



Babes-Bolyai University Faculty of Psychology and Educational Sciences Department of Clinical Psychology and Psychotherapy

PH.D. THESIS

PSYCHOLOGICAL INSULIN RESISTANCE AND IRRATIONAL BELIEFS. ASSESSMENT AND INTERVENTION

(ENGLISH SUMMARY)

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Notes:_____

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(b) Parts of the thesis have been already published, in press, or submitted for publication; appropriate citations for these publications were included in the thesis. Other co-authors have been included in the publications, if they contributed to the exposition of the published text, data interpretation etc. (their contribution was clearly explained in the footnotes of the thesis);

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2. All the Tables and Figures are numbered within the corresponding chapter or subchapter of the thesis.

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CHAPTER ONE. THEORETICAL BACKGROUND

General Overview and Rationale

Diabetes mellitus is now one of the most common non-communicable diseases globally. It is the fourth or fifth leading cause of death in most high-income countries and there is substantial evidence that it is epidemic in many economically developing and newly industrialized nations (Shaw, Sicree, & Zimmet, 2010). Complications from diabetes, such as coronary artery and peripheral vascular disease, stroke, diabetic neuropathy, amputations, renal failure and blindness are resulting in increasing disability, reduced life expectancy and enormous health costs for virtually every society (Nathan et al., 2009). Diabetes is undoubtedly one of the most challenging health problems in the 21st century (Shaw et al., 2010).

At the same time, diabetes is an illness that does not have an etiological treatment at present. The interventions used to control it are mostly symptomatic and do not lead to a permanent solution. Moreover, a lot of the medical recommendations (taking medication, following a diet, exercising, monitoring blood glucose levels, taking insulin, etc.) have to be performed every day, several times a day (Alam, Sturt, Lall, & Winkley, 2009). Thus, a lot of changes must be incorporated in someone's daily schedule for long periods of time. This is the place where psychological interventions could facilitate the efficacy of pharmacological or dietary medical interventions.

Unfortunately, there is a problem that prevents people with diabetes from receiving the most effective treatment available, insulin, and in the literature it is usually named *psychological insulin resistance*. It generally refers to psycho-social barriers to insulin use and more specifically to insulin initiation refusal, insulin injection omission, or refusal to intensify the number of injections a day (Brod, Kongsø, Lessard, & Christensen, 2009).

After a number of years, people with type 2 diabetes need insulin in order to control their blood sugar (glycemia) levels and this opposition towards insulin use exposes them to high glycemia levels, which in time determine the complications

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mentioned above (DCCT, 1986). The estimated percentage of insulin initiation refusal is about 30% of the patients first prescribed insulin (UKPDS, 1998).

Research Relevance

Each new developed complication (e.g., feet ulcerations, diminished vision, kidney failure, myocardial infarction) in a patient with diabetes greatly enhances the personal and social burden for each individual, significantly decreasing one's quality of life and augmenting the medical costs (Shaw et al., 2010).

Consequently, a worldwide problem would be to decrease the number of patients who refuse insulin treatment and thus of those exposed to high blood sugar levels for this reason.

This is what the present research has as its main objective, and therefore we set out to investigate possible mechanisms of adherence to an insulin treatment and also an intervention to facilitate the acceptance of insulin treatment by people with diabetes who need it.

CHAPTER TWO. RESEARCH AIMS AND OVERALL METHODOLOGY

Thus, the **general objective** of the thesis is to investigate **psychological insulin resistance (PIR)** from the framework of Cognitive Behavioral Therapies in order to highlight specific factors that explain PIR and that could be further used to reduce barriers towards insulin use (see Figure 1).

THE PROBLEM

The prevalence of Diabetes has grown alarmingly in the last decade. High blood sugar levels lead to complications, such as coronary artery and peripheral vascular disease, stroke, diabetic neuropathy, amputations, renal failure and blindness are resulting in increasing disability, reduced life expectancy and enormous health costs.

PROBLEM: more than **30%** of people with type 2 Diabetes **are NOT ADHERENT to insulin** treatment when it becomes necessarily _____ exposure to high blood sugar levels.

GENERAL OBJECTIVE:

To investigate the factors that influence adherence to insulin treatment, to test and design an intervention that improves it.

Figure 1. General objective

First, we set out to summarize the literature on *psychological insulin resistance (PIR)*, the factors that influence non-adherence to insulin treatment. To achieve this, a systematic review was developed, taking into consideration how most previous studies defined PIR, the instruments used to measure this concept, the highlighted explanatory factors and the proposed strategies.

Second, by conducting a meta-analysis, we aimed to investigate the *psychological predictors of adherence* in diabetes and whether the present psychological interventions help people adhere to their treatment recommendations and have better diabetes outcomes. As the state of the literature did not allow for a single meta-analysis to answer to this first objective, two separate ones had to be designed.

Thus, the first meta-analysis was conducted to investigate the *association of between beliefs about diabetes and adherence* and the second to examine *the*

efficacy of psychological interventions for emotional, behavioral and biological outcomes involved in adherence.

Fourth, our next objective was to examine the role of *dysfunctional beliefs* and depression as predictors for the negative appraisal of insulin treatment. A cross-sectional design was created to test the association of these factors and the meditational quality of the dysfunctional beliefs factor in the depression – negative evaluation of insulin treatment relation.

Fifth, in order to gain a deeper understanding of the influence of dysfunctional beliefs in psychological insulin resistance, our further aim was to *construct a scale that measures specific functional and dysfunctional beliefs about insulin*, since in the literature the existent instruments do not use this approach. Items construction was analyzed by experts and a set of questionnaires was administered to test fidelity, validity and internal structure.

Sixth, the next objective was to *design an intervention that restructures dysfunctional beliefs about insulin* in order to enhance the acceptance rate of insulin treatment. A controlled clinical study was used as design, with two experimental groups: placebo and the active cognitive restructuring intervention.

CHAPTER THREE. ORIGINAL RESEARCH

META-ANALYTIC STUDIES

Study 1 - Psychological Insulin Resistance. A Critical Review of the Literature¹

Aims

The objective of this review was to conduct a critical review of the factors that account for PIR and of the available strategies to reduce it.

 Psychological Insulin Resistance. A Critical Review of the Literature
SPECIFIC OBJECTIVE: To investigate the factors that account for lack of adherence to insulin and the existent interventions to reduce it
METHOD: A critical review of the published literature
RESULTS: The factors that explain non-adherence to insulin are: emotional (anxiety about insulin, depression), cognitive (distorted beliefs about insulin consequences or treatment effects), social (influence from the health care team or from peers, stigma about insulin use Educational and psychological strategies to improve adherence are suggested, but no RCT intervention to test them has been designe yet.
PRACTICAL IMPLICATIONS: RCT interventions are much needed to guide
clinicians which of the proposed interventions are more efficient in facilitating adherence to insulin regimens.
FURTHER INVESTIGATION: As most explaining factors were found to be of a
cognitive nature, we set out to investigate other beliefs that promote adherence in diabetes and that could guide us in a deepe further analysis.

Figure 2. First Study Summary

¹ Parts of this chapter were published:

Gherman, A., Veresiu, I.A., Schnur, J.B., Scheckner, B.A., Montgomery, G.H. (2011). Psychological Insulin Resistance. A Critical Review of the Literature. *Practical Diabetes International*, Volume 28, Issue 3, 125-128; doi: 10.1002/pdi.1574

The authors have contributed to the article as follows:

Gherman, A.: study design, conducting the study, analyses and results interpretation, writing the manuscript Veresiu, I.A.: results interpretation, consultation for writing the manuscript from the medical perspective Sassu, R.A.: implementing the search strategy

Schnur, J.B.: results interpretation, re-organizing the results presentation

Scheckner, B.A.: doubled the search process, English proofed the manuscript

Montgomery, G.H.: consultation for the exposition of the manuscript.

Method

Medline, PubMed, Cochrane reviews, PsycInfo, ProQuest, Science Direct, EBSCO data bases were searched and 60 studies were included in the final review. Topics reviewed included: PIR definition across studies, research methods, instruments to assess PIR, PIR in patients and in the medical care team, and proposed strategies for overcoming it.



Figure 3. Flow Diagram of Included Studies

Results

The results point out that a large number of factors account for PIR in patients (see Figures 2a and 2b). The main categories are emotional (Karter et al., 2010; Khan, Lasker, & Chowdhury, 2008; Larkin et al., 2008; Sharma, Yeo, & Garber, 2008), cognitive (Bogatean & Hâncu, 2004; Makine et al., 2009a; Nakar, Yitzhaki, Rosenberg, & Vinker, 2007), social/cultural (Campos, 2007; Funnell, 2008), and interaction with health providers (Bogatean & Hâncu, 2004; Hayes, Fitzgerald, &

Jacober, 2008; Korytkowski, 2002; Oliveria et al., 2007). Physicians mainly delay insulin because they lack knowledge on guidelines or pancreas physiology, they fear inducing hypoglycemia in elderly or impaired patients, and/or they lack time or personnel resources to teach initiation.

Strategies proposed to reduce PIR are educational and psychological (exposure, desensitization, relaxation and counseling), however, no intervention study tested the efficacy of any of these proposed strategies (Jenkins, Hallowell, Farmer, Holman, & Lawton, 2010; Joy, 2008).

What are the factors that account fo	r non-adherence to insulin?
Insulin Naïve Patients Lack of knowledge Fear of needles or injection pain Fear of hypoglycemia Fear of weight gain Daily interference with activities Diabetes is seen as worse or more serious Personal failure Believing that insulin	Patients Who Already Have an Insulin Treatment Weight management Eating disorders Interference with life Pain/bruising Social stigma Depression
causes complications Diabetes is NOT regarded as serious enough	Health Care Providers
Dependence Low self-efficacy Insulin will not be effective Relationship with the health care team Social stigma Depression Believing that good glycemic levels	Knowledge not in accordance with guidelines and protocols Fear of hypoglycemia in type 2 diabetes patients that are old, with serious comorbidities Lack of time and/or personnel

Figure 4. First Study Overall Summary Results

can be achieved otherwise Physician recommendation

Discussion

In conclusion, there is a great need of evidence-based interventions that help remove psychological barriers about insulin use in patients, as well as in health care providers. The practical implications of this review regard the dissemination of most efficient techniques towards diabetes educators and physicians in order to influence more patients.

to teach insulin initiation

Study 2 - How are Adherent People More Likely to Think? A Meta-analysis of Health Beliefs and Diabetes Self-Care²

Aims

Diabetes is increasingly prevalent, and non-adherence with diabetes treatment regimens is associated with physical and social costs (Rosenblum & Kane, 2003). Psychological predictors of adherence have been investigated in the literature, including cognitive factors. The first meta-analysis was conducted to investigate the association of between beliefs related to diabetes and adherence to diabetes regimens.

How are Adherent People More Likely to Think? 2 A Meta-analysis of Health Beliefs and Diabetes Self-care SPECIFIC OBJECTIVE: To investigate the factors that are associated with adherence in diabetes. **METHOD:** A meta-analysis of the published literature **RESULTS:** A large correlational effect was found for self-efficacy beliefs and adherence, and a medium one for relationship with the health care provider, beliefs about adherence per se and about treatment. **PRACTICAL IMPLICATIONS:** The instillation of these types of beliefs in order to improve adherence to insulin use could be further tested FURTHER INVESTIGATION: The effectiveness of existent psychological interventions for adherence to diabetes self-management, distress and medical outcomes



Method

Studies that both: a) measured beliefs, perceptions or cognitions about diabetes, and b) measured the relationship between such cognitive factors and blood glucose levels or other adherence behaviors were included. This research

The authors have contributed to the article as follows:

² Parts of this chapter are in press:

Gherman, A., Schnur, J.B., Montgomery, G.H., Veresiu, I.A. & David, D. (2011). How Are Adherent People More Likely to Think? A Meta-analysis of Health Beliefs and Diabetes Self-care. *The Diabetes Educator*, Volume 37, Number 3. (Published online first - doi: 10.1177/0145721711403012)

Gherman, A.: study design, conducting the study, analyses and results interpretation, writing the manuscript Schnur, J.B.: results interpretation, re-writing parts of the manuscript according to feedback, doubling the search process

Montgomery, G.H.: decision-making on the inclusion criteria, re-organizing the results presentation, consultation for the writing of the manuscript

Sassu, A.R.: results interpretation, data verification

Veresiu, I.A.: results interpretation, consultation for writing the manuscript from the medical perspective David, D.: study design, methodology, consultation for exposition of the manuscript

focused on adults with any type of diabetes, reaching a final sample of 48 studies.





Figure 6. Flow Diagram of Included Studies According to PRISMA Guidelines

Results

The types of beliefs most strongly associated with adherence were selfefficacy, perceiving a positive relationship with physician and beliefs about the personal consequences of adherence.

ES r for All	Beliefs an	d All Outcomes
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Model	Study name	ADHERENCE	Statistics for		s for eac	h study			Co	Correlation and 95% Cl		
		с	orrelation	Lower limit	Upper limit	Z-Value	p-Value					
	Pevrot 2010	insulin	0.140	0.053	0.225	3 148	0.002		1	1-86-		- I
	Morowatisbarifabad 2010	self-care behaviors	0.140	-0.020	0.330	1 746	0.081				_	
	Williams 2009	self-care behaviors + 410	0.100	0.020	0.000	6 357	0.000					
	Sloan 2009	A1C	0.310	0.254	0.364	10 292	0.000					
	Moreau 2009	self-care behaviors	0.123	0.006	0.238	2 057	0.040					
	Mann 2009	self-care behaviors	0.410	0.268	0.535	5 200	0.000				_■↓	
	Lerman 2009	diet + insulin	0.400	0.039	0.669	2 160	0.031					
	Lee 2009	self-care behaviors + A10	0.240	0.154	0.323	5 346	0.000					
	Julien 2009	diet	0.420	0.332	0.501	8 518	0.000					
	Daly 2009	self-care behaviors + A10	0.420	0.007	0.249	2 067	0.000					
	Aikops 2009	modication	0.100	0.007	0.120	1.600	0.000					
	Chai 2009	medication	0.000	0.003	0.123	2.276	0.003				_	
	White 2007	self-care behaviore	0.130	-0.027	0.343	1 797	0.023					
	Searle 2007	solf care behaviors	0.080	0.074	0.201	1.017	0.072					
	Searce, 2007	sen-care behaviors	0.060	-0.074	0.230	0.212	0.009					L
	Sacco, 2007	sen-care benaviors	0.740	0.035	0.018	9.313	0.000					r
	Euroton 2007	comic attenuance	0.040	-0.170	0.202	0.300	0.719					
	Puerles, 2007	self-care behaviors	0.040	-0.142	0.219	0.429	0.000				_	
	Bean, 2007	sen-care benaviors + A IC	0.155	-0.058	0.354	2.002	0.152					
	Symons, 2006	exercise	0.000	0.223	0.700	3.092	0.002					· •
	Sacco, 2005	self-care benaviors	0.440	0.200	0.630	3.438	0.001					
	Rubin, 2006	self-care behaviors	0.360	0.336	0.384	26.918	0.000					
	Peyrot, 2005	exercise + giucose monit	. 0.040	-0.003	0.083	1.813	0.070					
	Hill-Briggs, 2005	medication	0.150	0.000	0.293	1.965	0.049				_	
	Farmer, 2005	self-care behaviors	0.190	0.012	0.356	2.089	0.037					
	Chao, 2005	medication	0.230	0.140	0.316	4.924	0.000					
	Vincze, 2004	glucose monitoring	0.060	-0.075	0.193	0.871	0.384					
	Tan, 2004	self-care behaviors	0.430	0.277	0.562	5.142	0.000					
	Syrjala, 2004	self-care behaviors + A10	0.265	0.109	0.408	3.280	0.001					
	Barnes, 2004	diet + medication	0.170	-0.036	0.362	1.620	0.105					
	McKean-Skaff, 2003	self-care behaviors + A10	0.150	0.007	0.287	2.061	0.039					
	Daniel, 2002	A1C	0.020	-0.320	0.356	0.111	0.911					
	Schoenfeld, 2001	eye care	0.060	0.019	0.101	2.884	0.004					
	Senecal, 2000	diet	0.080	0.002	0.157	2.020	0.043					
	Hampson, 2000	self-care behaviors + A10	0.255	0.068	0.424	2.659	0.008					
	Peyrot, 1999	A1C	0.260	0.083	0.421	2.854	0.004					.
	Kneckt, 1999	self-care behaviors	0.760	0.679	0.823	11.532	0.000				*	-
	Garay-Sevilla, 1998	diet + medication	0.420	0.281	0.541	5.538	0.000			_ I _		
	Glasgow, 1997	self-care behaviors	0.210	0.168	0.251	9.659	0.000					
	White, 1996	A1C	0.220	0.014	0.408	2.086	0.037					
	Tillotson, 1996	self-care behaviors	0.180	0.095	0.262	4.138	0.000				· I	
	Pham, 1996	self-care behaviors	0.110	-0.118	0.327	0.944	0.345				- 1	
	Anderson, 1993	self-care behaviors	0.050	-0.007	0.107	1.716	0.086					
	Polly, 1992	self-care behaviors + A10	0.120	-0.076	0.307	1.200	0.230					
	Aikens, 1992	self-care behaviors + A10	0.260	0.011	0.479	2.044	0.041					
	Padgett, 1991	self-care behaviors + A10	0.210	0.050	0.360	2.558	0.011					
	McCaul, 1987	self-care behaviors	0.210	-0.005	0.406	1.919	0.055					
	Brownlee-Duffeck, 1987	self-care behaviors + A10	0.155	-0.009	0.311	1.849	0.064				-	
	Harris, 1985	self-care behaviors + A10	0.155	-0.050	0.348	1.482	0.138			-	- 1	
Randon	n effects model ESr		0.225	0.177	0.271	9.098	0.000			I ●		
								-1.00	-0.50	0.00	0.50	1.00
								lower adh	erence		higher ad	herence

Note: the diamond is the graphic representation of ES r

ES r for A1C

lodel Study name	ADHERENC	E Statisti	cs for e	ach stud	iy		с	orrelation and	95% CI		Weight (Fi	ked)
		Lower Correlationlimit	Upper limit	Z-Valuep	-Value						Relative weight	Relative weight
Williams, 2009	A1C	-0.110 -0.153	-0.067	-4.982	0.000	1		# 1		- I	34.63	8.50
Sloan, 2009	A1C	-0.310 -0.364	-0.254	-10.292	0.000			_			17.54	8.23
Lee, 2009	A1C	-0.100 -0.188	-0.011	-2.191	0.028		_				8.12	7.65
Daly, 2009	A1C	-0.160 -0.278	-0.037	-2.552	0.011						4.25	6.84
Aikens, 2009	A1C	0.066 -0.003	0.135	1.881	0.060						13.61	8.07
Bean, 2007	A1C	-0.130 -0.333	0.084	-1.191	0.234						1.41	4.72
Syriala, 2004	A1C	-0.190 -0.340	-0.030	-2.324	0.020						2.48	5.90
McKean-Skaff, 2003	A1C	-0.190 -0.324	-0.049	-2.623	0.009			-			3.16	6.35
Daniel, 2002	A1C	-0.020 -0.356	0.320	-0.111	0.911			_	_		0.53	2.65
Hampson, 2000	A1C	-0.260 -0.429	-0.074	-2.714	0.007						1.77	5.21
Peyrot, 1999	A1C	-0.260 -0.421	-0.083	-2.854	0.004			- I			1.96	5.42
White, 1996	A1C	-0.220 -0.408	-0.014	-2.086	0.037						1.48	4.82
Polly, 1992	A1C	-0.090 -0.280	0.106	-0.898	0.369						1.68	5.10
Aikens, 1992	A1C	-0.400 -0.591	-0.167	-3.254	0.001		_	_			1.00	3.97
Padgett, 1991	A1C	-0.020 -0.181	0.142	-0.240	0.810			_			2.45	5.87
Brownlee-Duffeck, 1987	A1C	-0.110 -0.269	0.055	-1.307	0.191						2.38	5.82
Harris, 1985	A1C	-0.150 -0.343	0.055	-1.434	0.152						1.53	4.90
ndom effects model ESr		-0.154 -0.220	-0.086	-4.421	0.000	1		+				
						-1.00	-0.50	0.00	0.50	1.00		
						higher ad	herence		lower a	dherence		

Note: the diamond is the graphic representation of ES r

Figure 7. Summary of ES

Model	Study name	ADHERENCE	5	Statistics	for each	study			с	orrelation and 95%	сі	Weight (I	Fixed)
			Correlation	Lower limit	Upper limit	Z-Value	p-Value					Relative weight	Relative weight
	Peyrot, 2010	insulin	0.140	0.053	0.225	3.148	0.002	1	1		1	2.23	2.64
	Morowatisharifabad, 2010	self-care behaviors	0.160	-0.020	0.330	1.746	0.081					0.52	2.15
	Williams, 2009	medication	0.160	0.117	0.202	7.280	0.000			- I. 🖷 -		9.11	2.79
	Moreau, 2009	self-care behaviors	0.123	0.006	0.238	2.057	0.040					1.23	2.50
	Mann, 2009	self-care behaviors	0.410	0.268	0.535	5.299	0.000				-∰i÷	0.66	2.27
	Lerman, 2009	diet + insulin	0.400	0.039	0.669	2.160	0.031					0.12	1.16
	Lee, 2009	self-care behaviors	0.370	0.290	0.445	8.483	0.000					2.14	2.63
	Julien, 2009	diet	0.420	0.332	0.501	8.518	0.000					1.62	2.57
	Daly, 2009	self-care behaviors	0.100	-0.024	0.221	1.586	0.113				_	1.12	2.47
	Aikens, 2009	medication	0.062	-0.007	0.130	1.751	0.080					3.58	2.71
	Choi, 2008	medication	0.190	0.027	0.343	2.276	0.023					0.63	2.24
	White, 2007	medication	0.130	-0.012	0.267	1.797	0.072					0.85	2.37
	Searle, 2007	medication	0.080	-0.074	0.230	1.017	0.309				_	0.72	2.30
	Sacco, 2007	medication	0.740	0.635	0.818	9.313	0.000			L		0.43	2.04
	Lawson, 2007	clinic attendance	0.040	-0.176	0.252	0.360	0.719					0.36	1.94
	Fuertes, 2007	self-care behaviors	0.040	-0.142	0.219	0.429	0.668					0.51	2.14
	Bean, 2007	self-care behaviors	0.180	-0.033	0.377	1.658	0.097				- L	0.37	1.96
	Symons, 2006	exercising	0.550	0.223	0.766	3.092	0.002					0.11	1.14
	Sacco, 2005	self-care behaviors	0.740	0.592	0.840	6.920	0.000				_ ━━	0.24	1.66
	Rubin, 2006	self-care behaviors	0.360	0.336	0.384	26.918	0.000			L		22.84	2.82
	Peyrot, 2005	exercising + mon	0.040	-0.003	0.083	1.813	0.070					9.19	2.79
	Hill-Briggs, 2005	meds	0.150	0.000	0.293	1.965	0.049					0.76	2.32
	Farmer, 2005	self-care behaviors	0.190	0.012	0.356	2.089	0.037				-	0.53	2.16
	Chao, 2005	medication	0.230	0.140	0.316	4.924	0.000					1.98	2.62
	Vincze, 2004	monitor	0.060	-0.075	0.193	0.871	0.384				_	0.94	2.41
	Tan, 2004	self-care behaviors	0.430	0.277	0.562	5.142	0.000					0.56	2.19
	Syrjala, 2004	self-care behaviors	0.340	0.190	0.475	4.279	0.000					0.65	2.26
	Barnes, 2004	diet + medication	0.170	-0.036	0.362	1.620	0.105				-	0.40	2.00
	McKean-Skaff, 2003	exercising	0.110	-0.033	0.249	1.506	0.132					0.83	2.36
	Schoenfeld, 2001	eye care	0.060	0.019	0.101	2.884	0.004			12		10.32	2.79
	Senecal, 2000	diet	0.080	0.002	0.157	2.020	0.043					2.84	2.68
	Hampson, 2000	diet	0.250	0.063	0.420	2.605	0.009					0.47	2.09
	Kneckt, 1999	self-care behaviors	0.760	0.679	0.823	11.532	0.000					0.60	2.22
	Garay-Sevilla, 1998	diet + medication	0.420	0.281	0.541	5.538	0.000					0.69	2.28
	Glasgow, 1997	self-care behaviors	0.210	0.168	0.251	9.659	0.000					9.19	2.79
	Tillotson, 1996	self-care behaviors	0.180	0.095	0.262	4.138	0.000					2.31	2.65
	Pham, 1996	self-care behaviors	0.110	-0.118	0.327	0.944	0.345					0.33	1.88
	Anderson, 1993	self-care behaviors	0.050	-0.007	0.107	1.716	0.086					5.27	2.75
	Polly, 1992	self-care behaviors	0.150	-0.046	0.335	1.504	0.133					0.44	2.06
	Aikens, 1992	self-care behaviors	0.120	-0.134	0.359	0.926	0.354					0.26	1.74
	Padgett, 1991	self-care behaviors	0.400	0.255	0.528	5.084	0.000					0.64	2.25
	McCaul, 1987	self-care behaviors	0.210	-0.005	0.406	1.919	0.055					0.36	1.94
	Brownlee-Dutfeck, 1987	self-care behaviors	0.200	0.037	0.353	2.399	0.016					0.63	2.24
_	Hams, 1985	self-care behaviors	0.160	-0.045	0.352	1.531	0.126				- 1	0.40	2.01
Random	effects model ESr		0.241	0.189	0.291	8.917	0.000	1.00	1	I –	1		
								-1.00	-0.50	0.00	0.00	.00	
Note: the o	liamond is the graphic repre	sentation of ES r						lov	ver adherence		higher adherence		

ES r for Self-care Behaviors

Figure 8. Summary of ES

Table 1

Summary Data of ES for Types of Beliefs

Reliefs	Number	OT F	Sr	95% Confidence	n
Dellets	studies		.51	Interval	þ
Illness beliefs	1/		na	05 - 14	n-0.000
lilless beliefs	14		09	.0514	p=0.000
Treatment beliefs	15	•	16	.1418	p=0.000
Adherence beliefs	18		19	.1424	p=0.000
Self-efficacy beliefs	13	.4	42	.2755	p=0.000
Locus of control beliefs	9	.(09	.0414	p=0.000
Perception of relationship with	8		20	.0732	p=0.002
health care provider					
Coping strategies	4		22	.1530	p=0.000

What are the cognitive factors (beliefs, attitudes, perceptions) associated with adherence in diabetes?

Effect on Outcomes	ES r						
Glycemic control	- 1 0						
Taking medication or insulin	(95% Cl22 to8) .17 (95% Cl .11 to .23)						
Diet	0.18 0 (95% Cl .11 to .25)						
Exercise	0 (95% CL 04 to 17)						
Glucose monitoring	0 (95% CL 03 to 18)						
Types of Beliefs	ES r						
Types of Beliefs Self-efficacy beliefs	ES r .42						
Types of Beliefs Self-efficacy beliefs Perception of relationship with physician	ES r .42 0 (95% CI .27 to .55) .20 0 (95% CI .07 to .32)						
Types of Beliefs Self-efficacy beliefs Perception of relationship with physician Beliefs about adherence	ES r .42 0 (95% CI .27 to .55) 20 0 (95% CI .07 to .32) .19 0 (95% CI .07 to .32) 1 (95% CI .14 to .24)						
Types of Beliefs Self-efficacy beliefs Perception of relationship with physician Beliefs about adherence Beliefs about treatment	ES r .42 0 (95% CI .27 to .55) 20 0 (95% CI .07 to .32) 19 0 (95% CI .07 to .32) 19 0 (95% CI .14 to .24) .16 0 (95% CI .14 to .18)						

RESULTS (48 studies)

Note: ES r of .10 is small, .30 is medium and .50 is large (Cohen, 1988).

Figure 9. Second Study Overall Summary Results

Discussion

People that are more adherent have a higher level of confidence in their ability to follow medical recommendations, expect more meaningful positive consequences for adherence, and perceive a more positive relationship with their health care provider. Educators and clinicians could employ cognitive restructuring techniques in order to facilitate these types of beliefs and perceptions in people with diabetes.

Study 3 - Are Psychological Interventions Effective in Diabetes Care? A Meta-

analysis

Aims

Several studies have investigated the effect of psychological interventions in diabetes management and the aim of this study was to conduct a meta-analysis in order to find out their general impact (Alam et al., 2009; Winkley, Ismail, Landau, & Eisler, 2006).

3 Are Psychological Interventions Effective in Diabetes Care? A Meta-analysis
SPECIFIC OBJECTIVE: To investigate the psychological and medical efficacy of
psychological interventions in diabetes care.
METHOD: A meta-analysis of the published literature.
RESULTS: The impact of the psychological interventions on glycemic control is
medium, whereas the impact on adherence behaviors, blood
pressure and emotional distress is small.
PRACTICAL IMPLICATIONS: The content or structure of the psychological
interventions could be improved in order to achieve better medical,
behavioral and distress outcomes.
FURTHER INVESTIGATION: A deeper analysis of the cognitive factors that
influence adherence is needed in order to possibly augment the
efficacy of the existent interventions. The Cognitive Therapy
background could offer valuable predictors of adherence behaviors
(e.g. taking insulin).

Figure 10. Third Study Summary

Method

Databases were searched for studies that were randomized clinical trials and that investigated the effect of any kind of psychological intervention on the biological outcomes in diabetes, such as glycemias, blood lipids, blood pressure, weight loss, etc. Seventeen studies satisfied the inclusion criteria and were introduced in the meta-analysis.



Figure 11. Inclusion Flow-chart according to PRISMA guidelines

Results

Randomized clinical trials investigated cognitive-behavioral interventions (CBT) in the "active" group; no other forms of psychotherapy were tested. The results show that CBT applied to help people become more adherent has a medium effect, similar to a reduction of about .57% in glycated hemoglobin, which is comparable to the effect that some medications have (except insulin).

Discussion

Thus, CBT techniques are very helpful as facilitators of medical interventions in type 2 diabetes. However, a worldwide problem is that adherence targets in diabetes are far from being met and thus more effective interventions are needed to help people with diabetes perform daily self-care behaviors and face the burden of a lifetime treatment.



ES=-.61 (95% CI: -.7; -.5); St. error=.06 Follow-up ES=-.32 (95% CI: -.53; -.11); St. error=.11

Effect size for BMI



Follow-up ES=.17 (95% CI: -.04; .38); St. error=.11



ES=-.33 (95% CI: -.47; -.19); St. error=.07 Follow-up ES=-.14 (95% CI: -.32; -.04); St. error=.09

Figure 12. Effect size for Medical and Psychological Variables

Effect size for Adherence Behaviors



ES=.19 (95% CI: .03; .35); St. error=.08 Follow-up ES=.11 (95% CI: -.03; .25); St. error=.07





Note: ES d of .2 is small, .5 is medium and .8 is large (Cohen, 1988).

Figure 13. Second Study Overall Summary Results

FUNDAMENTAL RESEARCH

Study 4 - Depression and Dysfunctional Beliefs. Predictors of Insulin Treatment

Aims

Insulin treatment refusal is a serious public health concern as it prevents people with diabetes from taking insulin, which is one of the most effective treatments available and thus exposes them to high glycemia levels and the risk of developing complications (Brod et al., 2009). This study aimed to investigate the relation between depression (Makine et al., 2009) and dysfunctional beliefs about life in general (derived from the theoretical background of cognitive therapies -Alford & Beck, 1998; Butler, Chapman, Forman, & Beck, 2006; David, Lynn, & Ellis, 2009; David, Montgomery, Macavei, & Bovbjerg, 2005; Ellis, 1994) on one hand, and a negative appraisal of insulin on the other hand.



Figure 14. Fourth Study Summary

Method

The hypotheses were that a higher level of depression symptoms and of general dysfunctional beliefs are associated with a more negative view of insulin and that the general dysfunctional beliefs mediate this relation. 406 people with type 1 and type 2 diabetes, with a mean age of 57 years and evenly distributed among genders, agreed to participate in the study. A cross-sectional design was used and a set of questionnaires was administered to evaluate: negative appraisal of insulin treatment, depression symptoms, dysfunctional beliefs.

Results

Data showed that a higher level of depression is more related to negative insulin appraisal and, of the general dysfunctional beliefs, thinking that one cannot tolerate difficult situations is also more associated with a negative view of insulin.

Table 2

Matrix of Correlations

Pearson Correlation (r)	Negative	Appraisal	of	Depression symptoms
	Insulin Trea	tment		
Negative Appraisal of	1			.32**
Insulin Treatment	N=215			N=102
Depression symptoms	.32**			1
	N=102			N=111
Demandingness towards	.29*			.29*
self	N=105			N=105
Low frustration tolerance	.33*			.53**
	N=105			N=105

Note: ** Correlation is significant at the .01 level; * Correlation is significant at the .05 level.

Depression and Dysfunctional Beliefs -Predictors of Negative Appraisal of Insulin Treatment



Mediational diagrams for models testing the interrelations among depression, low frustration tolerance, absolute demands and negative appraisal of insulin treatment. Note: Mediational diagrams are presented according to the "best-fit" of the data. Values presented are standardized parameter estimates. Values above lines reflect bivariate relations; values below lines reflect multivariate relations accounting for other predictors in the regression equation. NS = non significant

Figure 15. Fourth Study Overall Summary Results

Discussion

At the same time, a limit of this study is that general dysfunctional beliefs may not highlight correctly how people who view insulin in a negative manner think. Therefore, a more specific instrument, that measures specific dysfunctional beliefs about insulin treatment, may bring more accurate results. The practice implications of these findings are that clinical psychologists or diabetes educators could help people with diabetes accept insulin easier by restructuring the belief that one cannot face difficult events and by referring them for a depression treatment.

Study 5 - Measuring Psychological Insulin Resistance from the Cognitive Therapy perspective: Development of the Beliefs about Insulin Scale (BIS)

Aims

Despite the fact that a large number of studies have found cognitive factors to contribute to psychological insulin resistance, there currently exists no PIR questionnaire derived from the theoretical background of cognitive therapies. Therefore, the aim of this study was to *construct a scale that measures functional and dysfunctional beliefs about insulin (BIS)*.





Method

Items were constructed according to the cognitive therapy theories (e.g., Beck, Ellis) and were then analyzed by experts. The BIS and comparator measures (e.g., measures of general functional and dysfunctional beliefs) measures were administered to a sample of 356 patients with diabetes to test the fidelity, validity, and internal structure of the scale.

Results

The BIS has strong psychometric properties for the dysfunctional items: high reliability and adequate content and construct validity, supported by both moderate associations with other PIR and beliefs measures and factor analysis for internal structure.

Table 3

Exploratory Factor Analysis

		Factor loadings			
Type of belief	Item	Dysfunctional	Functional		
Dysfunctional					
Taking insulin is awful	21	.749 ^a	139		
Terrible even if glycemias are lower	12	.724 ^a	114		
Will bring more problems	22	.719 ^a	093		
Cannot stand injecting	18	.717 ^a	215		
Being in the final stage	4	.706 ^a	016		
Cannot stand the idea	3	.687 ^ª	187		
Nothing worse than insulin	6	.660 ^ª	245		
Being a weak person	5	.650 ^ª	.007		
Bad things will follow	8	.626 ^ª	176		
Being less of a person	13	.538 ^ª	106		
Must not take insulin	14	.523 ^ª	458		
Could become blind/require amputation	20	.518 ^ª	008		
Should never take insulin	1	.445 ^a	263		
Being the only one at fault	16	.238 ^ª	.042		
Functional					
Unfortunate, but can bear it	11	239	.715 ^b		
Wishing one did not need insulin	10	011	.655 ^b		
Preferring not taking insulin	19	.084	.652 ^b		
Hard to inject, but could manage	7	.061	.579 ^b		
There are worse situations	15	080	.573 ^b		
Would not make one inferior	9	154	.472 ^b		
It's not the worst thing	2	150	.402 ^b		
Would be just as valuable	17	238	.304 ^b		

Notes: ^a = loadings on the dysfunctional beliefs factor, ^b = loadings on the functional beliefs factor

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Rotated Component Matrix (rotation converged in 3 iterations).

Dysfunctional beliefs about insulin treatment					Total	
	Should	lť's	Can't	Feeling less	Incorrect	
	not take	awful	stand	of a person	assumptions	
	it		it			
General dysfunct	ional beliefs	5				
Total ABS II	-	.28	.27	.30	.33	.33
Total SPB	-	.26	.22	-	.24	.23
Shoulds (ABS II)	.19	.20	.30	-	-	.25
Shoulds (SPB)	.27	.25	.22	-	.22	.24
Awfulising (ABS	-	.23	-	-	.25	.21
II)						
Awfulising (SPB)	-	-	-	-	-	-
Can't tolerate	-	-	-	.33	.33	.29
(ABS II)						
Can't tolerate	-	-	-	-	.23	.20
(SPB)						
Global	-	.21	-	.20	.21	.21
evaluation (ABS						
II)						
Global	-	.27	-	.27	.24	.26
evaluation (SPB)						
Incorrect	-	.19	-	.37	.38	.32
assumptions						
(ATQ)						

Table 4Correlations with Validity Check Measures

PIR measure (ITAS) - negative appraisal of insulin

	.41	.63	.53	.55	.64	.71
Realistic beliefs about insulin treatment To						Total
	Prefer	Not the	worst	Can	Self-	
	not take	thi	ng	manage	acceptance	
	it					
General functional beliefs (ABS II)						
	.38	.2	5	-	-	.43
Preferences	.30	.2	3	-	-	.31
Could be worse	.42	.4	2	-	.29	.40
Can tolerate	-	.2	3	-	.25	.23
Self-acceptance	.31	-		-	.30	.33
PIR measure (ITAS) - positive appraisal of insulin						
	-	.1	6	-	-	

Note: all correlations (r Pearson) are significant at an alpha level of p≤.05; df=379

Beliefs about Insulin Scale

SUBSCALES

Demandingness; Awfulizing	2 items
Low frustration tolerance; Self-downing	each
Cognitive distorsions - 6 items	

14 items = specific dysfunctionality score

Preferences; Non-awfulizing	2 items
High frustration tolerance; Self-acceptance	each

8 items = specific functionality score

Scored on a Likert scale of 1 to 5. High scores show high levels of dysfunctionality/ functionality. A **total score** is computed by summing up:

- the dysfunctional items scored directly and

- the functional ones scores in reverse.
- A high total score = high level of dysfunctional beliefs

about insulin.

PSYCHOMETRIC PROPERTIES

Cronbach Alpha < .88 for dysfunctional items

Construct validity:

- 1. Dysfunctional and functional general beliefs measures: modest to moderate correlations (they measure the same construct, but they do not overlap).
- 2. Psychological insulin resistance measures: large correlations.
- 3. Theoretical structure: Exploratory Factor Analysis - there were two main factors corresponding to the functional and dysfunctional worded items and all the items were loaded on the factor that they were expected to.

Figure 17. Fifth Study Overall Summary Results

Discussion

From a practical point of view, the scale could be used to offer guidelines as to which patient beliefs clinicians should restructure to promote insulin adherence.

APPLIED RESEARCH

Study 6 - Cognitive Restructuring for Psychological Insulin Resistance. A Randomized Clinical Intervention

Aims

Based on the data of the previous studies, a very important "active" ingredient of this intervention was cognitive restructuring and we set out to investigate the efficacy of a psychological intervention in the reduction of the percentage of people with diabetes that refuse insulin treatment.

(6) Cu	ognitive Restructuring for Psychological Insulin Resistance. A Randomized Clinical Intervention
SPECIFIC O I i i	BJECTIVE: To test the efficacy of a cognitive restructuring ntervention, based on the data of the previous study, in order to ncrease the percentage of people who accept insulin therapy.
METHOD: 1 k l t	The intervention protocol included restructuring dysfunctional beliefs such as: absolute demands about starting insulin, awfulizing ow frustration tolerance, self-downing and expectancies to accept his treatment. In a randomized clinical study, these techniques were compared to a control group (placebo – where patients were
e RESULTS: TI (a	encouraged to share their emotions and views about insulin) he cognitive restructuring intervention had a success rate of 40% 12 participants out of 30) in convincing patients to accept insulin, as compared to the placebo which was only 16.1% effective
(PRACTICAL a th d	IMPLICATIONS: The practical impact of this study is quite high, s for about 40% of the people with diabetes who accepted insulin he personal and social costs of possible future complications could ecrease.

Figure 18. Sixth Study Summary

Method

Thus, we employed an experimental design, with two groups: experimental and placebo, to which the patients were assigned in a randomized manner. The first step in the study procedure was patients being referred to counseling by the specialist Diabetologist, after they had refused insulin treatment at least once. The patients that accepted to participate signed an informed consent. The counseling session, active or placebo, lasted about 30 minutes. The active intervention protocol was performed in the framework of motivational interviewing and included restructuring dysfunctional beliefs such as: absolute demands about starting insulin, awfulizing, low frustration tolerance, selfdowning and expectancies to accept this treatment and also medical education about diabetes progression and the role of insulin. In the placebo group patients were encouraged to share their emotions and views about insulin and then counseling about dietary guidelines was offered.

Results

The active intervention had a success rate of 40% (12 out of 30 patients), compared to the placebo intervention -16.6% (5 out of 30).

Discussion

Thus, the cognitive restructuring techniques, combined with motivational interviewing and medical education, seem efficient in reducing psychological insulin resistance. The practical impact of this study is quite high, as for about 40% of the people with diabetes who accepted insulin the personal and social costs of possible future complications could be decreased.



Figure 19. Sixth Study Overall Summary Results

CHAPTER FOUR.

GENERAL CONCLUSIONS AND DISCUSSIONS

In the first place, a comprehensive synthesis of the PIR studies was conducted, with a focus on the definitions used in the literature, on the instruments used to measure this construct and on the factors that were found to explain the opposition towards insulin use.

Further, two meta-analytic studies revealed the types of beliefs that are associated with a higher degree of adherence in diabetes self-care and also the efficacy of psychological interventions in improving biological, behavioral and distress outcomes relevant to this illness.

Theoretical Developments

The role of specific dysfunctional beliefs in discriminating between patients who accept and who refuse insulin treatment was investigated, revealing another piece of the puzzle in explaining psychological insulin resistance.

Methodological Developments

In order to measure these specific functional and dysfunctional beliefs about insulin a new instrument was constructed, an instrument that was not previously available in the literature and that presently proved to have good reliability and construct validity. It can be further used to identify specific beliefs about insulin that people have in order to guide a more targeted intervention.

Practical Implications

Perhaps the most salient implications of the present thesis are the practical outcomes: the designed intervention significantly reduced the number of patients that refused insulin treatment and thus it has the potential to facilitate reaching the glycemic targets of patients who are no longer served by oral medication in self-management. In the long run, it can help in reducing the number of people exposed to high glycemia levels and that can further develop life threatening complications. On the whole, the most important practical implication of the present research is reducing the number and gravity of diabetes related complications, such as heart problems, ulcerations/ amputations, renal failure, loss of sight.

29

DEVELOPMENTS

THEORETICAL

A systematic synthesis of Psychological Insulin Resistance.

Highlighting the types of beliefs that are associated with higher adherence Determining the impact of psychological interventions on self-care and medical outcomes.

Bringing into focus the specific dysfunctional beliefs about insulin that differentiate patients who accept from those who refuse insulin treatment.

METHODOLOGICAL

The construction of a specific instrument *Insulin Beliefs Scale* (it measures specific functional and dysfunctional beliefs about insulin treatment)

PRACTICAL

Designing and intervention that enhances acceptance of insulin treatment

Reducing the number of those who refuse insulin treatment by **40%**

Potential less exposure to high glycemia levels

Potentially less complications

Figure 20. Research Developments

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