USING AN ACT-BASED PROTOCOL
IN A SAMPLE OF ITALIAN DIABETIC PATIENTS

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INTRODUCTION

Diabetes is the most frequent human metabolic disease and a problem of great public health importance. It is caused by a low or inappropriate function of insulin − a hormone secreted by Langherans' beta cells. Hyperglycemia is the major sign of diabetes and is caused by a number of insulin dysfunctions. The most common types of diabetes are: type 1 - an autoimmune disorder, and type 2 - a form of insulin resistance. Diabetes needs a constant self-care in order to lower the risks of health complications: patients should do careful monitoring of hyperglycemia, observe a regular pharmacologic therapy and follow a proper diet.

Data from literature show that psycho-education helps to develop healthy behaviors and well-being, however, can not guarantee a persistent improvement in self-care (Gregg et al., 2007). Some studies highlighted the efficacy of ACT (Acceptance and Commitment Therapy; Hayes et al., 1999, 2012) in diabetes increasing psychological flexibility by using acceptance and mindfulness strategies together with commitment and coping strategies (Gregg et al., 2007; Massey et al., 2019; Nordally et al., 2017). ACT interventions seem to improve both medical and psychological symptoms by reducing stress levels (Zeinab et al., 2016; Norris et al., 2002) leading to a reduction of up to 1% of glycated hemoglobin levels (HbA_{1C}).

OBJECTIVES

This study is aimed at testing the ACT approach according to Gregg et al. (2007) *"Acceptance and Commitment Therapy for Diabetes Self-Management - Therapist Manual"*, in a sample of Italian diabetic type 2 patients. The hypothesis to be tested is that learning ACT skills mediates the improvement of glycated hemoglobin.

METHOD

Project
In this study we are going to use the ACT-based protocol elaborated by Gregg et al. (2007) for diabetic patients, as presented in *Acceptance and Commitment Therapy for Diabetes Self-Management-Therapist Manual*. The protocol has been translated and adapted for Italian clinical patients.

In February 2020, we started the enrollment process in the Metabolism and Diabetology Unit at University of Pisa, but we were forced to interrupt it because of lockdown due to the COVID19 pandemic.

Our project is designed to collect at least 30 patients with Type 2 diabetes, an age comprised between 18 and 70 and a duration of illness of at least 1 year.

Patients will be randomized in two groups: 1) complete ACT protocol (5 modules) and 2) psychoeducation (ADA Diabetes Education Manual, Callaghan et al., 2005). The two interventions will be provided during a 7-hours group workshop. The interventions are administered by a leader trained in ACT protocols and in diabetes processes, complications, and treatments.

The ACT intervention includes both psycho-education and ACT modules. The treatment is divided into 5 main modules:

I: Education and Information: patients are given information about diabetes, its complications, and the effects of high and low glucose on one's body. Functions of glucose and insuline are explained. Instructions on the management of glycemic levels and laboratory analyses are provided.

II: Education and information Food, Diabetes and Your health; information is provided about how to eat in order to prevent surges and dips in blood glucose.

III: Exercise and Diabetes: it provides education about the impact of exercise on blood glucose, and setting up an exercise routine suited for each person.

IV: Coping and Stress Management: it helps validating diabetes-related stress, and addresses avoidance of dysfunctional thoughts and feelings in diabetes, and how they may interfere with effective self-management.

V: Acceptance and Action: it focuses patients on moving in the direction of their values, integrating the didactic and acceptance elements of the treatment.

For each module, patients are also given a handbook with material after treatment.
This will be single-blind study: only the researcher doing the study knows which intervention the participant is receiving. Medical doctors responsible of medical care will be unaware of participants' treatment condition assignment until the end of follow-up.

Table 1. Sample description (n=30). Demographic and clinical characteristics of 30 patients with Type 2 Diabetes

	ACT (n=X)		Psychoeducation (n=X)		X2/p
GENDER	N	%	N	%	
Male					
Female					
	M	sd	M	sd	t/p
AGE (yrs)					
DURATION OF ILLNESS					
Glycemia					
HbA1c (baseline%)					

Instruments
Before the workshop and after 3 months (follow-up) patients will undergo the following evaluations:
- Levels of blood glucose
- Levels of glycated hemoglobin (HbA_{1C}). A sample of blood will be taken and send to the laboratory of the Diabetology Unit of the University of Pisa
- Acceptance and Action Diabetes Questionnaire (AADQ), is an 11-item Likert-type scale constructed from a widely used ACT process measure (the Acceptance and Action Questionnaire; Hayes et al., 2004). The AADQ measures acceptance of diabetes-related thoughts and feelings and the degree to which they interfere with valued action (e.g., "I avoid thinking about what diabetes can do to me.") and will be used to measure changes in ACT processes.
- Two subscales of the Diabetes Care Profile (DCP) will be analyzed to rate the understanding of diabetes and satisfaction with treatment.
- Self Management of diet, exercise and glucose monitoring is a three-item scale taken from Toobert et al. (2002).

Outcome Measures
Together with levels of glycemia, HbA_{1C} level represents the principal outcome measure. By measuring the number of glucose molecules attached to hemoglobin, laboratory assay of a single blood draw reveals the average blood glucose levels over the previous 2 to 3 months in the form of a percentage value. In non-diabetic subjects, HbA_{1C} remains at a value of about 5%. In diabetics, HbA_{1C} values that remain below or equal to 7% are considered to be indicators of good blood glucose control over time, while values above 8-9% relate to a high risk signal.

Secondary outcome measures are the scores of AADQ (Cronbach's, 1994) and of Diabethes Care Profiles (DCP; Fitzgerald et al, 1996), and Self Management (Toobert et al., 2002), which will be administered before the workshop (baseline) and after 3 months (follow-up).

RESULTS

This study is aimed at testing the ACT approach in a sample of Italian patients affected by type 2 diabetes. We expect that, compared with control group, in the group that will undergo the complete ACT protocol, glycemic levels will become significantly lower, as well as the HbA_{1C} levels, as a result of implemented exercise, more fit diet, and better drug management. Moreover, patients of the ACT group are expected to develop better self-management of the illness and higher levels of quality of life, as could result from scores of AADQ, DCP and Self Management scale.

Table 2. The effect of ACT treatment compared with psychoeducation in two groups of patients with Type 2 Diabetes

	ACT (n=X)		Psychoeducation (n=X)		X2/p
	Baseline	Baseline	Baseline	Baseline	
	M (sd)	M (sd)	M (sd)	M (sd)	t/p
Glycemia					
HbA1c (%)					
AADQ					
Understanding					
Self - Management					

REFERENCES

Callaghan, G. M., Gregg, J. A., Ortega, E., & Berlin, K. (2005). Psycho-social interventions with patients with type 1 and 2 diabetes. In W. T. O'Donohue, M Byrd, D. Henderson, & N. Cummings (Eds.), *Behavioral integrative care: Treatments that work in the primary care setting* (pp. 323–339). New York: Brunner-Routledge.

Dahl, J., Wilson, K. G., & Nilsson, A. (2004). Acceptance and commitment therapy and the treatment of persons at risk for long-term disability resulting from stress and pain symptoms: A preliminary randomized trial. *Behavior Therapy, 35*, 785–802.

Fitzgerald, J. T., Davis, W. K., Connell, C. M., Hess, G. E., Funnell, M. M. & Hiss, R. G. (1996). Development and validation of the Diabetes Care Profile. Evaluation of Health Professions, 19, 208–230.

Gregg, J. A., Callaghan, G. M., Hayes, S. C. & Glenn-Lawson, J. L. (2007). Improving diabetes self-management through acceptance, mindfulness, and values: A randomized controlled trial. Journal of Consulting and Clinical Psychology, 75(2), 336-343.

Gregg J. Callaghan GM, Hayes SC. Acceptance and Commitment Therapy for the Self-Management of Diabetes. Oakland, CA. New Harbinger Publications, 2007

Hayes, S. C., Strosahl, K. D., & Wilson, K. G. (1999). Acceptance and commitment therapy: An experiential approach to behavior change. New York, NY: Guilford.

Hayes, S. C., Strosahl, K. D., & Wilson, K. G. (2012). Acceptance and commitment therapy: The process and practice of mindful change. Second Edition. New York, NY: Guilford.

Luoma, J. B., Hayes, S. C., and Walser, R. D. (2017). *Learning ACT. An Acceptance and Commitment Therapy Skills Training Manual for Therapists. Second edition.* Oakland, CA: Context press.

Massey, C. N., Feig, E. H., Duque-Serrano, L., Wexler, D., Moskowitz, J. T., & Huffman, J. C. (2018). Well-being interventions for individuals with diabetes: A systematic review. *Diabetes research and clinical practice.*

Noordali, F., Cumming, J., & Thompson, J. L. (2017). Effectiveness of mindfulness-based interventions on physiological and psychological complications in adults with diabetes: a systematic review. *Journal of health psychology, 22*(8), 965-983.

Norris, Lau, Smith, Schmid e Engelgau (2002). Effectiveness of self management training in Type 2 diabetes: A systematic review of randomized controlled trials. *Diabetes Care, 24, 561-587.*

Shayeghian, Z., Hassanabadi, H., Aguilar-Vafaie, M. E., Amiri, P., & Besharat, M. A. (2016). A randomized controlled trial of acceptance and commitment therapy for type 2 diabetes management: the moderating role of coping styles. *PloS one, 11*(12).

Toobert, D. J., Glasgow, R. E., & Hampson, S. (2002). The summary of diabetes self-care activities measure: Results from seven studies and a revised scale. *Diabetes Care, 23*, 943–950.

https://www.sjsu.edu/people/jennifer.gregg/courses/c3/s1/ACT_ED_therapist_manual.pdf