



# Efficacy of the holistic, psychonutritional approach of *Centro DAI e Obesità di Città della Pieve* in the management of type 2 diabetes among patients with obesity and dysfunctional eating

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## Abstract

**Purpose** Dysfunctional eating is strongly associated with obesity and worsens type 2 diabetes (T2DM) outcomes. The aim of this study was to investigate the effectiveness of the psycho-nutritional treatment (PNT) of “*Centro DAI e Obesità*” of Città della Pieve on weight loss and glucose management in dysfunctional eaters with obesity and T2DM.

**Methods** PNT includes psychotherapeutical, nutritional, physical and social activities. Subjects with obesity, T2DM and dysfunctional eating habits who completed the 8 weeks residential program between 2010 and 2019 were compared with obese, T2DM, dysfunctional eaters who underwent to a conventional, hospital-based, nutritional treatment (CT). Anthropometric variables, glucolipid panel, and body composition were assessed at baseline and at the end of the program. Weight and HbA1c were also measured after one year from the completion.

**Results** Sixty-nine patients completed the PNT and reduced weight ( $-7 \pm 3.2\%$ ;  $p < 0.001$ ), BMI ( $-7 \pm 3.1\%$ ;  $p < 0.001$ ), and triglycerides, AST, GGT and ALT ( $p \leq 0.008$ ); glycemic control improved (HbA1c:  $-1.1 \pm 1.5\%$ , mean fasting glucose:  $-41 \pm 46$  mg/dl,  $p < 0.001$ ). Eleven% of subjects requiring diabetes medications at baseline discontinued the therapy. In the insulin treated group (49%), mean daily units were halved ( $-32.6 \pm 26.0$ ,  $p < 0.001$ ). At one year, weight loss ( $-6 \pm 7.4\%$ ,  $p < 0.001$ ) and HbA1c reduction ( $-0.52 \pm 1.4\%$ ,  $p = 0.029$ ) persisted. Fifty-five patients completed the CT: HbA1c reduced ( $p = 0.02$ ), but weight ( $-0.6 \pm 3.7\%$ ), BMI ( $-0.7 \pm 3.8\%$ ), and insulin units' reduction ( $-2.5 \pm 11.7$ ,  $p = 0.20$ ) were lower compared to the PNT.

**Conclusion** PNT is effective in improving T2DM management in patients with obesity and dysfunctional eating.

**Keywords** Binge eating disorder · T2DM · Obesity · Dysfunctional eating · Psychotherapy · Nutrition

**Level of evidence:** Level IV.

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## Introduction

Dysfunctional eating, an excessive and non-homeostatic feeding behaviour, is strongly associated with overweight and obesity, risk factors for the development of insulin resistance, metabolic syndrome, and type 2 diabetes (T2DM). The term “diabesity” describes the pathophysiological link between T2DM and obesity/overweight, which leads to severe clinical complications, decreases quality of life (QoL) and increases cardiovascular and mortality risks [1, 2].

Diabesity is particularly frequent among patients with dysfunctional eating [3, 4]. Binge eating disorder (BED), a distinct type of eating disorder [5] characterized by dysfunctional eating conducts i.e., episodes of excessive food consumption (bingeing) that are not driven by hunger or

metabolic needs and that are not followed by compensatory behaviour, such as vomiting or laxative abuse, predisposes to T2DM onset. According to the national guidelines [6], eating disorder therapy requires an interdisciplinary approach lead by different professionals (therapeutical équipe), in dedicated, highly specialized centres.

As T2DM is associated with microvascular, macrovascular and metabolic complications, hence atherosclerosis and cardiovascular events [7], effective therapies able to guarantee an optimal glycaemic management are a priority among patients with this condition. Furthermore, since the management of T2DM complications has an enormous impact on the health care system expenses, new effective, tailored-made approaches are strongly needed to prevent short, medium and long-term complications. Lifestyle interventions can improve T2DM outcomes [8, 9] and prevent its complications among subjects with obesity [10].

Dysfunctional eating, particularly BED, deeply impacts patients' behaviour, making all attempts to manage weight and glycaemic status, including lifestyle interventions, particularly challenging [11]. The efficacy and durability of any treatment, i.e., pharmacological, nutritional, and surgical approaches, is in fact particularly challenging in this population [3].

The centre for the treatment of BED and obesity *Centro DAI e Obesità di Città della Pieve* is the first Italian centre entirely dedicated to BED and obesity treatment. Its person-based approach consists of psycho-nutritional rehabilitation and involves a, interdisciplinary, built-in équipe including experts in the field of psychology, medicine, nutrition, and physiotherapy [12].

The primary aim of this article is to investigate the impact of the holistic interdisciplinary approach of *Centro DAI e Obesità di Città della Pieve* on weight and glucose management in patients suffering from dysfunctional eating in the short (8–12 weeks) and medium term (one year). The secondary objective is to compare this intervention with a conventional, hospital-based, treatment for obesity on glycaemic management, in the short and medium term.

## Methods

### Study population of Centro DAI e Obesità di Città della Pieve

We studied obese patients with T2DM who underwent the residential psycho-nutritional rehabilitation of *Centro DAI e Obesità di Città della Pieve* from 2010 to 2019 (hereafter referred to as PNT group).

Inclusion criteria were: age between 18 and 70 years; presence of III-degree obesity ( $BMI \geq 40 \text{ kg/m}^2$ ), or obesity of any degree ( $BMI \geq 30 \text{ kg/m}^2$ ) plus psychiatric or

medically stable conditions (e.g.: cardiovascular, metabolic, orthopaedic illnesses); documented diagnosis of T2DM; able to walk and take care of themselves; presence of a dysfunctional eating attitude or a specific eating disorder.

Exclusion criteria were: any acute or severe illness; untreated obstructive sleep apnoea syndrome; any kind of addiction (i.e., smoking, drug or alcohol abuse and gambling). Overweight subjects ( $25 \leq BMI < 30 \text{ kg/m}^2$ ) were not included in the study.

Obesity was defined by a  $BMI \geq 30 \text{ kg/m}^2$ . Weight was measured using a weighting scale and expressed in kg, while height was assessed with a stadiometer and expressed in meters. The degree of obesity was classified according to WHO charts (I-degree obesity:  $BMI 30\text{--}34.9 \text{ kg/m}^2$ , II-degree obesity:  $BMI 35\text{--}39.9 \text{ kg/m}^2$ , III-degree obesity:  $BMI \geq 40 \text{ kg/m}^2$ ) [13]. Diagnosis of T2DM was based on international guidelines values ( $HbA1c > 6.5\%$  or fasting glucose  $> 125 \text{ mg/dl}$  or a random plasma glucose  $> 200 \text{ mg/dL}$ ) [14]. Presence of a dysfunctional eating attitude or a specific eating disorder was diagnosed according to DSM-V criteria [5]; as for BED, recurrent (at least once a week for three months) episodes of binge eating: eating, in a discrete period of time, an amount of food that is definitely larger than most people would eat in a similar period, with a sense of lack of control over eating during the episode, associated with three or more of the following: eating much more rapidly than normal, until feeling uncomfortably full, eating large amounts of food when not feeling physically hungry, alone because of feeling embarrassed by how much one is eating; feeling disgusted with oneself, depressed, or very guilty afterwards, marked distress regarding binge eating is present; in the absence of compensatory behaviour (for example, purging). Night Eating Syndrome (part of Other Specified Eating Disorder, OSFED, according to DSM-V classification) was diagnosed when history of evening hyperphagia (consumption of 25% or more of the total daily calories after the evening meal) and/or nocturnal awakening and ingestion of food two or more times per week was reported. Among USFED (Unspecified Eating Disorder) where classified all patients with other kind of dysfunctional eating, such as grazing (the repetitious and unplanned eating of small amounts of food) or any other non-homeostatic feeding behaviour that cause clinically significant distress or impairment in social, occupational, or other important areas of functions.

### Psycho-nutritional therapy at Centro DAI e Obesità di Città della Pieve

Average residential treatment lasts between 8 and 12 weeks. During this period, patients live together, in double rooms, share common areas and are allowed to use personal phone or other devices only in the evening,

after dinner or during weekends. A weekly plan defines all daily activities which are performed from Monday to Friday; starting from the third week, at weekends, patients are allowed to go home or meet their relatives to test their new behavioural achievements in their family environment. The nutritional intervention follows a cognitive-behavioural approach to re-establish a functional eating behaviour through repetitive experiences and new knowledge. Each patient plans a personalized therapeutic project together with the interdisciplinary team that includes experiential, social and psychological, group or individual activities, i.e., medical evaluation, psycho-nutritional educational classes, individual dietetic and body composition assessments. Patients are trained to solve complex issues underlying their disorders: problem solving and stress management strategies, nutritional counselling, food diary completion, weekly meals plan, and planned food portions using visual servings were exploited [15]. Patients learn to recognize their innermost biological signs (hunger, satiety, satiation, hedonic eating impulse) and physical circadian rhythm, and to properly respond to them. They hence learn to plan their meals, balance their caloric needs based on their activities, and learn about the function of each macro and micronutrient, how to read nutritional label, how to recognize food deceptive advertising, and learn about false beliefs and misconceptions. Lifestyle changing needs to be embraced from the whole patients' environment, starting with the family one. The overall goal of such therapeutic approach is to make patients realize the deep dynamic and mechanisms driving dysfunctional eating to counteract them with positive behaviours [6].

### Physical activity and rehabilitation at Centro DAI e Obesità di Città della Pieve

Planned daily physical activity is also part of patients' therapeutic project and is planned on weekly basis, based on individuals' abilities, weight loss trend and dietetic program. Activities include Nordic walking performed daily at an increasing level (start from 15 to 30 minutes, up to one hour daily) throughout the residential stay; once a week, physiotherapy to improve mobility and proprioception and dance movement therapy to enhance the ability to perceive individuals' own body in the surrounding space [16]. Patients also performed additional activities such as exercise in water at the thermal centre of *Chianciano Terme*, to deal with the exposure of their body in public, work on their muscular tone, working on their social skills [17]; hippotherapy to improve interpersonal interaction, self-esteem, self-confidence, and social functioning through the interaction with horses [18].

### Body composition, anthropometry, and biochemical evaluation

Anthropometric parameters, i.e., height, weight, BMI, waist circumference (WC) were measured at the beginning and at the end of the treatment and one year following patients' discharge. A bio-electrical impedance analysis (BIA, Akern®) was also conducted to assess body composition at the baseline and right before patients' discharge. BIA and anthropometric parameters were acquired by the same operator (nutritionist or dietitian) after an overnight fasting (at least 12 hours), far from menses period (for women). BIA data were processed using Bodygram Plus® 1.2.2.6, Akern 2016 software. Fasting blood samples to assess glucose, total and LDL and HDL cholesterol, triglyceride, glycated haemoglobin (HbA1c) and liver functionality indices (AST, ALT, GGT) were also collected at the three study timepoints and analysed using the methodology described elsewhere [19]. In brief, biochemical analyses were performed at the local clinic. Around 7 ml of blood were collected from each subject: serum total cholesterol, triglycerides, transaminase were assessed by a colorimetric assay (Menarini Diagnostics, Florence, Italy); serum HDL cholesterol were measured using a direct enzymatic method (Menarini Diagnostics, Florence, Italy), HbA1c by high-performance liquid chromatography (Menarini Diagnostics, Florence, Italy). Plasma glucose was measured by a Beckman glucose analyzer (Menarini Diagnostics, Florence, Italy); LDL cholesterol was calculated using the Friedewald formula (total cholesterol – HDL – triglycerides/5) in mg/dL [20].

### Patients undergoing hospital-based conventional therapy

A cohort of age and gender-matched subjects with obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) detected during medical examination, a documented history of T2DM (as previously described) and dysfunctional eating attending the walk-in endocrine clinic at the *Azienda Ospedaliera S. Maria della Misericordia* of Perugia between 2010 and 2019 were included in our study (conventional treatment group, hereafter referred to as -CT-). This educational intervention includes a dietetic nutritional counselling focused on lifestyle modifications necessary to achieve weight loss and improve glycaemic control. Personalized diet schemes were administered to patients, based on their anthropometric variables, their T2DM therapy, and their eating habits, based on Mediterranean Diet principles, according to the national recommendations and guidelines [21, 22]. Body composition assessment was not performed. Anthropometric parameters and blood sample at baseline, after 12 weeks and following one year were collected as described above.

## Statistical analyses

Data distribution was assessed by Shapiro-Wilk test; data not normally distributed were log-transformed. The analyses were paired analyses; significance within groups was determined by paired t-tests, while differences between groups were determined by ANOVA of the percent differences adjusted for covariates. Categorical variables were studied by Chi-square test. A p value of  $\leq 0.05$  was considered significant. In tables, data are presented as means  $\pm$  standard deviation (SD), while in graphs, data are plotted as mean  $\pm$  standard errors (SE). Data were managed using Microsoft Excel and IBM Spss Statistics Data Editor (v.24.0).

## Results

From 2010 to 2019, a total of 360 patients suffering from obesity and dysfunctional eating were admitted at *Centro DAI e Obesità*. Presence of dysfunctional eating was assessed by the équipe and included: diagnosis binge eating disorder or low-frequency binge eating disorder; night eating syndrome; grazing, snacking, and eating in response to emotional triggers such as anxiety, stress, boredom. Seventy-one patients suffered T2DM, 69 of which completed the program and were included in our analyses (PNT). Two patients dropped-out during the first week of treatment, as they believed the program did not suit them. Mean treatment duration was 7.45 weeks; baseline PNT population characteristics are described in Table 1. All patients suffer from dysfunctional eating: among them, fourteen were diagnosed with BED, twenty-seven with OSFED (Other Specified Eating Disorder), sixteen with UFED (Unspecified Feeding or Eating Disorder) based on DSM-V [5].

At baseline, PNT displayed higher average fat mass (FM) values and lower fat free mass (FFM) compared with the reference parameters assigned by the software based on sex, age, and physical activity levels; extracellular water was

higher and phase angle was at the lower end of the range of normality. Mean HbA1c was  $7.9 \pm 1.8\%$ , mean fasting glucose was  $165 \pm 59$  mg/dl. Concerning therapies, 35 PNT patients (49%) were on insulin (24 with a basal bolus scheme, 9 with basal daily injection): the average insulin unit at baseline was  $66.9 (\pm 29.7)$ . LDL and GGT were above the range of normality (Table 1).

At the end of the 8-weeks treatment, the PNT group significantly reduced total weight ( $-7.0 \pm 3.2\%$ ;  $p < 0.001$ ), BMI ( $-7.0 \pm 3.1\%$ ;  $p < 0.0001$ ) and WC ( $-5.3 \pm 2.7\%$ ;  $p < 0.001$ ). Weight loss paralleled body composition improvements: PNT patients experienced a significant reduction in mean FM, accompanied by a significant increase in FFM (Table 2). After 8 weeks of therapy, the PNT group significantly improved glucose parameters: mean HbA1c ( $-1.1 \pm 1.5\%$ ;  $p < 0.01$ ) and fasting glucose ( $-41 \pm 46$  mg/dl;  $p < 0.001$ ) decreased (Table 2). Furthermore, 11% of subjects suspended the therapy for T2DM management. No one required dose increase. The insulin-treated subgroup significantly reduced insulin doses, mean daily units were in fact halved:  $34.2 \pm 25.2$  UI, ( $p < 0.01$ ) at the end of the 8 weeks treatment (Fig. 1). Furthermore, PNT experienced a significant reduction in triglycerides ( $-69.7 \pm 77.8$  mg/dl,  $p < 0.01$ ), GGT ( $-25.6 \pm 29.1$  U/l,  $p < 0.01$ ), AST ( $-7.2 \pm 8.4$  U/l,  $p < 0.01$ ) and ALT ( $-10.3 \pm 15.4$  U/l,  $p < 0.01$ ) at the same timepoint (Table 2).

After one year, PNT gained back part of the weight which was however still  $6.0 \pm 7.9\%$  lower than the baseline one ( $p < 0.001$ ), similarly to BMI  $-6.2 \pm 8.1\%$  ( $p < 0.001$ ). Importantly, mean HbA1c was significantly lower one year after intervention completion as compared to baseline value ( $-0.5 \pm 1.4\%$ ;  $p = 0.029$ ).

## Comparison with the conventional treatment group

We then analyzed the anthropometric and glucose control variables of our CT group and compared them with the ones obtained from the PNT group. Data from 55 subjects with obesity and T2DM were collected, and baseline characteristics are reported in Table 3. Mean treatment duration was 12 weeks. At baseline, CT subjects presented significantly lower body weight compared to the PNT group ( $p < 0.001$ ). However, there were no differences in biochemical parameters between PNT and CT subjects: CT subjects had impaired fasting glucolipid profile with LDL ( $109.7 \pm 40.8$  mg/dl), TG ( $187.2 \pm 107.2$  mg/dl), GGT ( $48.9 \pm 38.3$  U/l) and fasting glycaemia ( $170 \pm 67.6$  mg/dl), mean HbA1c was  $7.7 \pm 1.6\%$ ; 35 of 55 CT subjects were on an intensive insulin scheme. Among the insulin-treated subgroup, average insulin doses at baseline were  $45.8 \pm 29.4$  unit (Fig. 1).

After 12 weeks of follow up, CT weight ( $-0.6 \pm 3.7\%$ ) and BMI loss ( $-0.7 \pm 3.8\%$ ) were significantly lower than the ones of the PNT group, after adjusting for age, mean

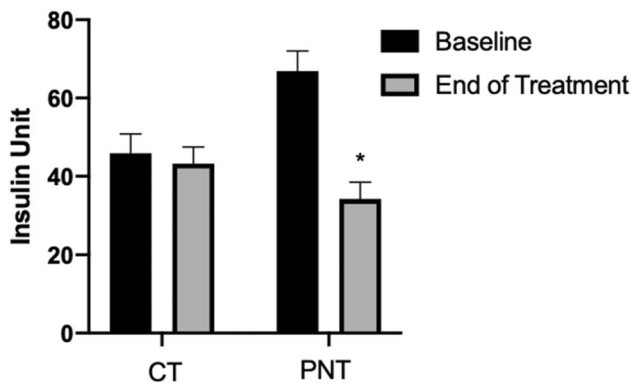
**Table 1** Baseline characteristics of the PNT group treated at Centro DAI e Obesità

(n = 69)	Mean value ( $\pm$ SD)
Female, n (%)	40 (58)
Treatment duration (weeks)	7.5 ( $\pm 2.3$ )
Age (years)	55 ( $\pm 13.2$ )
Weight (kg)	122.8 ( $\pm 23.2$ )
Waist Circumference (cm)	134.7 ( $\pm 14.6$ )
BMI (kg/m <sup>2</sup> )	44.8 ( $\pm 7.2$ )
Fasting glucose (mg/dl)	164.7 ( $\pm 59.0$ )
HbA1c (%)	7.9 ( $\pm 1.8$ )

**Table 2** Anthropometric parameters, body composition and biochemical values of the PNT group

		Before treatment	End of treatment	Absolute change	P value
Anthropometry	Weight (kg)	122.8 (±23.2)	114.1 (±20.6)	-8.6 (±5.2)	<0.01
	Waist Circumference (cm)	134.7 (±14.6)	127.5 (±13.5)	-7.1 (±4.3)	<0.01
	BMI (kg/m <sup>2</sup> )	44.8 (±7.2)	41.5 (±6.4)	-3.14 (±1.8)	<0.01
Body Composition (BIA)	Fat Mass %	45.0 (±7.7)	43.06 (±7.5)	-1.9 (±2.8)	<0.001
	Free Fat Mass %	54.9 (±7.7)	56.1 (±8.5)	+1.2 (±1.2)	0.19
	Muscle Mass %	34.3 (±6.7)	36.1 (±7.6)	+1.78 (± 5.1)	0.01
	Extracellular Water %	45.7 (±3.9)	45.2 (±6.8)	-0.51 (±6.4)	0.57
	Phase Angle	6.0 (± 0.9)	5.9 (±1.9)	-0.07 (±1.6)	0.77
	Basal Metabolism (Kcal)	1706.5 (±403)	1701.2 (±480)	+5.31 (±290.9)	0.90
	Biochemical Values	Fasting glucose (mg/dl)	164.7 (±59)	135.0 (±48.3)	-41.2 (±46.3)
HbA1c (%)		7.9 (±1.8)	7.05 (±1.4)	-1.1 (± 1.5)	<0.01
Total Cholesterol (mg/dl)		176.9 (±38.6)	161.6 (±43)	-11.8 (±39.2)	0.15
HDL (mg/dl)		45.2 (±19.5)	42.0 (±9.3)	-6.15 (±21.8)	0.22
LDL (mg/dl)		96.4 (±31.8)	93.6 (±32.8)	+2.4 (38.3)	0.80
Tryglicerides (mg/dl)		196.7 (±101.6)	166.1 (±76.0)	-69.7 (±77.8)	<0.01
AST (U/l)		24.2 (±11.2)	19.4 (±4.5)	-7.2 (±8.4)	<0.01
ALT (U/l)		29.4 (±15.7)	21.9 (±6.4)	-10.3 (±15.4)	<0.01
GGT (U/l)		54.7 (±51.9)	36.1 (±48.5)	-25.6 (±29.1)	<0.01

PNT psycho-nutritional treatment, BIA bioimpedance analyses. Data are presented as Means ± SD



**Fig. 1** Mean insulin units before and after the treatment in the two studied groups

treatment duration and baseline glucose control therapy (Fig. 2). Furthermore, the CT group did not experience significant changes in all blood biochemical variables during the following six months (data not shown).

After 12 weeks, mean fasting glucose didn't change significantly in the CT group (mean values: 143 ± 36 mg/dl, p value 0.16), even if mean HbA1c was 7.1 ± 1.0% (p=0.02). CT was not able alone to reduce mean insulin doses (average insulin units at the end of the treatment: 43.2 ± 27.8; -2.5 ± 11.7 units, p=0.20) in the subgroup on insulin therapy (Fig. 1).

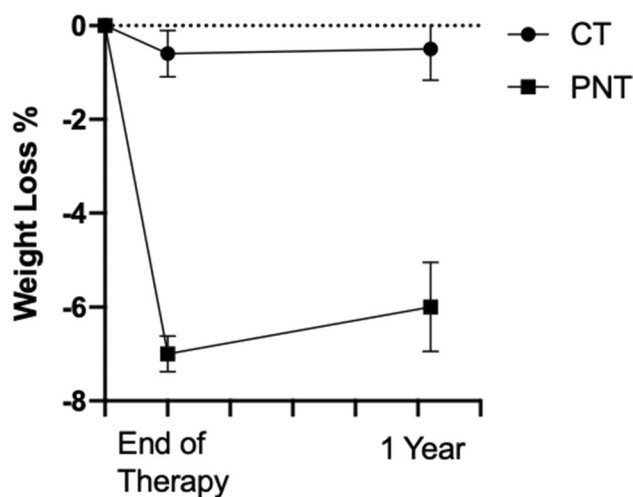
One year following the conventional therapy, CT group gained back more weight compared to PNT (-6.0 ± 7.9% in

**Table 3** Baseline characteristics of the CT group

(n = 57)		Mean (± SD)
General characteristics	Female; n (%)	30 (52.6)
	Treatment duration (weeks)	12 (±6.8)
Anthropometry	Weight (kg)	99.2 (±13.9)
	Waist Circumference (cm)	116.1 (±9.8)
	BMI (kg/m <sup>2</sup> )	36.1 (±5.2)
Biochemical Values	Fasting glucose (mg/dl)	170.0 (±67.6)
	HbA1c (%)	7.7 (±1.6)
	Total Cholesterol (mg/dl)	190.7(±35.8)
	HDL (mg/dl)	48.3(±11.3)
	LDL (mg/dl)	109.7(±40.8)
	Tryglicerides (mg/dl)	187.2(±107.2)
	AST (U/l)	25.5(±11.9)
	ALT (U/l)	26.5 (±12.9)
	GGT (U/l)	48.9(±38.3)

PNT vs -0.5 ± 4.9% in CT, p < 0.001, Fig. 2). Furthermore, CT group HbA1c increased at one year compared to baseline (Fig. 2).

Lastly, our analyses including the entire study population (PNT and CT groups) revealed a significant correlation between body weight changes and HbA1c variation at the end of treatment and after one year (Fig. 3). Consistently with the evidence from the literature [23], insulin use affected weight loss: patients who were not on insulin treatment, lost more weight at the end of the therapy



**Fig. 2** Mean weight loss (%) at the two timepoints of the study after the psycho-nutritional treatment (PNT) and the conventional treatment (CT). PNT allowed a significant weight loss at the end of the treatment (~10 weeks) and after one year, whereas the CT did not significantly affect weight changes. Data adjusted for baseline age, treatment duration and glucose control therapy

( $p=0.016$ ) and maintained a similar, not significant trend after one year ( $p=0.061$ ), data not shown. Furthermore, a significant correlation between insulin dose reduction and percentage of weight loss at the end of the treatment ( $r: 0.610, p < 0.00$ ) and after one year ( $r: 0.422, p=0.001$ ) were detected (Fig. 4).

### A sub-analysis of the glycaemic endpoints

HbA1c reflects average glycaemia over approximately 3 months and is the major tool for assessing glycaemic control. A reasonable HbA1c goal for adults is  $<7\%$  [24] and we decided to consider a threshold value of  $7.5\%$  to define uncontrolled T2DM.

At baseline, 39% of the PNT population were out of target (mean HbA1c:  $9.3 \pm 1.6\%$ ; mean fasting glucose  $203 \pm 50$  mg/dl); 100% of this last group was insulin-treated: the TDD (total daily dose) was  $66 \pm 33$  (Table 4). In this subgroup, PNT allowed a significant reduction in weight ( $p < 0.001$ ) and BMI ( $p < 0.001$ ), a significant reduction in mean fasting glucose ( $p < 0.001$ ) and HbA1c ( $p < 0.01$ ) after the 8 weeks treatment. The mean TDD was reduced, from  $66 \pm 33$  to  $37 \pm 25$  UI ( $p < 0.01$ ); 11% of patients interrupted the insulin therapy: one among them, starting from a TDD of 68 UI, gradually down escalated it, until therapy suspension. After one year, in this sub-group weight and BMI remained stable; HbA1c and TDD slightly increased but remained significantly lower than values at baseline.

Among CT population, 37% of subjects was considered out of glycaemic target at baseline (mean HbA1c:

$9.1 \pm 1.5\%$ , mean fasting glucose  $219 \pm 80$  mg/dl); 90% used insulin and the mean TDD was  $51 \pm 36$  UI. After CT, mean weight and BMI did not change significantly. Mean fasting glucose and HbA1c slightly improved, but TDD was not significantly affected. After one year, HbA1c and TDD increased and did not significantly differ from the baseline values (Table 4).

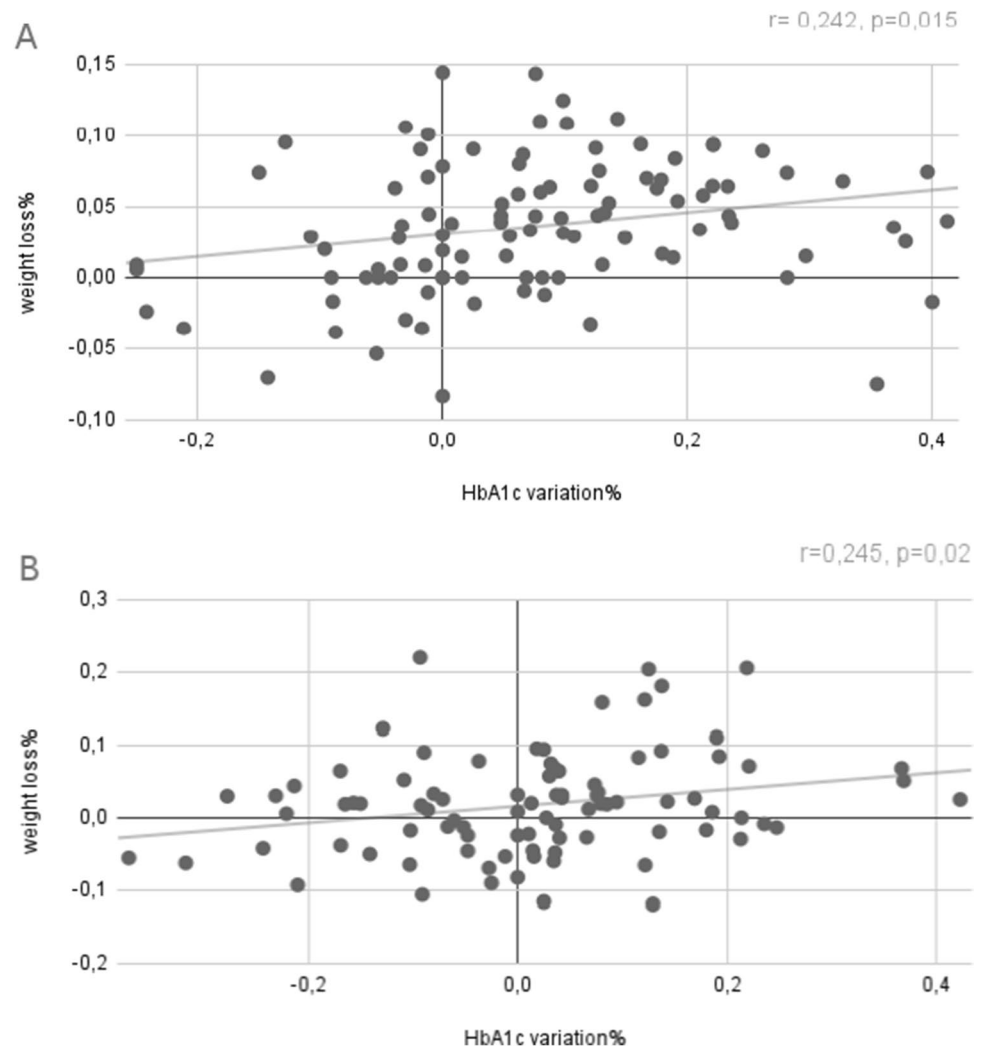
## Discussion

Our study demonstrates that a person-based, interdisciplinary, psycho-nutritional therapy is effective in managing T2DM outcomes in patients with obesity and dysfunctional eating, in the short- (8 weeks) and medium-term (one year). In addition, based on our data, the same PNT intervention is more effective compared to a hospital-based conventional treatment in promoting medium term T2DM improvements. Given the complexity of the management of T2DM in patients with obesity and dysfunctional eating, our study provides a useful framework worth further investigation.

Dysfunctional eating is a risk factor for obesity onset. An example of dysfunctional eating is in fact BED, a distinct eating disorder [5] which often coexists with obesity [3]. Both obesity and BED, as well as other dysfunctional eating patterns, are risk factors for T2DM development [25]. They in fact worsen the course of the disease [4, 26] and contribute to the loss of insulin sensitivity, acting as additional risk and maintenance factors [26]. It is estimated that 10–15% of subjects with T2DM suffer from an eating disorder [4, 27]. In a study involving 895 Italian patients with T2DM, Petroni et al., reported that 82% of them were overweight, 21.5% suffered from dysfunctional eating, 17.5% of whom practiced bingeing conducts; the prevalence of dysfunctional eating in T2DM population was closely associated with the progressive increase in BMI class, reaching the top of 81.4% in obesity class III [28].

Dysfunctional eating worsens compliance and efficacy of glucose control therapies, whereas weight management interventions promoting a regular eating pattern favourably impact glucose control [21, 22, 28]. In this context, intensive lifestyle interventions have been demonstrated to be more effective than pharmacological therapies in preventing the onset of T2DM, with health benefit lasting over 10 years [29–31]. Lifestyle interventions are hence recommended in people with T2DM [21, 32], also due to their ability to prevent cardiovascular diseases incidence and associated mortality [33]. Structured program, based on low-calorie diet and exercise, lead to T2DM remission in subjects with obesity and a brief history of diabetes, relative to conventional therapies and self-management programs [34, 35]. However, benefits persist partially over the time [36, 37], and

**Fig. 3** Weight changes at the end of the treatment (A) and after one year (B) were related to HbA1c variation at the same time points in the whole study population



data concerning the efficacy of T2DM management among dysfunctional eaters are lacking [38].

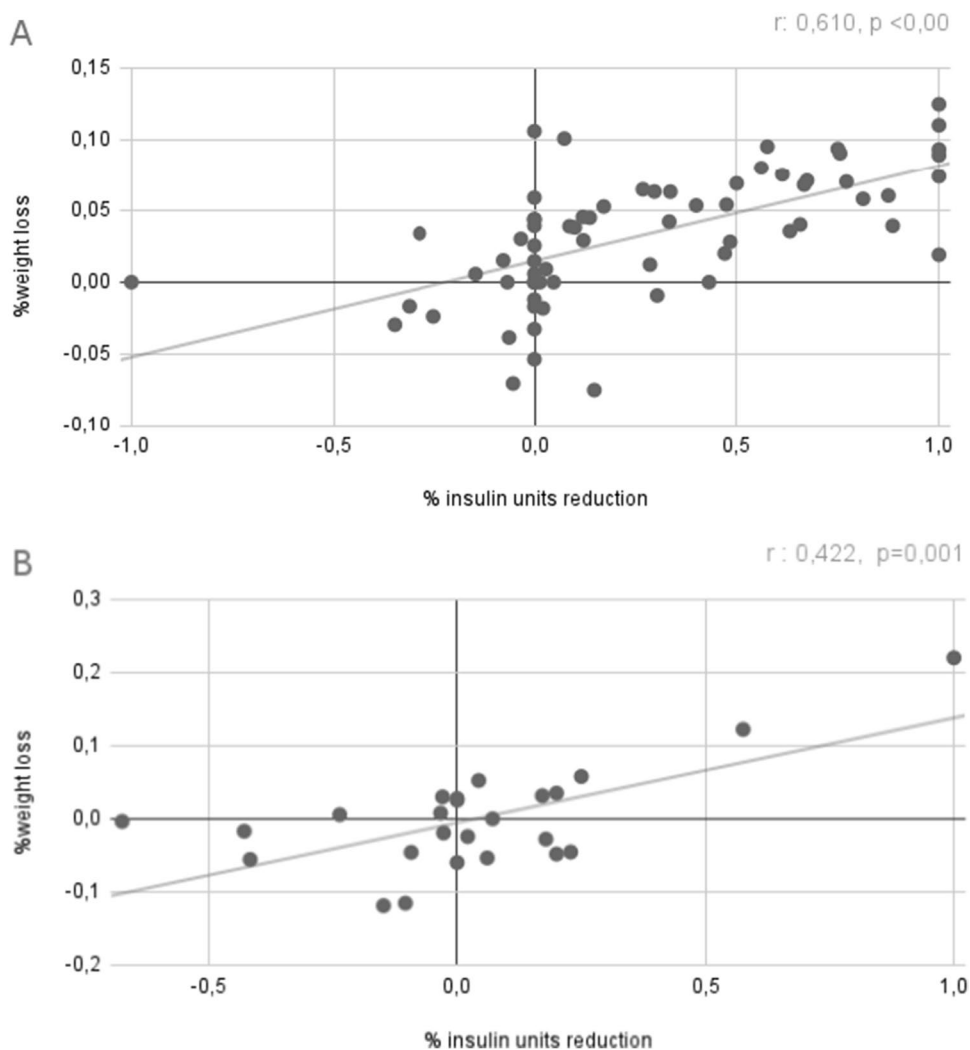
In this study, we propose the holistic, psycho-nutritional therapeutic program of *Centro DAI e Obesità di Città della Pieve*, which goes beyond the simple lifestyle intervention consisting of the combination of diet and exercise, as an effective strategy to improve T2DM outcomes in patients with obesity and dysfunctional eating. Our PNT group in fact not only significantly lost weight, but also improved glucose control and other metabolic parameters (such as liver enzymes and triglycerides) at the end of the intensive treatment and at one year follow-up. Obesity is closely associated with metabolic liver dysfunction (non-alcoholic fatty liver disease and steatohepatitis) [39]. T2DM is one of the strongest risk factors for progression of steatosis and steatohepatitis [40]. Evidence for lifestyle modifications derives from many observational studies [41–44]. Although is beyond the scope of this investigation to assess the role of PNT in reducing the risk of metabolic liver disease, our results suggest PNT beneficial effect not only in weight loss and T2DM

outcomes, but also on associated biochemical anomalies, including liver enzymes and triglycerides.

Furthermore, such PNT intervention was demonstrated to be more effective than the conventional pharmacologic and dietetic treatment in a similar population. This is deeply relevant in those who are not able to reach the glycaemic goals. HbA1c levels in the population with T2DM has a strong predictive value for the disease-related complications (a curvilinear relationship between HbA1c and microvascular complications is demonstrated) [45, 46]: the higher the HbA1c, the more the patient need an intensive treatment to reduce complications risks. In our study, only PNT treatment was able to improve weight and glycaemic targets in the subgroup with uncontrolled T2DM, and to reduce TDD maintaining such improvement at one year follow-up.

Based on our findings, in 11% of our PNT group, T2DM treatment was interrupted at the end of the treatment and benefits persisted after one year, together with the improvement in weight and glycaemic control. Our data are consistent with the Look AHED Trial, conducted on

**Fig. 4** Relation between insulin doses and percentage of weight loss at the end of the treatment (A) and after one year (B)



**Table 4** Effectiveness of the interventions in the subgroup with uncontrolled T2DM at baseline

	PNT n: 27 (39%) Mean treatment duration (weeks): 6.7 ± 1.7			CT n: 21 (37%) Mean treatment duration (weeks): 12.5 ± 6.8		
	Before treatment	End of treatment	One year	Before treatment	End of treatment	One year Mean ± SD
Weight (kg)	120.2 ± 20	113.1 ± 18.7**	113.2 ± 22.1***	99.7 ± 18.9	98.6 ± 18.3	100.4 ± 18.5
BMI (kg/m <sup>2</sup> )	43.4 ± 5.4	40.8 ± 4.8***	40.6 ± 6.1***	36.5 ± 5.1	35.9 ± 4.7	36.5 ± 4.7
Insulin use	100%	89%	–	90%	90%	–
TDD‡ (UI)	66 ± 33	37 ± 25**	48 ± 32**	51 ± 36	47 ± 32	55 ± 33
Fasting glucose (mg/dl)	203 ± 50	159 ± 54**	–	219 ± 80	157 ± 42*	–
HbA1c (%)	9.3 ± 1.6	7.7 ± 1.5**	8.3 ± 1.5*	9.1 ± 1.5	8.0 ± 0.9*	8.5 ± 0.8

PNT psycho-nutritional treatment, CT Conventional treatment

Data are presented as Means ± SD. Uncontrolled T2DM is defined with a HbA1c values > 7.5%; ‡Total Daily Dose. \**p* < 0.05 compared to baseline; \*\**p* < 0.01 compared to baseline; \*\*\**p* < 0.001 compared to baseline

5145 overweight or obese American patients [47] which demonstrated that intensive lifestyle therapy results in T2DM remission and drug-therapy discontinuation in 11%

of patients after one year of treatment [47, 48]. Interestingly, a post hoc analysis of the same trial, showed that the population reported bingeing conducts at the beginning



of the trial (11% of general population, via a self-report questionnaire based on the Questionnaire on Eating and Weight Patterns) were less likely to complete the full 1-year assessment and to reach weight loss [49]. On the other side, four-year's results showed that dysfunctional eating affected weight loss over time, even though no data concerning T2DM management was described [50].

The failure of weight-loss treatments based on lifestyle modification in dysfunctional eaters is generally ascribed to powerful environmental, psychological, and biological pressures causing patients to overeat; novelty of our approach is the inclusion of educational, motivational, and psychological therapeutic strategies, based on cognitive-behavioural therapy (CBT), recommended for obesity and BED treatment [51]. Such strategy in fact significantly improves eating patterns regardless of body weight and can reduce body image concerns, an element perpetuating the dysfunctional behaviour. A CBT-based approach is able to reduce cardiovascular risk among subjects with obesity [51], and to improve T2DM self-management [52]. Based on our data, CBT is also an effective strategy to manage T2DM outcomes in the subgroup of subjects with obesity and dysfunctional eating. Nonetheless, it must be acknowledged that part of the efficacy of psycho-nutritional treatment can be attributed to the intensive setting of care.

Strength of the PNT approach consists of its primary focus on eating attitudes and behaviours that, as a consequence, leads to weight loss and improvements in glucose control and reduction in insulin requirements as compared to CT. Dysfunctional eating behaviours results in weight gain and negatively impacts glycaemic control, leading to insulin doses increase [23], overall making the management of T2DM and obesity challenging [53].

Our results underline that interventions centred on dysfunctional behaviours and psychological factors influencing behaviours should be adopted prior to any other therapeutic strategy, as they result in durable benefits among subjects with obesity, dysfunctional behaviour and T2DM.

### Strength and limits

This study has several limitations: first, it is a retrospective analysis lacking several insulin resistance parameters (e.g., insulin levels, HOMA-IR). Second, although the CT group was age and gender matched and suffered from the same condition as the PNT one (obesity, T2DM and dysfunctional eating), it displayed a significantly lower body weight at baseline, difference that may have affected weight loss outcomes (even though our analyses was adjusted for baseline weight).

### What is already known on this subject?

Dysfunctional eating is a risk factor for obesity and T2DM onset and worsens compliance and efficacy of both weight-oriented and glucose therapies.

### What this study adds?

This is the first study demonstrating the efficacy of a psycho-nutritional intervention for T2DM management in patients with obesity and dysfunctional eating. This study is of relevance also considering the increased incidence of dysfunctional eating pattern during the COVID-19 pandemic [54]. Further studies, with a larger sample size are required to assess the long-term effect of such PNT in both weight and T2DM management, as well as assess the ability of such approach to prevent diabetes-related complications.

**Data availability** Raw data will be provided by the corresponding author upon direct request.

**Code availability** software application or custom code.

### Declarations

**Conflict of interest** None.

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