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## Research Program on Type 1 Diabetes and Youth Depression in Puerto Rico

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### Abstract

This work reviews the progress and current state of a research program on Diabetes and youth depression in Puerto Rico. Given the high depression rate, its impact in youth with Type 1 Diabetes (T1D), and the lack of interventions to target this link in an integrative way, the manual titled Cognitive-Behavioral Treatment for Depression in Adolescents with T1D was developed. After its first use in an Open Trial, we currently assess the initial efficacy of its revised version to reduce depression and improve glycemic control, self-care, and quality of life. We present its approach, and initial data on its feasibility, acceptability and potential to reduce emotional problems in T1D youth. We discuss implications of this line of research for health psychology, and its utility to model the development of interventions alike focused on other chronic illnesses.

### Resumen

Este trabajo reseña el progreso y estado actual de un programa investigativo sobre la Diabetes y la depresión juvenil en Puerto Rico. Ante la alta prevalencia y el impacto de la depresión en menores con Diabetes Tipo 1 (DT1) y la falta de intervenciones que atiendan de modo integrado este vínculo, se desarrolló el Manual para el Tratamiento Cognitivo-Conductual de la Depresión en Adolescentes con DT1. Tras su uso original en un ensayo clínico abierto, evaluamos ahora la eficacia inicial de su versión revisada para reducir la depresión y mejorar el control glucémico, el autocuidado, y la calidad de vida. Presentamos su enfoque junto a datos iniciales que apoyan su viabilidad, aceptación y potencial para reducir los problemas emocionales en jóvenes con DT1. Discutimos algunas implicaciones de esta línea investigativa para la psicología de la salud y su utilidad para modelar el diseño de intervenciones similares para otras enfermedades crónicas.

### Keywords

adolescents; depression; diabetes; psychosocial interventions

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## Palabras clave

adolescentes; depresión; diabetes; tratamientos psicosociales

Diabetes is a chronic illness associated with medical costs and productivity loss in the United States (US) estimated in \$245 billion (Shakiba & Frost, 2015). In Puerto Rico (PR), its medical cost at 2013 was of \$138.4 million (Puerto Rico Department of Health [PRDH], 2015). Among chronic illnesses, Diabetes has one of the most prevalent and harmful comorbidities with depression (DEP) (Lloyd, 2010). If untreated, DEP become chronic, recurrent, and increasingly devastating. Among people with DEP and chronic illnesses, those with Diabetes reported the greatest decrement in health (Moussavi et al., 2007). Pediatric patients with Diabetes are a very understudied and underserved population in PR, particularly with regard to their mental health. Emotional problems are the most common mental health comorbidity in this population.

In this article we document the main findings of a series of research projects funded by the National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK] and particular psychological studies about youth Diabetes and DEP, conducted at the University of Puerto Rico (UPR), Río Piedras Campus, since 2000, and discuss its implications for the progress of health psychology in PR. First, we will revise epidemiological data on Diabetes among Puerto Ricans, and explain the link between Diabetes, emotional problems and health complications. Then we will present results of a first major project aimed to assess psychological variables in children and adolescents with T1D, including DEP. Later, we will highlight results of two pilot clinical studies that adjusted and tested a group cognitive-behavioral therapy (CBT) to reduce DEP and improve glycemic control in adolescents with T1D. We will also document results from some individual studies published or presented as part of those major research projects. We conclude discussing future directions of this line of research, and its potential contribution to health psychology and the design of new interventions focused on other chronic illnesses.

## Current Epidemiological Data on Diabetes among Puerto Ricans

The combined age-adjusted prevalence estimates of diagnosed Type 2 (T2D) and Type 1 Diabetes (T1D) in PR reported in 2011–2013 (crude estimates in parenthesis) were of 13.3% (13.5%), 15.2% (16.4%) and 13.8% (14.9%), respectively (Centers for Disease Control and Prevention [CDC], 2014, 2015; PRDH, 2014), with higher rates for females, older age groups, and those from lower household income and educational levels. According to the Health Promotion Division of the PRDH, preliminary data for 2014 suggest a crude prevalence of 15.7% (Metro Puerto Rico Editor, 2015). Diabetes was Puerto Rico's third cause of death from 2004–2013, with 443,844 persons making at least one medical claim in 2013 (PRDH, 2015), but more than half million with a diagnosis. As the CDC (2014b) affirmed, Puerto Ricans in the US have the second highest rate (14.8%) of Diabetes, only surpassed by American Indians/Alaska Natives. Age-adjusted incidence of diagnosed Diabetes from 2009 to 2010, and prevalence rates from 1996 to 2013, was higher in PR than in any state or the District of Colombia (CDC, 2015b).

Hispanics (particularly Puerto Ricans) have the highest T1D incidence among minority youth in the US (CDC, 2014b). Incidence rate for people <20 years old in the US is around four times higher for T1D than for T2D (CDC, 2014b; NIDDK, 2008), a difference that may be higher in PR (Pérez-Perdomo, Perez-Cardona, Allende-Vigo, Rivera-Rodriguez, & Rodriguez-Lugo, 2005). From an estimated population of 910,764 persons under 20 years old in PR, at least 16,148 (around 18 per each 1000) received medical treatment for Diabetes in 2013 (PRDH, 2015); so it could be inferred that at least 1.8% of our children has diagnosed Diabetes, mainly T1D. If accurate, the T1D prevalence in Puerto Rican children would be nearly seven times higher than the rate (0.25%) in the US (CDC, 2014b). The combined T2D and T1D prevalence in youth 18–24 years old in PR was 2.2% in 2011 (CDC, 2015) and 2.7% in 2012 (PRDH, 2014b).

## Diabetes, Emotional Problems and Health Complications

DEP has been linked to increased Diabetes symptom severity, complications, treatment resistance, mortality rates and health care costs (De Groot, 2012). People with T1D have DEP rates up to three times higher than those without (Roy & Lloyd, 2012). Anxiety symptoms (AS) and combined anxiety and depressive symptoms (DS) are also common among this group (Maia et al., 2014). By 2012, 25.9% of the Diabetes patients 18 years old in PR have presented DEP, and 26.0% of adults with DEP had Diabetes (PRDH, 2014b). Age-adjusted prevalence of lifetime DEP among people with Diabetes in PR was 25.4% in 2013 (CDC, 2014). According to the PRDH (2015), the 10–14 years old age group had the highest mean annual per patient health cost (\$469) for Diabetes in that year. T1D youth are at high risk for emotional problems such as DS and AS (Corathers et al., 2013). Published studies reflect that between 36.7% (Rivera, González-Nieves, Vélez, & Colón de Martí, 2007) and 45.5% (Rosselló & Jiménez-Chafey, 2007) of T1D youth in PR present significant DS.

Diabetes treatment adherence (DTA) is very difficult, particularly for adolescents, who often view self-care (SC) and management as stressful and overwhelming (Rubin & Peyrot, 2012). This picture is worse when youth present untreated depression (Hood, Rausch, & Dolan, 2011). DEP in youth has been related with poor glycemic control (GC) and DTA, higher rates of short-term complications, more frequent admissions to hospital care, longer duration of inpatient treatment, reduced quality of life (QOL), lower self-esteem and self-efficacy, negative cognitive style, and helplessness (De Groot, 2012; Plener et al., 2015). DEP-related variables that also affect DTA and GC in T1D youth include behavior problems and family functioning (Cohen, Lumley, Naar-King, Partridge, & Cakan, 2004; Ellis et al., 2007). Indeed, DEP has a strong negative influence in T1D course and complications, including medical, behavioral, cognitive, affective, and relational outcomes. Interventions to address DEP- and T1D-related variables are likely to have a great impact on the QOL and the management of T1D in this age group. Based on this knowledge, and to provide baseline data on the psychological aspects of T1D in Puerto Rican youth, the first major research project was conducted.

## 1<sup>st</sup> Project: Psychological Adjustment and Metabolic Control in T1D Youth (R03DK58943)

Our program started in 2000 under the leadership of Dr. Jeannette Rosselló. Considering the prevalence of T1D in children and the lack of scientific knowledge about the psychological variables associated with this illness in PR, she and her collaborators conducted a first project to assess the psychological adjustment of youth aged 8–17 years ( $M=12.28$ ;  $SD=2.33$ ) with T1D and its relationship with GC (Jiménez-Chafey & Rosselló, 2009; Rosselló & Jiménez-Chafey, 2007). The main study included a community sample of 101 youth (55.4% females). Most were from mid-low or low socioeconomic status. Their mean time with T1D was about 4 years. Children and their parents completed self-report measures about T1D and youth psychological adjustment.

Results showed that most children have a poor GC, according to the American Diabetes Association (ADA) standards of glycosylated hemoglobin (HbA1c) levels suggested at that time. In fact, using current ADA (2016) standards, 74.5% of the sample would reflect problems with GC. Almost half of the sample (45.5%) reported mild to severe DS and nearly 3 out of 5 (62.8%) reported AS ranging from mild to severe (Rosselló & Jiménez-Chafey, 2007). About 16.3% of youth informed suicide ideation in the past two weeks: 15.2% had thoughts with no intent and 1% wanted to attempt suicide (Rosselló, Ortiz, & Duarte-Vélez, 2003). Gender differences were found on DS and hopelessness, with females endorsing higher rates of both. Children and adolescents with DS were more anxious and hopeless, and had lower self-concept and social support, than those not depressed (Rosselló & Jiménez-Chafey, 2007). DS showed a significant association with difficulties and worries experienced by youth regarding T1D management, and T1D worries also correlated with hopelessness scores (Rosselló & Maysonet-Guzmán, 2006). The association between DS and more recent HbA1c results obtained in distinct laboratories and dates was not significant. However, unpublished subsequent analyses showed that DS did correlate ( $r=.20$ ,  $p .05$ ) with *youth perception* of their GC (higher DS were related with a perception of poorer GC), as was the case with youth self-concept problems and GC. Linear regression models were examined to explain the variance of HbA1c results (Rosselló & Jiménez-Chafey, 2007). The best model identified included hopelessness, self-concept and time with T1D as predictors, being the last one the only significant predictor (more time with T1D, greater GC problems) in this sample ( $R^2 = .13$ ). Meanwhile, DS variance was explained in a model that included gender, age (being older), self-concept, hopelessness and time with T1D. Self-concept problems and being female were the only significant predictors for DS in youth ( $R^2 = .51$ ). Unpublished later analyses showed that parents' reports about delinquent and aggressive behaviors in their children were also significantly related with youth perception of their GC.

Self-concept problems were significantly associated with both DS and AS, being the relationship with DS stronger (Rosselló & Berríos, 2003). Besides, those diagnosed for more than two years reported lower self-concept. This difference was attributed to the attention and support received by youth in different stages of the condition. Usually, when the diagnosis is given, a child receives much attention and support, but the attention tends to

decrease with time due to tiredness, which could weaken self-concept. Precisely, the relationship among perceived social support (PSS), GC and AS was also examined (Rosselló & Pérez, 2003), but no significant two-tailed correlations were found. Furthermore, no difference was found on PSS between youth with inadequate GC and those with adequate control. However, a significant difference was found in which those who told they take care of T1D reported more PSS than those who do not. Youth who admitted to disrupt their diet reported being more anxious than those who do not. Finally, T1D worries were negatively related to PSS (Rosselló & Maysonet-Guzmán, 2006).

Given that parents play an important role in pediatric diabetes care (ADA, 2016), the reactions, worries and difficulties of having a child with T1D were also examined (Rosselló, Méndez, & Jiménez, 2005). Based on parents reports, 85.8% of their children had felt annoyed, had complained or had cried because of having T1D. About 70% regularly complained about having to use insulin and most also complain about following a meal plan. The diagnosis of T1D in youth has also a significant psychological impact on their caregivers. In fact, a third of the parents reported that they felt sad or cried when his/her child was diagnosed, about 18% were on denial and the rest mentioned they: were worried, felt too bad, were in shock, felt anxiety or fear, or felt angry-rebellious, anguished, frustrated, confused, or traumatized. Only 12.2% indicated that they had a normal reaction or felt good when told about it. About 38% were still worried, anxious, sad or accepting their child condition after years from the diagnosis. Almost 64% felt worried all the time about their child T1D, particularly because of complications and relapse at hospitals, but also for their treatment non-adherence, and the possible death/suicide of their child. Parental emotional impact of T1D diagnosis in children may interfere with their responsibilities to provide help, support and supervision in the diabetes care of their son or daughter.

Along with emotional problems, eating disorders are common in T1D youth. Rosselló and Maysonet-Guzmán (2004) compared symptoms of Bulimia Nervosa in adolescents with and without T1D and their relationship with GC. The sample included 46 T1D youth (54.3% females) from 11 to 17 years old ( $M=14.11$ ;  $SD=1.72$ ) and 72 without T1D (73.6% females) with ages 11 to 19 ( $M=14.61$ ;  $SD=1.95$ ). Those with T1D endorsed significantly more bulimic symptoms. About 17% had clinically significant bulimic symptoms, compared to only 6.9% of those without T1D. The most frequent features related to Bulimia in the T1D group were: body image worries and obsession, weight gain worries, use of extreme methods to control weight, binge eating and fasting. Most (75%) with T1D and bulimic symptoms also reported poor GC.

Overall, these results are congruent with the research literature. Puerto Rican T1D youth are also at high risk for emotional and other psychological problems. Their SC, GC and QOL are affected by their emotional problems, increasing their risk for diabetic complications (DCs) and hospitalizations (Stewart, Rao, Emslie, Klein, & White, 2005). As DCs rise DEP risk, and reduces the durability of DEP treatment gains in adults, it is essential to treat DEP in T1D youth before DCs develop (Stewart, Rao, & White, 2005). Given the need for psychological treatments to reduce emotional problems and improve GC, Rosselló and colleagues move to the next step and develop a group CBT for targeting DEP and GC in adolescents from PR.

## 2<sup>nd</sup> Project: Group CBT for Depression in Puerto Rican Youth with T1D (R21DK064747)

In 2003, Dr. Rosselló was awarded a second grant to adapt the group CBT for Adolescent Depression (AD) for use with T1D youth. After a cultural adaptation process, the initial group CBT for AD had been proved as efficacious reducing DEP in the general population (Rosselló, Bernal, & Rivera-Medina, 2008). The model attempts to identify thoughts and actions that influence depressive feelings, Its goals are to decrease depressive feelings, shorten periods of DEP, teach ways to prevent DEP, and increase youth sense of control over their lives. Sessions are divided into three major modules of four sessions each, focusing on how thoughts, activities and social interactions affect mood. Its adaptation for T1D youth is known as CBT-DM. As delivered in group format, CBT-DM has an introductory and a termination session, besides the standard CBT structure described, for a total of 14 two-hour sessions. Along with CBT goals, CBT-DM also aims to teach ways to feel in control of T1D, and improve SC and GC. The first adaptation of CBT for AD into CBT-DM is described in Rosselló and Jiménez-Chafey (2006). Its adaptation also included elements of a CBT for depressed adults that have been used with Latinos (Muñoz & Mendelson, 2005). Issues related to diabetes management were incorporated, and also strategies for dealing with common worries and concerns mentioned by T1D adolescents in previous studies (Rosselló & Maysonet-Guzmán, 2006). During sessions, participants have the opportunity to address feelings, concerns and questions, while providing and receiving feedback from others. Each week, adolescents participate in discussion and educational segments integrating issues about T1D and DEP, as well as games, exercises, worksheets review (i.e., Mood Thermometer, Glucose Monitoring Sheet, Pleasant Activities Worksheet, Negative and Positive Thoughts Worksheet) and sharing of individual experiences.

In this pilot study, using a pre-post design, initial data was collected about treatment gains in T1D youth who presented with DS at baseline. CBT-DM weekly sessions were co-led by two doctoral level psychologists. Each participant received a copy of the manual containing a summary of each session topics, in-session exercises and worksheets for home practice. Analyses of feasibility and acceptability revealed that it was well accepted by all youth ( $N=11$ ). Results of this open trial showed that youth DS significantly decreased, while self-esteem, diabetes self-efficacy, QOL, and functionality increased (Rosselló & Jiménez-Chafey, 2006). At one with various studies of psychosocial interventions for youth conducted until that time, SC and GC remained unchanged. Lack of knowledge about T1D care was observed as a possible reason for these findings. While preliminary, results seemed promising to further study the CBT-DM's efficacy to reduce DS, and improve self-esteem, diabetes self-efficacy, QOL, and functionality. Findings also suggested the need for more adaptations to impact diabetes-related variables.

Jiménez-Chafey and Rosselló (2005) examined more closely the QOL of youth, focusing in the negative impact of T1D, worries about having T1D and life satisfaction. Their sample included 18 youth aged 12–18 years old ( $M=14.6$ ;  $SD=1.3$ ) who completed the screening for the open trial. Most were female (66.7%), lived in urban area, attended to public schools, had inadequate GC (88.2%) and have had T1D for more than 2 years. Results showed that

T1D had a moderate or severe impact in the lives of 77.8% of them. Reasons included: parental worries about T1D, overprotection, parents acting as if T1D was their own illness, restrictive meal plans, eating something not included in the diet instead of telling others they have T1D, feeling pain related to T1D treatment, explaining others what means to have T1D, and feeling ashamed to deal with T1D in public. Regarding their concerns about T1D, 72.2% reported moderate to severe worries of having DCs, fainting, as well as not being able to have children or finding the employment they want. Despite their concerns, 72.2% evaluated their life satisfaction as moderate and 16.7% as high. Still, they reported to be less satisfied due to the burden T1D imposes to their families, the diet's flexibility, time spent in glucose monitoring and time taking general care of their T1D.

Other study resulting from this second project evaluated the relationship among DS, GC, and parent-child relations in a group of Puerto Rican adolescents with T1D (Sáez-Santiago & Cumba-Avilés, 2014). Twenty youth were part of the open trial and the others were recruited from the community. Participants were 12 to 18 years of old ( $M=14.55$ ;  $SD=1.54$ ). We evaluate both parental emotional involvement and criticism toward the youth. Variables were measured separately to obtain adolescents' ratings of both maternal and paternal behavior. Results showed that all variables significantly correlated with DS and GC, except maternal criticism with GC. Paternal emotional involvement and criticism were the best predictors of variance on DS in youth, while maternal emotional involvement best predicted their GC. Findings suggested that parental interventions aimed at reducing criticism and improve healthy emotional involvement could be essential for the prevention and treatment of DEP and poor GC in T1D youth, and that such intervention could be a complement to CBT-DM.

In fact, for more than a decade, CBT, diabetes education and family interventions have hold promise as interventions aimed to decrease DEP and improve GC in T1D youth (Kanner, Hamrin, & Grey, 2003; Winkley, Ismail, Landau, & Eisler, 2006). Latino youth are particularly in need of such interventions due to their high T1D prevalence and risk of co-morbid DEP. Yet, until 2010, no other study had used CBT with Latino T1D youth since the open trial with T1D Puerto Rican youth conducted by our research team, and "no clinical trial (meaning randomized clinical trials) of DEP treatment had been conducted" (p. 142) in youth with T1D (Jaser, 2010).

### **3<sup>rd</sup> Project: Exploring CBT-DM Efficacy in T1D Depressed Latino Youth (R03DK092547)**

To ensure new adaptations to CBT-DM would enhance its potential to impact T1D variables, we strengthened its distinction from CBT for AD. In 2010, we proposed to improve CBT-DM by adding more developmentally- and culturally-appropriate psycho-educational content about T1D. We opted for a CBT-DM vs. CBT design instead of pursuing further test of CBT-DM against an inert control condition (such as an attention control), because this design will permit us to both enhanced the CBT-DM manuals and test its initial efficacy to impact T1D-related variables over the known impact that standard CBT has shown on AD. Our current project (that started on September 2011) is the third step in this research program aimed to bring the benefits of evidence-based treatment development to Latino

youth with T1D and DEP. Currently such research program is available only for Hispanic adults with T2D (Ell et al., 2009).

### Study overview

Our main goals were to revise CBT-DM manuals, and explore both its initial efficacy and added impact over CBT for AD. After an initial focus on manuals refinement, we pilot-tested CBT-DM versus CBT by comparing changes on DS, self-esteem, functionality, self-efficacy, QOL, GC and SC. We also assessed the feasibility and acceptability of treatment. Youth continued to visit their nutritionist and endocrinologist as needed. Assessments occurred at baseline, weeks 6 and 10 (during therapy), post-treatment, and 3 and 6-month follow-ups. An adapted semi-structured interview schedule was used to obtain youth diabetes information from parents, such as age of onset, adherence, etc. The assessment battery included the HbA1c laboratory test, youth and parent self-report measures and clinical evaluators' ratings, and addressed the following domains of functioning: a) youth health status/T1D knowledge, b) youth DEP/mental health diagnoses and symptoms, c) youth behavior/global functioning, d) youth cognitive/affective factors, e) parent/family functioning, and f) process variables.

### Inclusion and Exclusion Criteria

For the treatment phases, youth must be 12 to 17 years old, have T1D, and obtain a Children's Depression Inventory total score  $\geq 13$  or a Children's Depression Rating Scale-Revised score  $\geq 44$ . Inclusion required that at least one caregiver be willing to participate in assessments and to take youth to the UPR-Medical Science Campus for laboratory analysis (HbA1c) at baseline, termination, and 3- and 6-month follow-ups. Youth must be willing to attend 14 CBT-DM or CBT group sessions. Exclusion criteria were: 1) current youth psychotherapy or medication for DEP, 2) legal involvement (youth or parent), 3) youth history of any psychotic or organic brain disorder, 4) youth history of bipolar or schizoaffective disorder, 5) youth current or past-year substance abuse/dependency, 6) evidence of any medical/neurological or severe cognitive problem that could limit their participation, and 7) active suicidal intent or imminent risk. Youth with co-morbid mental health conditions that were not exclusion criteria were accepted (e.g., those with learning, anxiety, attention or behavioral disorders). Those whose co-morbid condition needed immediate attention were referred. Even when a diagnosis was not required, most adolescents met criteria for some depressive disorder.

### Further CBT-DM Refinement and Pre Pilot Study

After initial expert review by our research staff, we conducted in-depth interviews with 6 community service providers (CSPs) at diabetes clinics/community organizations to refine the manuals and incorporate their feedback. Prior to the interviews, CSPs were given 2–3 weeks to study the manuals. We elicited their feedback on the structure, approach, sequence, and content of the manuals, and their pertinence to target problems experienced and coping strategies used or needed by T1D youth to manage T1D and DEP. We also conducted a pre-pilot study (PPS) of CBT-DM and CBT to inform the initial manual revisions, pilot-test the assessment battery, evaluate the feasibility of procedures, train therapists to deliver the CBT-DM ( $n=5$ ) and CBT ( $n=5$ ), and incorporate any feedback we receive from therapists and



participants into the manuals. For the PPS we recruited 10 youth and one caregiver of each patient. After treatment, separate focus groups were conducted with these participants and their parents. Eight of 10 adolescents and their parents participated in the focus groups and provided additional feedback about CBT-DM and its distinctiveness for CBT for AD. Although results from this phase are fully discussed elsewhere (Cumba-Avilés, Sáez-Santiago, Jiménez-Chafey, Rosselló, & Bernal, 2016), preliminary findings will be summarized here.

CBT-DM manuals undergo significant revision by expert review. Some adaptations were related to: 1) introduce content intended to increase diabetes care knowledge and SC behaviors since the first session; 2) revise the balance between DEP and T1D content (including examples and exercises) along the whole manual; 3) incorporate additional material on relational issues affecting mood and T1D (Jiménez-Chafey & Rosselló, 2005); 4) integrate stress management strategies; and (5) emphasize the importance of good doctor-patient/family communication (Snoek, Van der Ven, & Lubach, 1999). Specific time guidelines were provided for each activity or topic in the therapists' manual. Some of the main DEP-related worksheets were shortened to accommodate T1D-related examples, to integrate examples that emphasized the T1D-DEP relation, or simply to ease participants' burden. Language in some worksheets was changed to reflect adolescents' current jargon. Consistent with Latino cultural values and the characteristics of the T1D population, snacks and refreshments were also provided during each therapy session.

All CSPs considered CBT-DM to be culturally-sensitive to youth with T1D. They described the intervention as “very good”, “useful”, “very necessary”, “focused in what they (adolescents) need”, “very comprehensive”, and “highly valuable”. They expressed that both the CBT approach and the group modality were appropriate for this population and age group. All preferred the integrated (not segregated) presentation of the T1D and DEP content, and the use of combined psychotherapy and psycho-educational strategies, and were satisfied with the format and content of the sessions, the structure and sequence of the intervention, as well as with the balance between hands-on in-session exercise and conceptual discussion included in manuals. They recommended that CBT-DM therapists should be active but also flexible, and agreed to include additional psycho-educational material about T1D across the sessions. They proposed to shorten and make some changes in the language used in some worksheets, considered CBT-DM to be feasible, and anticipated it would be very well accepted by the youth and their parents. Finally, CSPs assessed very positively CBT-DM potential to impact outcome variables, even those related to T1D, and one of them expressed: “Targeting psychological aspects of Diabetes is essential for its effective short- and long-term management”. Modifications to the manuals suggested by CSPs or during expert review were integrated in the version used during the PPS.

After the first therapy cycle (PPS), significant improvements were observed in both groups in youth DS and AS, suicide ideation, self-efficacy for diabetes, and functionality, among other domains. Although an increased in self-reported SC behaviors was noted, it was not statistically significant. The increase was somewhat higher in the CBT-DM group. An overall significant improvement in parental knowledge about T1D was also noted from pre to post, with parents in the CBT-DM condition showing the major increase (although we had

no statistical power to detect any differences between groups). No changes were observed in GC during the PPS cycle. However, participants in each group reported a cohesive and empathic climate between members and from therapists. Satisfaction levels in both groups were very high.

Focus groups conducted with PPS participants began with a brief overview, followed by open-ended questions and selected topic guides. We presented detailed outlines of both interventions content and elicited their opinions about how CBT-DM and CBT differs, suggestions (if any) to strengthen this distinction, ways (if needed) to enhance CBT-DM's potential to impact T1D-related variables, and youth skills and knowledge needed to deal effectively in the management of T1D and DEP. Each focus group lasted approximately 2 hours and 15 minutes divided in two one-hour segments with a 15 minutes break for snacks/ refreshments. Both parents and adolescents could identify main differences between the interventions, and expressed (as did the CSPs) that CBT-DM is responsive to the needs of youth with T1D and DEP. Youth gave great value to the chance provided in therapy for sharing experiences with others who presented the same illness and similar mood problems and difficulties in life. They highlighted the importance of *personal motivation* to accomplish that learned skills and progress achieved in psychological or emotional outcomes could translate into better SC and GC. Parents considered a great idea to share with them the content of the manuals and showed great interest in the design of a *parent intervention* aimed to provide them with tools to help their children in managing T1D and mood problems.

### **Pilot Randomized Clinical Trial (RCT): Preliminary Findings**

We are currently completing the follow-ups of the final study phase, in which 41 additional youth with T1D and DS were randomized to either CBT-DM or CBT. Preliminary results for the pre-post comparison were presented in scientific forums in PR (Cumba-Avilés & Sáez-Santiago, 2015; Cumba-Avilés, Sáez-Santiago, Jiménez-Chafey, Bernal, & Rosselló, 2015) and Europe (Cumba-Avilés, Sáez-Santiago, Jiménez-Chafey, Bernal, & Rosselló, 2015b). Overall, using CBT with T1D youth resulted in significant decreases in youth DS, suicide ideation, problems with QOL, social withdrawal, aggressive behavior, and DEP-related interpersonal, cognitive and activity problems. Increases were observed in their functionality, self-efficacy, and SC. Parents reported reductions in their DS and AS, and an increase in the overall quality of family relationships. Final analyses comparing the differential impact of the CBT conditions are in progress. However, based on preliminary findings, CBT-DM was related with a small but statistically significant difference over standard CBT in youth GC at post-treatment, after controlling for pre-treatment scores in HbA1c and global functioning. Their efficacy to reduce DS is equivalent.

### **Secondary Studies**

During our third research project, we also validated some measures and conducted secondary analyses from baseline data collected in the pilot RCT. We validated scales that assess youth diabetes knowledge, SC, and family social support. Besides, we provided evidence on the psychometric properties of several measures completed by parents of T1D youth, including a measure of youth DEP, and one to assess the quality of family

relationships. We also evidenced the reliability and sensitivity to change of two process measures: one about therapeutic factors linked to group process and another related to therapists' interactions with the group. Other studies conducted included topics such as: the relation of SC with both perceived socio-economic status and the specific treatment regimen (insulin pump or multiple daily injections) for T1D; developmental- and DEP-related cognitive difficulties; predictors of family conflict; predictors of suicide ideation and QOL; and predictors of family behaviors intended to support and youth actual perception of such support, among others (Specific information about secondary studies is available from the first author upon request). Finally, we have also presented individual clinical cases at scientific conferences to illustrate the impact of standard group CBT for AD (Sáez-Santiago, Fernández-Vargas, Rodríguez-Corcelles, & Cumba-Avilés, 2014) and CBT-DM (Ruiz-Raíces et al., 2015) on several clinical outcomes, and submitted for publication a group clinical case to illustrate the cultural adaptation of an evidence-based treatment for adolescents with a chronic illness and comorbid DEP (Cumba-Avilés, 2016).

### Future Directions of Our Research Program

As observed in our studies, caring for a chronically ill child put parents at an increased risk for emotional problems (Cousino & Hazen, 2013). Parents must deal with the loss of their child's health, hospitalizations, episodes of hypo/hyperglycemia, and further DCs. They must also face the daily stress of the medical regimen and its financial costs. Family adaptation to deal with the burden of T1D is a mediator of youth health and psychological status (Ellis et al., 2007). Family cohesion, conflict resolution, and effective communication have been related to SC and GC in youth (Anderson, 2004; Cameron et al., 2008). Parent-youth conflict has been related to poor DTA, GC, QOL and psychological adjustment (Wysocki et al., 2007). Parental involvement in T1D management is desirable and beneficial as it increases DTA and GC in youth (Horton, Berg, Butner, & Wiebe, 2009). When teamwork is implemented and parental involvement is maintained, GC improves and conflict is reduced. Successful family-centered interventions may assist in preserving health and preventing long-term DCs for T1D adolescents.

McBroom and Enriquez (2009) reviewed several studies that used family-centered interventions to help parents deal with problems arising from low DTA and/or improve health outcomes. Only one was designed (in Spain) for Spanish-speaking families, but it targeted parents of children under 8 years old. Some have shown potential to improve GC, reduce diabetes-related conflict and improve family relationships (McBroom & Enriquez, 2009; Wysocki & Anderson, 2012). Although interventions improving family communication and problem-solving skills, as well as CBT and diabetes education, hold promise to decrease DEP in T1D youth, still no psychosocial intervention has established efficacy to both improve health status and reduce DEP in T1D adolescents. So far, findings from our ongoing study could be first to document such improvements. Despite that, family variables need to be targeted to optimize and sustain health outcomes. As Weiler and Crist (2009) argued, the socio-cultural influences that affect diabetes management practices must be integrated into clinical practice. Among Latinos, those influences points to the inclusion of family (particularly primary female caregivers) in diabetes care, and as a source of supervision and support, especially during the medical/mental health treatment process. We

believe that by adding a parent psychoeducational intervention to CBT-DM, including parents group sessions as well as parent-youth sessions to practice problem solving skills under therapists' supervision, we could optimize the treatment of T1D Latino youth and their families. Such intervention should focus on learning about mood and relational problems and their impact on T1D management and youth GC.

Qualitative data obtained from interviews with non-T1D depressed Puerto Rican youth who participate in a DEP treatment study (Rosselló et al., 2008) as well as data from a pilot study on the feasibility and acceptability of a psycho-educational intervention for their parents (Sáez-Santiago, Bernal, & Reyes, 2012), suggested that parents and youth view family involvement as essential to increase treatment gains. Such involvement was thought to help parents avoid displaying at home inappropriate behaviors that could jeopardize the gains that youth have achieved at therapy. We received similar feedback in our focus groups. Results from an RCT using individual CBT for AD conducted at University of Puerto Rico (Bernal et al., 2016) also suggested that family sessions additional to CBT and/or parent psychoeducation are needed in many cases to deal with the complexity of conflict, communication and cohesion problems found in families of depressed youth (Weitzman, 2006). Precisely, these aspects are significantly related to poor SC and GC in T1D youth. Thus, targeting them should have a strong and positive direct impact on emotional problems, but also both a direct and an indirect impact (through improvement in emotional problems) on youth DTA and GC. Since family sessions, and not only parent psycho-education, seem necessary when working with non-T1D depressed Latino youth to optimize treatment, it is logic to think this is also the case with T1D youth with DS. Hence, as a next step in our research program, we plan to conduct a study in which CBT-DM is augmented by adding an intervention combining group parent psychoeducation with individual parent-adolescent sessions. After all, as found by Rosselló et al. (2005), 75.5% of parents in the first project were interested in participating of support groups to deal with their child T1D and another 23.5% affirmed they will consider to participate. Based on previous findings and our knowledge of Latino culture, we think this next step will advance the field and close gaps in our knowledge about T1D youth, their families, and their treatment.

## Conclusion

The long-term goal of our program is to enhance the understanding of behavioral factors that influence T1D course and complications and the treatment of T1D Latino youth with emotional problems. Latino youth with these comorbid conditions are a critically understudied, underserved and burdened population. We seek to promote the early identification and treatment of emotional problems in this group. In our current study, we refined CBT-DM, and provided additional evidence on its feasibility and acceptability. After completing our study, we will be in position to evaluate its added impact over CBT for AD. Besides, by improving intervention manuals, this study will optimize the efficacy of CBT-DM, increasing its capacity to yield better outcomes on T1D-related variables. Furthermore, our current research will provide data to substantiate a larger and definite study (R01) with an extended follow-up period. By providing scientific evidence on the initial efficacy of this treatment, and developing an intervention for parents to increase the impact on T1D-related outcomes, this line of research could substantially help to reduce health disparities, improve

the quality and years of healthy life, and reduce the burdens of T1D and DEP not only among Puerto Rican youth, but also on other Latino youth in the US and other Spanish-speaking countries.

Our research program has significant implications for health psychology research and practice in PR. First, as recommended by ADA (2016), it reveals the urgent need to establish structured screening programs for emotional problems in youth with Diabetes both in private and public health services facilities, as well as support groups for parents. Beside ours, no other treatment study conducted with Latino T1D youth has had such a significant impact on the emotional problems and overall health of this group. This line of research could model similar programs aimed to study the occurrence, correlates and impact of emotional problems, or any other mental health symptoms, in patients (youth or adults) with other chronic illnesses (i.e., cancer, heart attack, coronary disease, stroke, asthma, arthritis, kidney disease, etc.) in PR. In fact, data from the PRDH (2014b) indicates that, at 2012, 50% of adults in PR presented at least 1 of the 9 most common chronic illnesses, and that most of these (data for cancer was not available) were comorbid with DS in a range from 29.2% (heart attack) to 42.3% (stroke). In addition, among Puerto Rican adults with these chronic illnesses, the prevalence of Diabetes ranges from 21.7% (asthma) to 46.3% (heart attack), while as much as 69.5% of Puerto Rican adults with Diabetes have at least one additional chronic illness (PRDH, 2014b). It is difficult, then, to ignore how much the design and implementation of this type of research program (especially if aimed to develop psychosocial interventions to improve mental health) could increase the QOL of our population and promote health psychology in PR.

Our program provides a foundation for the adaptation of promising psychosocial interventions for use in Latino youth with other chronic illnesses and co-morbid mental health problems. CBT-DM manuals could serve as training tools for psychology, psychiatry, social work, nursing, and medical students interested in treating Latino pediatric populations with T1D (or with similar chronic illness in which emotional problems are common) in a culturally-sensitive way. We hope our line of inquiry stimulates similar efforts from other researchers in PR, other Hispanic countries and the US, and look forward to establish diverse collaborative efforts that result in an improvement on access to mental health care and QOL of the pediatric population with comorbid chronic illness and emotional problems. Finally, we also hope this work serves to stimulate the collaboration between health psychology researchers in PR and its government agencies devoted to physical and mental health care, aiming to ease the translation and implementation of our research findings and products (with the required adaptations) into the primary care health system and among public mental health services facilities.

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