RESEARCH ARTICLE

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Diabetes and erectile dysfunction: The relationships with health literacy, treatment adherence, unrealistic optimism, and glycaemic control

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Abstract

Purpose: The aim of this study was to evaluate the relationships between health literacy, unrealistic optimism, and adherence to glycometabolic disease management related to erectile dysfunction (ED) in male patients with type 2 diabetes (T2D) or preDM.

Materials and Methods: This prospective observational study enroled 167 consecutive patients with T2D and ED. All patients underwent the following examinations: (a) medical history collection; (b) Body Mass Index (BMI) determination; (c) hormonal and biochemical assessment; (d) duration of T2D, complications and treatment; (e) International Index of Erectile Function-5 questionnaire to assess ED; and (f) validated questionnaire to evaluate health literacy, unrealistic optimism, and treatment adherence.

Results: Overall, mean age was 62.5 ± 9.4 years (range: 20–75) and mean BMI was 28.4 ± 4.8 kg/m^2 (range: 18.4–46.6). The mean IIEF-5 score was 15.4 ± 5.2 (range: 5–25). The majority of patients showed high health literacy. However, low health literacy was found in patients with higher IIEF-5 scores and high BMI. Unrealistic optimism was low in most patients. Higher adherence to treatment was found in patients who reported regular physical activity, who followed a diet, and in patients with a family history of T2D. Regarding anti-diabetic treatment, patients treated with insulin showed higher health literacy than patients not treated with other medications, whereas higher adherence was found in patients using SGLT2-i.

Conclusions: This study highlighted the close relationship between metabolic compensation, BMI, ED, and psychological attitudes, including health literacy and unrealistic optimism.

KEYWORDS
adherence, antihyperglycemic drugs, diabetes mellitus, erectile dysfunction, health literacy, sexual dysfunctions

1 | INTRODUCTION

The World Health Organization defined sexual function as an integral component of physical, emotional, mental, and social well-being. However, sexual dysfunctions, in both men and women, are currently underestimated.[1] In the male population, one of the main sexual dysfunctions is Erectile Dysfunction (ED), which is defined as the recurrent and persistent inability to achieve or maintain an erection to perform a satisfactory sexual intercourse. The global prevalence of ED reported in the literature ranges from 14% to 48%, increasing significantly with age.[2] Among the ED causes (age, lifestyle, distress, psychogenic, relational, inflammatory, mechanical, neurogenic, drug, vascular, etc.), metabolic/endocrine causes play a central role, especially in type 2 diabetes (T2D). In this regard, the prevalence of ED in the T2D population described in the literature is very heterogeneous, ranging from 35% to 90%.[2,3] Both T2D and prediabetes (preDM) may be responsible for sexual dysfunction with different pathogenetic mechanisms, including insulin resistance, alteration of endothelial and smooth muscle function, neuropathy, decreased mucosal hydration, increased risk of genital tract infections due to the state of hyperglycaemia, and hormonal alterations.[4,5]

However, in clinical practice, it has been observed that patients with T2D are not always aware of the association between ED and T2D and that the lack of awareness (i.e., health illiteracy) could negatively influence the decision-making processes related to the necessary therapies.[6,7] Nevertheless, the hypothesis of the relationship between awareness and adherence to therapies may seem somewhat simplistic in the context of "health psychology" framework. Indeed, it has been shown that some people, although aware of certain health risks, do not adhere to the recommended treatments or do not engage in healthy behaviours.[8] One of the dimensions that may explain the reason for this dynamic is unrealistic optimism, or the tendency of people to believe that they are less likely to experience negative events and more likely to experience positive events than others.[9] Thus, it is conceivable that even individuals with high levels of health literacy may not follow the suggested treatment because of high levels of unrealistic optimism. On the contrary, individuals with low health literacy are likely to adhere to the proposed treatment because they have low levels of unrealistic optimism, which leads them to implement healthy behaviours beyond the awareness of specific medical information.

The purpose of this study was to evaluate the relationships between health literacy, unrealistic optimism, and adherence to glycometabolic disease management related to ED in male patients with diabetes T2D or preDM.

2 | MATERIALS AND METHODS

This prospective observational study enroled 167 consecutive patients from November 2021 to March 2022. All patients were admitted to the clinic of Endocrinology and Diabetes of the University Campus Bio-Medico of Rome because they were affected by T2D or prediabetes. The inclusion criteria were (1) male sex, (2) age between 18 and 75 years, and (3) T2D or prediabetes. Exclusion criteria were the presence of uncontrolled acute diseases, psychiatric diseases with recent consumption of psychotropic drugs, and patients undergoing prostate surgery.

At enrolment, patients underwent the following examinations: (a) medical history collection and (b) Body Mass Index (BMI) determination, calculated using the formula: weight in kilograms/height in metres[2] (BMI categories: normal weight <25 kg/m^2, overweight 25–29.9 kg/m^2, obesity >30 kg/m^2); (c) hormonal and biochemical assessment.

In addition, anamnestic forms were administered by the physicians and answered by all participants. The forms contained: (a) personal information (date and place of birth), (b) personal and family history (parents or siblings) of T2D; (c) lifestyle habits, including cigarette smoking (not/yes/in the past) and physical activity (not/yes, evaluated as at least 150 min/week of moderate-intensity activities, as indicated in the Association of Diabetologists and Italian Society of Diabetes (AMD-SID) Guidelines[10]; (d) duration of T2D; (e) cardiovascular (CV) comorbidities (CV events) (not/yes); (f) hypertension (not/yes); (g) dyslipidemia (not/yes); (h) kidney failure (not/yes); (i) peripheral neuropathy (not/yes); (l) diet (not/yes); (m) Anti-hyperglycaemic drugs (metformin, dipeptidyl-peptidase-4 inhibitors (DPP4-i), sodium-glucose cotransporter-2 inhibitors (SGLT-2i), glucagon-like peptide-1receptor agonists (GLP-1ra), sulfonylureas, or insulin (basal bolus insulin therapy, continuous subcutaneous insulin infusion (CSII)—CSII, or basal insulin therapy); (n) Testosterone replacement treatment (TRT) (not/yes); previous PDE5i use.

The choice of the T2D or preDM pharmacological treatment was based on patient characteristics (age, glycaemic compensation, comorbidities) according to AMD-SID[11] and American Diabetes Association[12] guidelines.

Patients receiving metformin plus one of the other treatments were clustered according to the second one. Patients receiving insulin plus one or more than one of the other treatments were clustered in the insulin group, as previously described.[13]

Furthermore, blood samples were collected at 8:00 AM and plasma levels of total testosterone and glycosylated haemoglobin (HbA1c) were determined. Chemiluminescence microparticle immunoassay and immunoassay (CLIA) were used.

To assess erectile dysfunction, all patients completed the International Index of Erectile Function-5 questionnaire, a validated tool to outline ED (score: no ED > 21, mild ED 17–21, mild to moderate ED 12–16, moderate ED 8–11, severe ED 5–7).[14] The IIEF-5 questionnaire was self-completed by each participant in a dedicated hospital room without possible influence and/or interference from physicians or other health professionals and was completed using pen and paper. Patients who reported no regular sexual intercourse in the past 6 months, as required by the IIEF-5 questionnaire,[15] were excluded.

Health literacy was assessed using the following questions: Question 1: "Are you aware that ED is a complication T2D?" (yes/not). Question 2: "If you knew that ED is a complication of T2D,

would you follow your T2D treatment (diet and/or pharmacological) better"? (yes/not). In addition, the following validated question was used to assess unrealistic optimism[16]: Question 3: "Do you believe that your risk of developing ED due to diabetes is higher than that of other patients with diabetes of your same age?" (No, I believe my risk is lower/I believe my risk is the same/yes, I believe my personal risk is higher). Finally, the following validated question was used to assess treatment adherence[17]: Question 4: "How much have you followed the prescribed treatments in the last month?" (Never/Less than half the time/About half the time/More than half the time/Always).

The study was conducted in respect of the ethical standards of the Declaration of Helsinki (2000) and was approved by the Ethics Committee of the LAZIO 2 Azienda Sanitaria Locale Roma 2 (Protocol n. 0247297, Study 171/21).

3 | STATISTICAL ANALYSIS

Continuous data were described as mean ± standard deviation (SD) with minimum and maximum values. The normal distribution of data was assessed with the Shapiro-Wilk test, and t- or ANOVA tests were used to detect statistically significant differences between continuous data. Categorical data were described as absolute numbers and percentages. Fisher's exact or chi-squared tests were used to assess statistically significant differences. p-values<0.05 defined statistically significant differences. The software SPSS (IBM, USA) was used for statistics.

4 | RESULTS

A total of 167 patients with T2D or pre-DM were evaluated. Of these, 4 patients reported not having sex, and 7 did not complete the interview. Thus, the final sample consisted of 156 patients. The baseline characteristics of patients are described in Table 1. A total of 142 (91.0%) patients were affected by T2D, and the remaining 14 (9.0%) were affected by pre-DM. Overall, the mean age was 62.5 ± 9.4 years (range: 20–75) and the mean BMI was 28.4 ± 4.8 kg/m² (range: 18.4–46.6). The mean IIEF-5 score was 15.4 ± 5.2 (range: 5–25).

Overall, 19 (12.2%) patients were treated with diet, 51 (32.7%) with metformin, 19 (12.2%) with DPP4-i, 20 (12.8%) with GLP-1ra, 23 (14.7%) with SGLT2-i, 3 (1.9%) with SU and 21 (13.5%) with insulin (2 (9.5%) with CSII, 7 (33.3%) with basal bolus insulin therapy, and 12 (57.2%) with basal insulin therapy; among the latter, all patients were also treated with metformin and, in 8/12 with SGLT2-i or GLP-1ra).

Most patients answered "yes" to both Question 1 (118 [75.6%] vs. 38 [24.4%] answering "not", $p < 0.01$) and Question 2 (149 [95.5%] vs. 7 [4.5%] answering "not", $p < 0.01$). Interestingly, 73.7% ($n = 115$) of patients answered "yes, I believe my personal risk is higher" to the Question 3, 23.7% ($n = 37$) answered "I believe my risk is the same" and only 2.6% ($n = 4$) answered "No, I believe my risk is lower". The prevalence of the first answer was significantly higher than the

TABLE 1 Baseline characteristics.

Characteristics (n:156 patients)	
Age (years; mean ± SD, range)	62.5 ± 9.4 (20–75)
preDM (yes; n., %)	14 (9.0%)
IIEF5 score (mean ± SD, range)	15.4 ± 5.2 (5–25)
IIEF5 categories (n., %)	
No ED (>21)	21 (13.5%)
ED (5–21)	135 (86.5%)
Mild ED (17–21)	48 (30.8%)
Mild/Moderate (12–16)	45 (28.8%)
Moderate ED (8–11)	30 (19.2%)
Severe ED (5–7)	12 (7.8%)
BMI (kg/m²; mean ± SD, range)	28.4 ± 4.8 (18.4–46.6)
Physical activity (yes, n., %)	62 (39.7%)
Smoking habits	
No (n., %)	52 (33.3%)
Yes (n., %)	32 (20.5%)
In the past (n., %)	72 (46.2%)
Family history of T2D (n., %)	116 (74.4%)
T2D duration (years; n., %)	9.5 ± 8.0 (0–34)
CV comorbidities (n., %)	16 (10.3%)
Hypertension (n., %)	121 (77.6%)
Dyslipidemia (n., %)	116 (74.4%)
Kidney failure (n., %)	3 (1.9%)
Peripheral neuropathy (n., %)	5 (3.2%)
HbA1c (%; mean ± SD, range)	7.1 ± 1.3 (5–16)
Total testosterone (ng/ml; mean ± SD, range)	3.9 ± 1.8 (0.3–11.5)
Testosterone replacement treatment	11 (7.1%)
Previous PDE5i use	19 (12.2%)
Antidiabetic treatment	
Diet	19 (12.2%)
Metformin	51 (32.7%)
DPP4-i	19 (12.2%)
GLP-1ra	20 (12.8%)
SGLT2-i	23 (14.7%)
SU	3 (1.9%)
Insulin therapy	21 (13.5%)
- CSII	2 (9.5%)
- Basal bolus	7 (33.3%)
- Basal	12 (57.2%)

Abbreviations: BMI, body mass index; CSII, continuous subcutaneous insulin infusion; CV, cardiovascular; DPP4-i, dipeptidyl-peptidase-4 inhibitors; GLP-1ra, glucagon-like peptide-1 receptor agonists; IIEF, International Index of Erectile Function; PDE5i, Phosphodiesterase 5 inhibitors; SGLT2-i, sodium-glucose cotransporter-2 inhibitors; SU, sulfonylureas; T2D, type 2 diabetes.

others ($p < 0.01$). Finally, to Question 4, 4.5% ($n = 7$) of patients answered "Never", 21.8% ($n = 34$) "Less than half the time", 46.8% ($n = 73$) "About half the time", 19.9% ($n = 31$) "More than half the time," and 7.1% ($n = 11$) "Always." The prevalence of the response "About half the time" was significantly higher than the others ($p < 0.01$) (Figure 1).

After evaluating the presumed associations between responses to Questions 1–4 and IIEF5 scores (each as a value from 5 to 25 and categorised as no ED, mild ED, mild to moderate ED, moderate ED, and severe ED), the only significant difference was a higher IIEF-5 score in patients who responded "No" to Question 1 (17.5 ± 4.2, range 6–25, vs. 14.7 ± 5.3, range 5–25; $p < 0.01$; Figure 2).

For all other patient characteristics examined (i.e., age, BMI, family history of T2D, duration of T2D, smoking habits, physical activity, comorbidities, testosterone levels, HbA1c, TRT, PDE5i use) in terms of their association with the answers to Questions 1-4, we found: (i) a significantly higher BMI in patients who answered "No" to Question 2 (28.6 ± 4.8 vs. 24.6 ± 3.5 kg/m^2; $p = 0.03$), (ii) higher adherence to treatment (Question 4) in patients who reported regular physical activity (40.3% [25/62] said "About half the time", 41.9% [26/62] said "More than half the time," and 11.3% [7/62] said "Always" vs. 0% who said "Never" and 6.5% [4/62] who said "Less than half the time" in patients who did not report regular physical activity; $p < 0.01$), and in patients with a family history of T2D (49.1% [57/116] said
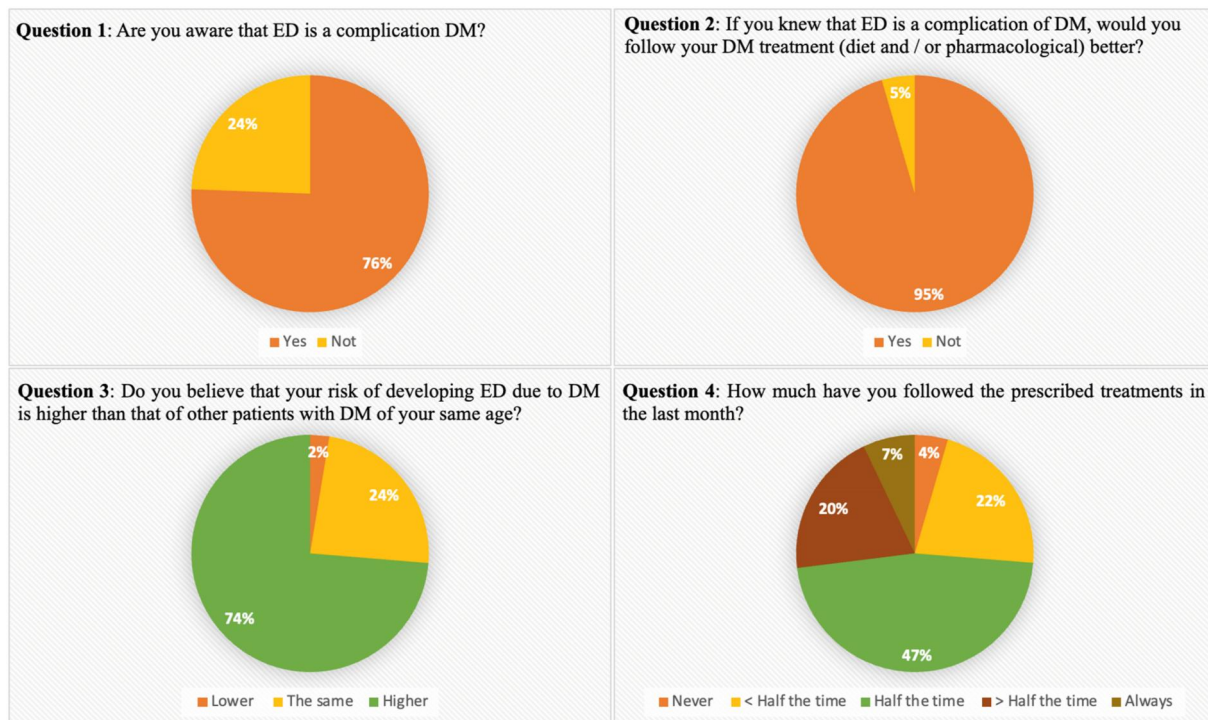

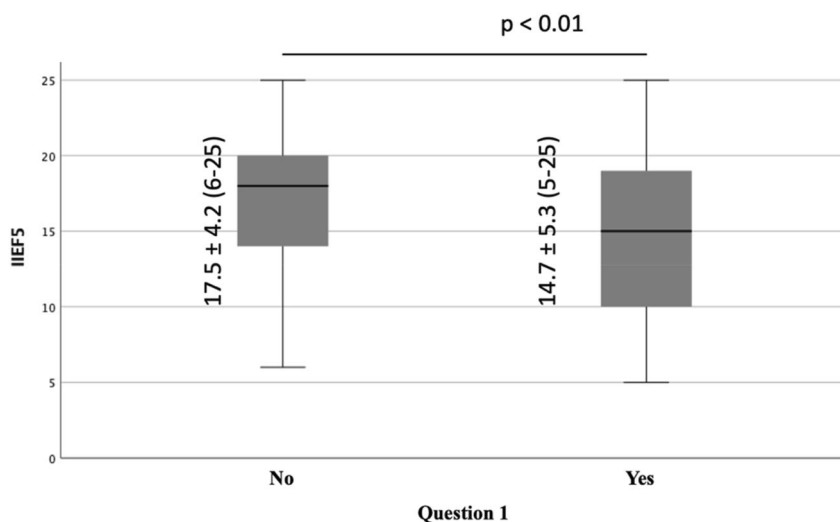**FIGURE 1** Question 1–4. DM, type 2 diabetes (T2D); ED, erectile dysfunction.

FIGURE 2 Mean, standard deviation, and range of the International Index of Erectile Function (IIEF)-5 score according to Question 1.

"About half the time," 14.7% [17/116] said "More than half the time," and 6.9% [8/116] said "Always" vs. 3.5% [4/116] who said "Never" and 25.9% [30/116] who said "Less than half the time" in patients with no family history for T2D; $p = 0.03$). Of note, we found that patients who previously used PDE5i answered "Yes" to Question 1 (3/19, 15.8%) less than the total group, but it did not reach a statistical significance ($p = 0.4$).

Finally, with respect to anti-diabetic treatment, we found: (i) a higher prevalence of "Yes" responses to Question 1 in patients treated with insulin (23/25 [92.0%] vs. 2/95 [8.0%] in patients not treated with this drug; $p = 0.04$), and (ii) a higher adherence to treatment (Question 4) in patients who followed a diet (50.5% [56/111] said "About half the time", 23.4% [26/111] said "More than half the time", and 9.0% [10/111] said "Always" vs. 1.8% [2/111] who said "Never" and 15.3% [17/111] who said "Less than half the time" in patients who did not a diet; $p < 0.01$), as well as in patients treated with SGLT2-i (53.3% [16/30] said "About half the time", 6.7% [2/30] said "More than half the time" vs. 6.7% [2/30] who said "Never" and 33.3% [10/30] who said "Less than half the time"; $p = 0.04$, respectively).

No other significant associations were observed among the remaining parameters (total testosterone levels and TRT included).

5 | DISCUSSION

In this study, we examined the associations between health literacy, unrealistic optimism, and adherence to glycometabolic disease management in relation to ED in a group of male patients with T2D or preDM.

Erectile dysfunction occurrence was very high in the T2D population, ranging from 35% to 90%.[2,3] Both T2D and preDM may be responsible for sexual dysfunction with different pathogenetic mechanisms.[4,5,18] Furthermore, T2D treatment seems to be closely associated with ED.[13,19]

Health literacy plays an important role in the knowledge about T2D, both in self-care and glycaemic control.[20] In this study, most patients answered "yes" to both Question 1 and Question 2, indicating high health literacy: this response seems to highlight that the majority of patients were adequately informed about their disease. Patients with inadequate health literacy were described as having a higher incidence of chronic conditions because they could not correctly recognise the symptoms of T2D and T2D complications.[21] Interestingly, patients who answered "No" to Questions 1, indicating low knowledge of ED as a complication of T2D, had a higher IIEF-5 score than individuals who answered "Yes". This result, which cannot be substantiated because of the lack of available data in the literature, raises speculation about an explanation. This result might suggest that good healthy literacy does not adequately protect against the onset of ED anyway. On the other hand, as with other diseases, higher health literacy could have a positive effect on ED diagnosis. In this regard, Demirbas et al[22] found that as health

literacy increases, ED becomes more important to patients. In line with this finding, sociocultural levels have also been described as a determinant of increased incidence and prevalence of ED.[23] Finally, good health literacy is known to lead to better self-control in preventing or updating T2D complications.

Interestingly, we found that patients with lower health literacy had significantly higher BMI. Previous studies have shown that lower health literacy is associated with lower frequency of health-promoting behaviours, higher frequency of risky health behaviours, and higher BMI.[24]

Curiously, we found a trend of low healthy literacy in patients who had already taken PDE5i; we speculate that this could depend on the fact that by assuming a "symptomatic" therapy, patients did not investigate the organic causes of ED. In this regard, the wide and early use of PDE5i , improving the erectile function, has led to a significant number of missed diagnoses of this underlying symptom.[25]

The evaluation of unrealistic optimism, defined as the erroneous judgement of personal risk as lower than the risk of others,[16] was lower in the majority of the population; therefore, most patients believed that their personal risk was higher than that of others. However, approximatively 25% of patients showed low adherence to T2D treatment; indeed, they responded that they never followed the physician's instructions or followed them less than half of the time. On the other hand, higher adherence to treatment was found in patients who reported regular physical activity and followed a diet, and in patients with a family history of T2D. The first finding was expected as patients with correct lifestyle habits are generally more willing to follow physician instructions. Indeed, self-care (i.e., physical activity and medication adherence) is essential for the prevention of complications in patients with T2D.[26]

As for the second aspect, family experience is usually considered as a source of knowledge. On the contrary, a recent study investigating factors associated with glycaemic control in patients with type 1 diabetes mellitus found that a family history of T2D worsened metabolic compensation.[27] Similar results were found in patients with T2D; specifically, family history of T2D was significantly positively associated with awareness but negatively associated with control.[28]

When considering anti-diabetic treatment, we found that patients treated with insulin had higher health literacy than patients not treated with other medications. This is probably due to the fact that patients treated with insulin have a longer history of the disease, which increases their knowledge. Indeed, patients treated with insulin must exert more effort than patients orally treated with anti-hyperglycaemic drugs to achieve optimal glycaemic control because they must adjust the dosage and frequency of insulin injections, self-monitor blood glucose, and avoid hypoglycaemia.[29] Anyway, we previously observed that across all treatment groups, the only significant difference in the IIEF-5 score was a higher mean value in patients using GLP-1ra compared to patients on insulin treatment.[13] The effect of insulin on sexual function that emerged from the study was difficult to compare to other studies, which were mainly based

on the comparison between types of administration (basal bolus insulin therapy or CSII)[30,31] and not between insulin and any other treatment. In the present study, we also evaluated the type of administration and found that the majority of patients used only basal insulin; however, no differences were observed according to insulin type of administration and psychological and sexual outcomes. These results are partially in accord with other studies that found better sexual function in patients who underwent CSII in both sexes[31,32]; this is probably due to the small sample of the subgroups.

Furthermore, patients taking SGLT2-i were found to have higher adherence to therapy. One possible explanation is that physicians are generally careful to provide information about the potential side effects of SGLT2-i (e.g., increased risk of genitourinary tract infections), so patients are more careful to take it correctly and therefore more likely to adhere to treatment.[12] Conversely, a recent meta-analysis found that despite increasing prescription of SGLT2-i, adherence and persistence to treatments in the general population is low.[33] However, the authors emphasised the need to identify goals to improve adherence and to take appropriate action.

The main limitations of this study are the absence of some anthropometric measures (i.e., waist circumference), and the relatively small sample of patients with neuropathy, which do not allow us to make an accurate assessment of its effect on psychological and sexological outcomes. Finally, a greater shame in declaring a disorder in the sexual sphere could influence the answers to the questions, mainly the first one.

In conclusion, this study demonstrates the close relationship between metabolic compensation, BMI, ED, and psychological attitudes, including health literacy and unrealistic optimism. Specifically, patients should be helped to develop the ability to obtain, understand, and apply health information, that is, health literacy, to make appropriate health decisions and increase adherence to treatment.

AUTHOR CONTRIBUTIONS

Conceptualisation, Giuseppe Defeudis and, Rossella Mazzilli; methodology, Giuseppe Defeudis, Rossella Mazzilli, Cristiano Scandurra; formal analysis, Giuseppe Defeudis, Rossella Mazzilli, Cristiano Scandurra, Danilo Cimadomo5; investigation, Giuseppe Defeudis; writing—original draft preparation, Giuseppe Defeudis, Rossella Mazzilli; writing—review and editing, Giuseppe Defeudis, Rossella Mazzilli, Cristiano Scandurra, Alfonso Maria Di Tommaso, Danilo Cimadomo, Rocky Strollo; supervision, Antongiulio Faggiano, Silvia Migliaccio, Nicola Napoli. All authors have read and agreed to the published version of the manuscript.

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CONFLICTS OF INTEREST STATEMENT

The authors declare no conflicts of interest about this manuscript.

ETHICS STATEMENT

All participants signed informed consent.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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PEER REVIEW

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