and level 3 reflecting severe impact on the person's ability to manage their disease.

Specific aspects defining each alert are included in detail as supplementary material. It is enough to present at least one element of each level to establish the alert.

For convergent validity, correlation analyses between the alert system and the diabetes questionnaires were performed. Regarding the diabetes quality of life questionnaire, coefficients were r = 0.21, r = 0.41, and r = 0.26 for cognitive, emotional, and social alerts respectively (p < 0.001). Correlation coefficients with the PAID questionnaire were: CA r = 0.23, EA r = 0.31 and SS r = 0.19, p < 0.001. Finally, the anxiety subscale of the HADS showed a correlation of r = 0.18 for CA, r = 0.40 for EA, and r = 0.23 for SS (p < 0.001). Coefficients between depression subscale and each alert were r = 0.23, r = 0.38 and r = 0.17, p < 0.001, respectively.

We interviewed 15 PwD who attended the diabetes center for the first to determine interrater agreement or the degree to which the evaluations of two independent psychologists (or raters) agree.

We sought to establish an inter-rater agreement to determine to what extent psychologists can consistently distinguish between the different levels of alerts. The two independent observers -psychologists- were trained in cognitive–behavioral techniques. The alerts were established using the criteria described in the supplementary material and unaware of the information from the self-report questionnaires in order to avoid confirmation bias. Kendall coefficients were obtained based on the results of the AAS, showing acceptable values for the three dimensions: Cognitive  $\tau = 0.78$ , Emotional  $\tau = 0.67$ , and Social  $\tau = 0.77$ , p < 0.05.

Finally, measures of metabolic variables included glycated hemoglobin (HbA1c), triglycerides, LDL-cholesterol, and blood pressure (BP). Achievement of metabolic goals defined by the National Committee for Quality Assurance (NCQA) criteria (2018) was considered as the primary outcome: HbA1c < 6.5%, triglycerides <150 mg/dl, BP <130-80 mmHg, and LDL cholesterol <100 mg/dl. 6 👄 H. VELÁZQUEZ-JURADO ET AL.

## Procedure

Comprehensive care program at the diabetes center consists of four monthly visits and one yearly visit conforming a total of nine specialty consultations of 30 min duration each. Each PwD receives endocrinological and ophthalmological treatment, diabetes education, nutritional and physical activity orientation, as well as foot and dental care, and psychological and psychiatric consultations, each occurring on the same week's day. Each consultation follows a set of procedures and establishes personalized goals with PwD. All the questionnaires and metabolic variables were measured at the first baseline visit, the subsequent visit three months later and the last one, one year after first contact to the clinic.

The CAIPaDi program was approved by the Institutional Ethics and Research Committees of the National Institute of Medical Sciences and Nutrition, Salvador Zubirán in Mexico City (Ref 1198) and registered in ClinicalTrials.gov (NCT02836808). People voluntarily agreed to participate and signed an informed consent form. The study was performed in accordance with the principles stated in the Declaration of Helsinki. The cognitive behavioral intervention is detailed below.

## Cognitive behavioral intervention

Before the first consultation at the CAIPaDi program, each PwD received the Patient Reported Outcomes (PRO) electronically (PAID, HADS, and DQoL), and were asked to answer them individually. Then, after answering the questionnaires, they were asked to send them back to the psychologists. Information collected was then analyzed in the first psychological consultation. The following five consultations comprising the cognitive behavioral intervention are then carried out by fully trained clinical psychologists.

The main purpose of the intervention was to identify and address barriers and obstacles for diabetes self-care, and to assess related cognitive and emotional aspects, as well as quality of social support. Intervention seeks to promote specific strategies for behavioral change according to Michie's BCT taxonomy (Michie et al., 2013), besides incorporating the basic principles of motivational interviewing (Miller & Roll-nick, 2002). Each interview was registered using a checklist or *clinical note* to ensure consistency in assessment procedures.

During the first visit, the psychologists conduct a complete assessment of the person living with diabetes addressing the following aspects: (a) the emotional reaction related to diabetes diagnosis, (b) the emotional burden at the time of medical evaluation, (c) perceived barriers to treatment, and (d) behavioral changes goals. Initial consultation comprises the following treatment components: *goal setting, action planning* and *problem solving* oriented to determine the adequate nutritional and pharmacological treatment, as well as frequency of exercise. We also address *negative emotions* by including *stress management;* AAS is included as a part of evaluation in each consultation.

The second and third consultations, which were conducted after one and two months, were problem-oriented, focusing on identifying potential barriers for achieving behavioral change and established metabolic goals. Strategies included *reviewing behavior goals, social support* through MI and *decisional balance*, and *problem solving*. If necessary,

avoidance/reducing exposure to cues for behavior (for nutritional and pharmacological treatment) and restructuring of social environment were applied.

The final consultation, which took place one month after the third visit, was focused on determining the scope of the behavioral and metabolic goals and providing strategies for abandonment prevention. It comprised *review outcome goals, feedback on outcomes of behavior, discrepancy between current behavior and goals, goal setting, social reward* and *problem solving* for *relapse prevention*.

After treatment completion, a one-year follow-up assessment was carried out, which corresponds to the fifth visit. The purpose was to assess PwD's health status and bring support and guidance for maintaining self-care strategies after treatment completion or resume treatment when necessary. Strategies addressed at follow-up focused on *problem solving, goal setting, discrepancy between current behavior and goal* and *social support*.

#### Statistical analysis

Interrater agreement was determined with Kendall's rank correlation coefficient, which determines the consistency between two independent observers with three or more measures. Comparisons between time points considering metabolic and anthropometric indicators as outcome variables were carried out using Friedman ANOVA. Statistical significance was determined at the 5% level.

We chose multiple logistic regression analysis due to the distribution of variables. Dichotomous variables were then constructed for each outcome variable. Before performing logistic regressions, associations between outcome and factor variables were assessed through t-tests, keeping those that resulted significantly for the analysis. Logistic regressions were then conducted, adjusting for sex and time of diabetes diagnosis.

Four multiple logistic regression models evaluated HbA1C and triglycerides control at post-test and follow-up. Odds ratios (OR) and 95% confidence intervals (95%CI) were obtained. HbA1c control was defined as 6.5% or fewer and 150 mg/dl or less for triglycerides.

Predictors were categorized as follows: PAID scores less than 40 points, DQoL less or equal to 75 points, HADS Anxiety less or equal to 7 points, and HADS depression less or equal to 6 points. All these variables were categorized as positive outcomes. We established the predictors according to what the literature describes as the variables usually associated with metabolic control or treatment adherence.

The model was tested by Hosmer-Lemeshow goodness of fit. Evaluation of possible confounders, interactions, outliers and influence statistics was also performed. All analyses were done with Stata/IC 15 (StataCorp, 2017).

# Results

Medians of the self-report questionnaires were compared at three moments, visit 1 (Pretest), visit 4 (Post-test), and Visit 5 (Follow-up) to determine the improvement of the variables evaluated (Table 1).

Table 1 shows that changes in all variables were statistically significant across visits, showing a decrease from Pre-test to Post-test and maintaining in-range scores at the

Table 1. Friedman's ANOVA with effect sizes between evaluations.

Variable	Pretest	Posttest	Follow up	X <sup>2</sup> (df)	<i>p</i> -value	Pre- Post Cohen's d	Pre-follow up Cohen's d
DQoL (score)	87 (72–105) <sup>a</sup>	67 (59–79) <sup>c</sup>	70 (60–83) <sup>b</sup>	797.4 (2)	<0.001	.97 (.91–1)	.82 (.74–.89)
PAID (score)	35 (17.5–55) <sup>a</sup>	11.2 (4–22.5) <sup>b</sup>	12.5 (5–26.2) <sup>b</sup>	941.7 (2)	< 0.001	1.1 (1–1.1)	.95 (.87–1)
HADa (score)	7 (5–10) <sup>a</sup>	4 (2–6) <sup>b</sup>	5 (3–7) <sup>b</sup>	620.5 (2)	< 0.001	.80 (.7486)	.61 (.54–.68)
HADd (score)	5 (3–8) <sup>a</sup>	3 (1–6) <sup>b</sup>	4 (2–6) <sup>b</sup>	269.1 (2)	< 0.001	.50 (.44–.56)	.43 (.36–.50)
HbA1c (%)	7.5 (6.4–9.8) <sup>a</sup>	6.2 (5.8–6.7) <sup>b</sup>	6.5 (6–7.4) <sup>b</sup>	850.4 (2)	< 0.001	.98 (.92–1)	.62 (.55–.69)
Triglycerides (mg/dl)	168 (122–235) <sup>a</sup>	115 (92–147) <sup>c</sup>	144 (109–197) <sup>b</sup>	514.8 (2)	< 0.001	.45 (.39–.51)	.24 (.17–.31)
Systolic blood pressure (mm Hg)	124 (115–133) <sup>a</sup>	117 (110–125) <sup>c</sup>	120 (113–127) <sup>b</sup>	302.1 (2)	< 0.001	.48 (.42–.54)	.28 (.22–35)
Diastolic blood pressure (mm Hg)	77 (72–81) <sup>a</sup>	73 (69–77) <sup>b</sup>	74 (70–79) <sup>b</sup>	285.3 (2)	< 0.001	.51 (.45–.57)	.36 (.29–43)
LDL-cholesterol (mg/dl)	114 (89–138) <sup>a</sup>	85 (71–101) <sup>c</sup>	103 (83–128) <sup>b</sup>	377.4 (2)	< 0.001	.80 (.74–.86)	.24 (.17–.30)

Notes: Medians and percentiles 25th and 75th are shown in each column. n = 1168. For Dqol >75 points, quality of life is considered deteriorated. For PAID, > 40 is considered diabetes-related distress. For anxiety in HADS, the cut-off point is >8 and >7 for depression. Superscripts indicate differences in *post hoc* comparisons using the Wilcoxon test where a > b > c. Bonferroni correction was performed.

one-year follow-up. Regarding the *post hoc* analysis, the records of both psychological and metabolic variables were higher in the pretest than those recorded in the posttest. This difference was statistically significant (p < 0.001).

In the paired comparisons between the posttest and the follow-up of the PAID, anxiety, and depression scores, as well as the HbA1c and diastolic blood pressure values, no significant changes were found. We observed a statistically significant but not clinically significant increase in quality-of-life scores and the variables of triglycerides, systolic blood pressure, and LDL cholesterol.

Effect sizes were calculated for pre–post and pre-follow-up through Cohen's d (Table 1). According to the results, effects were moderate to high in all variables, where the most robust ones were observed for quality of life, PAID anxiety, HbA1c and cholesterol-LDL. Effects were reduced in all variables at follow-up, remaining high on quality of life and PAID.

To determine the extent to which psychological adjustment predict metabolic changes logistic regression models were conducted. Results are summarized in Table 2, were HbA1c and triglycerides were considered as outcome variables both in post-test and follow-up. According to our findings, an improvement in quality-of-life ( $\leq$ 75 points) significantly increases the odds of achieving HbA1c and triglycerides control both at post-test and follow-up. In addition, maintaining PAID scores on its normal range (<40 points) increased the odds of achieving adequate control on HbA1c at post-test. No significant effects were found for the HADS depression and PAID scores in any of the outcome variables.

#### Alert assessment system (AAS)

Table 3 shows the distribution of PwD according to the alert system evaluation, where improvements were observed in all three dimensions (CA, EA, and SS) as indicated by a clear general reduction of dysfunction levels from pre-test to post-test. However, values hardly changed from pre to follow-up. Effect sizes for pre-post and post-follow-up comparisons were calculated by obtaining Cramer's v according to the Chi<sup>2</sup> analysis of association (Table 3), where low to moderate effects were found.

In the analysis of frequencies (Table 3), we observed a significant improvement in all three areas at post-test since the number of cases reporting the lowest impact (alert 1)

Outcome variables	Predictors	Adjusted OR	95% CI
HbA1C control at post-test	Model 1		
	PAID (≤40 points)	1.52*	1.07-2.16
	DQoL (≤75 points)	1.43*	1.16-1.76
Triglycerides control at post-test	Model 2		
	HADSd (≤6 points)	1.24	0.95-1.62
	DQoL (≤75 points)	1.30*	1.03-1.63
HbA1C control at follow-up	Model 3		
	HADSd (≤6 points)	1.33	0.98-1.79
	DQoL (≤75 points)	1.65**	1.28-2.13
Triglycerides control at follow-up	Model 4		
	HADSa (≤7 points)	0.71	0.50-1.00
	HADSd (≤6 points)	1.32	0.95–1.84
	DQoL (≤75 points)	1.42*	1.09–1.85

Table 2. Logistic regressions models for HbA1c and triglycerides control.

Note: Significant effects are shown in bold. \*p < 0.05, \*\*p < 0.001.

	Pretest (%)	Posttest (%)	Follow up (%)	<i>p</i> -value Pretest vs Posttest	<i>p</i> -value Posttest vs Follow-up	Pre-post Cramer's V	Pre-follow up Cramer's V
	Сс	gnitive resou	ırces				
Level 1	24.9	49.4	28.8				
Level 2	44.4	35.2	43.1	< 0.001	< 0.001	.30	.02
Level 3	29.5	15.3	33.1				
	Err	otional reso	urces				
Level 1	20.4	52	36.3				
Level 2	41.6	34.3	35.9	<0.001	< 0.001	.36	.18
Level 3	36.6	13.7	27.8				
	-	Social resourd	ces				
Level 1	34.1	47.1	28.6				
Level 2	42.1	38.3	44.5	<0.001	< 0.001	.18	.02
Level 3	22.3	14.6	26.9				

Taple 3. Alert Assessment System (AAS) for each dimension and effect sizes for each cor
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Notes: Differences between initial and post assessments, as well as between posttest and the follow-up assessment, were tested through Chi-square tests. The levels reflect the perceived impact on self-care: level 1 indicates no impact; level 2, moderate impact and level 3, severe impact. For more details see the supplementary material.

increased. Simultaneously, a reduction was observed in the number of cases in alerts 2 and 3 which reflect moderate and severe impact. At one year of follow-up, fewer cases were identified in alert 1, while reports on alerts levels 2 and 3 increased. These changes could reflect the presence of new cognitive, emotional and social stressors.

Associations between baseline and post-test, as well as between post-test and followup were assessed using chi-square tests, resulting all comparisons statistically significant (p < 0.001).

## Discussion

The purpose of the study was to assess changes in quality of life, diabetes-related distress, anxiety, and depression in people with recently diagnosed diabetes who received a cognitive-behavioral intervention, within a comprehensive care program to achieve successful diabetes management.

The results support the relevance of integrating cognitive behavioral interventions that seek to improve psychological wellbeing to achieve and maintain metabolic control and therapeutic adherence (Bilgin et al., 2022) Our intervention integrates both psychological and social aspects related to diabetes (McBain et al., 2016; Ovideo-Gómez & Reidl-Martínez, 2007) and managed to maintain psychological changes until the annual follow-up.

One of the main findings indicates that the clinical and statistical change in the quality of life may be attributable to the cognitive behavioral intervention implemented. Furthermore, we also identified a significant association between the quality of life and HbA1c and triglycerides control in the post-test and the annual visit. In addition, the favorable perception of self-care contributes to maintaining behavioral changes and, therefore, better long-term metabolic control.

Mainly, the quality-of-life construct comprises elements we address in the intervention through problem-solving, stress management or action planning. Therefore, psychological management helps to reduce the impact of treatment by addressing barriers such as poor management of hypoglycemia, the time dedicated to the treatment, or the interference that diabetes has in general in people's daily activities. Regarding DQOL, its psychometric properties (Robles et al., 2003) and the data obtained in this study indicate that the questionnaire is suitable for assessing quality of life in people with newly diagnosed diabetes. In particular, the literature mentions that general satisfaction with the treatment, a subdimension of DQOL, is positively associated with behavioral change necessary to achieve therapeutic goals and the assumption of functional coping strategies (Anguiano–Serrano, 2014; Conti et al., 2017).

According to the results regarding anxiety and depression, participants in this study did not show clinically significant symptomatology from the beginning of the intervention, which contrasts with what is frequently reported in the literature, indicating higher presence of both emotional responses (Chai et al., 2018; Chaturvedi et al., 2019; Darwish et al., 2018; Farooqi et al., 2022; González et al., 2020; Ryu et al., 2021).

Regarding DRD, findings indicate that people were able to reduce their emotional burden associated with the disease in general, and with self-care. A possible explanation for this is that distress experience may have reduced as a function of the coping strategies learnt, which in turn enhanced the adaptation and acceptance processes toward diagnosis, also increasing motivation (Anguiano–Serrano, 2014).

Additionally, we observed an improvement in all three dimensions of the Alert Assessment System in the way that people overcame social barriers, reduced their negative perception toward diabetes, and enhanced their overall well-being from pre to post-test. However, for the follow-up assessment, it was found that positive effects in emotional, cognitive and social dimensions decreased. This tendency in study variables suggests that hardships derived from the modification of everyday habits and the need for continuous health monitoring experienced when living with diabetes, significantly impact a person's general well-being (Conti et al., 2017; Theodoropoulou et al., 2019; Xie & Deng, 2017). The AAS constitutes a useful tool for evaluating the current psychological status of PwD suffering from diabetes, as well as changes in this variable over time.

Finally, we identified that the effect of the intervention fades between post-test evaluation and follow-up. A possible explanation is that during this time (one year), people could fail in their adherence to medical recommendations and their recently acquired healthy habits; some factors described in the literature include the perception of the lack of medical treatment effectiveness, work-related stress, and social pressure (Atinga et al., 2018). In this regard, shortening the follow-up periods and actively including the family circle are possible solutions, given that social support networks play an essential role in treatment adherence, both in reaching the established goals and relapse prevention (Rosland et al., 2008). Limitations of our study include the impossibility to include a control group besides not being able to randomly select the sample; both procedures could allow identifying the specific effects of the cognitive behavioral intervention on psychological and metabolic measures from the other clinical interventions. Another aspect that should be taken into consideration is that selection procedures allow applying these findings only to this cohort, limiting external validity of the study.

Additionally, inter-rater agreement could not be conducted with all participants, which constitutes another important limitation, however, results regarding convergent validity obtained from a larger sample supports the inclusion of the ASS as a useful tool in the attention of PwD with diabetes.

Still, the study does provide valuable information for supporting psychological and metabolic effects of comprehensive treatment.

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The study carries out some important advantages of approaching a population rarely studied such as recently diagnosed people; therefore, the study provides crucial information to effectively prevent potential complications associated to T2DM by providing tools in a timely manner. Finally, the inclusion of an annual follow-up assessment allows for evaluating the stability of the behavioral changes attained, which is usually an aspect questioned in the literature.

In conclusion, this study provides evidence on the importance of including the assessment of psychological aspects as part of the comprehensive care program in diabetes, since a large amount of the difficulties faced by people during treatment is usually linked to these variables. It becomes essential to properly identify them and to provide people with the necessary tools to improve their psychological adjustment and quality of life.

# **Geolocation information**

To index our paper's study area accurately in JournalMap's geographic literature database and make our article more discoverable to others we share the next information: Vasco de Quiroga 15, Colonia Belisario Domínguez Sección XVI, Tlalpan, 14080. Mexico City, Mexico.

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#### CAIPaDi Study Group:

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#### ORCID

Héctor Velázquez-Jurado D http://orcid.org/0000-0002-7660-9336 Athena Flores-Torres D http://orcid.org/0000-0002-6332-6855 Liliana Pérez-Peralta D http://orcid.org/0000-0003-1633-8164 *Edgar Salinas-Rivera* b http://orcid.org/0000-0003-0267-5602 *Marianne Daniela Valle-Nava* http://orcid.org/0000-0002-7832-1125 *Denise Arcila-Martinez* http://orcid.org/0000-0001-6382-3897 *Sergio Hernández-Jiménez* http://orcid.org/0000-0003-3080-8708

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