

## Is Severe Obesity a Form of Addiction?: Rationale, Clinical Approach, and Controlled Clinical Trial

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### ABSTRACT

For many, obesity is just a problem of energy input and expenditure: more energy input than expenditure. However, the clinical practice and epidemiological data clearly show that weight control is more complex than expected by this simple equation. This is particularly true in morbid obesity, a form of severe obesity in which a person's Body Mass Index (BMI, kg/m<sup>2</sup>) is over 40. If we compare the definitions and diagnostic criteria for "dependence" and "addiction" with the situation of many severe obese subjects, it is apparent that they match very well. Further, different neurological studies confirm this similarity: both addiction and obesity patients have a deficiency of dopamine receptors. Nevertheless, when we compare many of the actual obesity treatments with the ones used in the area of addictions it is possible to find relevant differences: obesity treatments neither consider different levels of type and intensity of care, nor a multidimensional approach. To overcome these limitations, in this paper we propose a bio-psychosocial approach—Experiential Cognitive Therapy—in which the genetic influence (lack of dopamine receptors) is matched by psychosocial issues (pressure for thinness and diet as main body image dissatisfaction treatment). Further, the paper outlines how this approach may influence the treatment options, by focusing both on the lessons coming from actual addiction treatment and the opportunities offered by virtual reality. Finally, the paper presents and discusses the outcome of a controlled trial, based on the proposed approach, including a 6-month follow-up (211 morbid obese females with a BMI of >40 and a documented history of failures).

### INTRODUCTION

**F**OR MANY, obesity is just a problem of energy input and expenditure: more energy input than expenditure. However, the clinical practice and epidemiological data clearly show that weight control is more complex than expected by this simple equation. Between 2000 and 2001, obesity prevalence climbed from 19.8% of American adults to

20.9% of American adults. Currently, more than 44 million Americans are considered obese by BMI index; that is, have a Body Mass Index (kg/m<sup>2</sup>) greater than or equal to 30. This reflects an increase of 74% since 1991.<sup>1</sup>

This is also true for severe forms of obesity including morbid obesity: a form of severe obesity in which a person's BMI is over 40. According to Flegal et al.,<sup>2</sup> morbid obesity increased significantly

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during the last 10 year, from 2.9% to 4.7%, within the U.S. population.

Why is obesity treatment so difficult? As suggested by Perri,<sup>3</sup> "the maintenance of treatment effects represents the single greatest challenge in the long-term management of obesity." A typical behavioral treatment can produce a 8–10% body weight reduction over the course of 20–24 weekly sessions.<sup>4</sup> However, at the end of the treatment participants gradually regain weight: in the year after the end of the treatment obese persons typically regain from 30% to 50% of their initial losses.<sup>5</sup> The situation is even worse on the long term and for morbid obesity.

A recent study examined the successful weight maintenance over three years in a community-based sample of 854 subjects.<sup>6</sup> More than half (53.7%) of the participants in the study gained weight within the first twelve months, only one in four (24.5%) successfully avoided weight gain over three years, and less than one in 20 (4.6%) lost and maintained weight successfully.

For morbid obesity, the only effective therapy is bariatric surgery.<sup>7</sup> Nevertheless, as summarized by Korenkov et al.,<sup>7</sup> when we check the complications and quality of life, there is no single operation for morbid obesity without drawbacks: "According to current opinion, gastric restrictive procedures (adjustable gastric banding, vertical banded gastroplasty) are generally considered safe and quick to perform, but the long-term outcome and quality of life have been questioned. By contrast, the long-term efficacy of adjustable gastric banding can be improved by the development of new band devices. More complex bariatric procedures, such as the Roux-en-Y gastric bypass or biliopancreatic diversion, have a greater potential for serious perioperative complications but are associated with good long-term outcome in terms of weight loss combined with less dietary restriction."

As noted by Jeffery et al.,<sup>5</sup> "Fresh ideas are needed to push the field forward." This is why in this paper we attempted to conceptualize obesity, and in particular morbid obesity, as a peculiar form of addiction. Even if this idea is not new—the roots of this vision lies in the studies of Schachter<sup>8,9</sup>—in this paper we propose a bio-psychosocial approach, in which the genetic influence is matched by psychosocial issues. Further, the paper outlines how this approach may influence the treatment options, by focusing both on the lessons coming from actual addiction treatment and the opportunities offered by virtual reality. Finally, the paper presents and discusses the outcome of a controlled trial, based on the proposed approach, including a 6-

month follow-up: the sample includes 211 morbid obese females with a BMI of >40 and a documented history of failures.

#### *Determinants of obesity*

As effectively summarized by Bray,<sup>10</sup> in obesity "genes load the gun, the environment pulls the trigger." On one side genes are currently thought to explain 25–40% of the variance in BMI.<sup>11</sup> On the other side, the changes in the eating and activity habits are the triggers that activate the obesity process.<sup>12</sup> Below we will try to describe the actual status of research related to the different determinants of obesity focusing on two emerging topics: the lack of dopamine receptors (genetic determinant), and the pressure for thinness pressure for thinness and use of diet as main body image dissatisfaction treatment (cultural determinant).

*Research on the genetic determinants of obesity.* In 1968, when Schachter proposed his internal-external model of obesity,<sup>9</sup> a critical question was the source of the insensitivity to somatic cues: was it external or internal? The results of his research on ventromedial-lesioned rats<sup>8</sup> provided an answer more focused on the physiological determinants. This position was also supported by Nisbett's set-point hypothesis<sup>13</sup>: the hypothalamus is set to defend a specific body weight; going below this weight stimulated a greater desire to eat.

Since then, even if the set-point hypothesis is now abandoned, there has been a bias in how obesity as addiction is conceptualized<sup>14</sup>: for many, obese subjects are locked into their disturbance by biological forces.

In the last decade this view was supported by the discovery of the OB gene and its protein product Leptin.<sup>15</sup> Under normal conditions, overeating leads to growth of white fat cells (adipocytes) which synthesize the protein Leptin and secrete it into the bloodstream. When this protein reaches the hypothalamus, it binds to the Leptin receptor and decreases appetite by inhibiting the synthesis of neuropeptide Y (Npy gene)—a neurotransmitter that tends to increase appetite.

Studies on rats showed that a genetic mutation on the OB gene could stop the production of Leptin inducing marked overeating, sedentariness, and obesity. This situation was reversed by the administration of recombinant Leptin.<sup>16</sup>

Unfortunately, obese humans have high Leptin levels<sup>17</sup> and tend to resist the weight-regulating effects of exogenously administered Leptin.<sup>18</sup>

As clearly underlined by Fernández-López et al.,<sup>19</sup> the research in this field did not allow the development of effective pharmacological solutions: few drugs have reached a minimum level of effectiveness, and even fewer are available in medical practice. At present, there are only two drugs for long-term use: Sibutramine, an inhibitor of both serotonin, dopamine and norepinephrine reuptake, and Orlistat, a lipase inhibitor that targets pancreatic lipases and reduces absorption of dietary fat. In general, all different approaches developed to obtain workable drugs rely in only four main lines of action:

- Control of energy intake, mainly through modification of appetite
- Control of energy expenditure, essentially through the increase of thermogenesis
- Control of the availability of substrates to cells and tissues through hormonal and other metabolic factors controlling the fate of the available energy substrates
- Control of fat reserves through modulation of lipogenesis and lipolysis in white adipose tissue

Their conclusion is clear<sup>19</sup>: “[actual] pharmacological approaches to the treatment of obesity have not resulted yet in effective drugs.”

A possible new drug is Axokine (rhvCNTF), a modified form of a naturally occurring protein—ciliary neurotrophic factor—that signals through leptinlike pathways in the hypothalamus.<sup>20</sup> Even if preliminary results are promising,<sup>18</sup> research on humans is at the first stage.

A different research path is given by studies on Rimonabant (SR14171), a selective central cannabinoid (CB1) receptor antagonist.<sup>21</sup> The cannabinoid system is an essential endogenous regulator of energy homeostasis via central orexigenic as well as peripheral lipogenic mechanisms. In particular, the activation of neuronal CB1 receptors by endogenous cannabinoids, such as anandamide, increases appetite. So Rimonabant should work by blocking endogenous cannabinoid binding to CB1.

Another approach comes from a recent study from Wang et al.<sup>22</sup> These researchers found that the brains of obese individuals have relatively few of the nerve cell components called D2 receptors through which dopamine acts to stimulate pleasurable feelings from basic activities such as eating and sex. This datum suggests that obese individuals, given the low level of D2 receptor, may need to overeat to compensate for reduced stimulation of their brain reward circuits. This characteristics of obesity is partially addressed by

Sibutramine, one of the only two agents (the other is Orlistat, a gastric lipase inhibitor that blocks the absorption of part of the fat contained in a meal) approved by the Food and Drug Administration for weight loss and the maintenance of weight loss. In fact, Sibutramine produces its therapeutic effects by norepinephrine, serotonin and dopamine reuptake inhibition.

*Research on the psycho-social determinants of obesity.* In contrast to the efforts to document the physical consequences of obesity, much less is known about the psychological correlates of excess weight.

To deepen this link, Friedman and Brownell<sup>23</sup> used meta-analysis to examine the relationship between obesity and different psychological variables.

The most interesting result of their study is related to body image: “there is somewhat consistent body image disturbance in the form of body image distortion in obese individuals.”<sup>23</sup> Moreover, although body image disparagement appears to vary across populations, “body image disparagement may in fact be high in obese individuals.”

This datum may be connected to the results of a later study. Stice et al.<sup>24</sup> used data from a prospective study of 496 adolescent girls who completed a baseline assessment at age 11–15 years and four annual follow-ups to investigate risk factors of obesity. They found that self-reported dietary restraint, radical weight-control behaviors, depressive symptoms, and perceived parental obesity were the variables predicting the obesity onset. High-fat food consumption, binge eating, or exercise frequency-predicted obesity onset were not significant predictors.

These data are linked by the common belief that the best way to improve one’s body image is to lose weight: I go on a diet to have a better body. However, recent studies have questioned this belief: dietary intervention, even if accompanied by significant weight loss, may be ineffective in reducing total body dissatisfaction.<sup>25,26</sup> Moreover, different studies have shown that both adolescent and adults with elevated scores on dieting scales are at increased risk for future onset of obesity.<sup>27–29</sup> Finally, radical weight-control behaviors, such as vomiting and laxative abuse, have predicted increases in body mass over time.<sup>28</sup>

Apparently, people go on diet to improve body satisfaction. But, both the failure of the diet and/or the reduced effectiveness of dieting in improving body satisfaction, will induce more radical weight-control behaviors, leading in the long term to obesity. This process may be exacerbated by the lack of dopamine receptors that makes diet very difficult

to achieve: overeating may be required to compensate for reduced stimulation of the brain reward circuits.

Given the importance of body image satisfaction, these findings argue for the potential benefits of treatment strategies for improving appearance satisfaction for obese individuals, despite the success of their weight-management efforts.<sup>30</sup> Unfortunately, obesity researchers have not added yet body image interventions in their programs. Only recently, Cooper et al. underlined the need to introduce in the cognitive-behavioral treatment of obesity a specific module addressing body image concerns.<sup>31,32</sup>

Another key issue for obesity treatment is long-term weight maintenance, as shown by the disappointing results of many follow-up studies.<sup>33</sup> As stated by Cooper et al.,<sup>32</sup> an important problem in actual treatments is the lack of distinction between the objective of maintaining weight loss and the one of maintaining it. In particular, weight maintenance requires the ability of the patient in defining a realistic target weight range, in monitoring eating behaviors and in managing the frustration related to weight fluctuations. Unfortunately, these dimensions are not targeted by many nutritional and/or behavioral obesity treatments.

#### *Obesity as an addiction*

*Definition of addiction/dependence.* According to the *Merriam-Webster English Dictionary*, the definition of "addiction" is a "compulsive need for and use of a habit-forming substance (as heroin, nicotine, or alcohol) characterized by tolerance and by well-defined physiological symptoms upon withdrawal; broadly: persistent compulsive use of a substance known by the user to be harmful."

More in detail, an addiction is defined by the following three characteristics<sup>14</sup>:

- The person's heightened and habituated need for a substance
- The intense suffering that results from discontinuation of its use
- The person's willingness to sacrifice all (to the point of self-destructiveness) for substance taking

The first editions of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM) described addiction as a physical dependency to a substance that resulted in withdrawal symptoms in its absence. However the latest editions, including DSM-IV TR,<sup>34</sup> have moved toward a diagnostic instrument that classi-

fies such conditions as "dependency", rather than addiction. In the Tenth Revision of the International Classification of Diseases and Health Problems (ICD-10), we find a definition of "dependence syndrome" as a cluster of physiological, behavioral, and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviors that once had greater value (for a detailed description of ICD-10 clinical description and diagnostic guidelines, see Table 1).

If we compare the above definitions with the situation of many morbid obese subjects, it is clear that at least these three diagnostic guidelines match very well:

- A strong desire or sense of compulsion to take the substance
- Difficulties in controlling substance-taking behaviour in terms of its onset, termination, or levels of use
- Persisting with substance use despite clear evidence of overtly harmful consequences

So, apparently, it is possible to describe morbid obesity as a peculiar form of addiction/dependence. This hypothesis is also supported by the Wang study presented above<sup>22</sup>: the study found that the brains of obese individuals have relatively few of the nerve cell components called D2 receptors through which dopamine acts to stimulate pleasurable feelings. Because a deficit of the same receptor has been implicated in addiction to cocaine, heroin, and other drugs of abuse (Fig. 1), the researchers suggest that it may be linked to a range of compulsive behaviors.

Discussing these and other data coming from positron emission tomography, Wang et al.<sup>35</sup> conclude: "In pathologically obese subjects, we found reductions in striatal DA D2 receptors similar to that in drug-addicted subjects. Moreover, DA D2 receptor levels were found to have an inverse relationship to the body mass index of the obese subjects. We postulated that decreased levels of DA D2 receptors predisposed subjects to search for reinforcers; in the case of drug-addicted subjects for the drug and in the case of the obese subjects for food as a means to temporarily compensate for a decreased sensitivity of DA D2 regulated reward circuits."

In summary, the lack of dopamine receptors make obese subjects less sensitive to reward stimuli, which, in turn make them more vulnerable to food intake as a means to compensate for this deficit.

TABLE 1. ICD-10 DEFINITION OF DEPENDENCE

**Clinical description**

A cluster of physiological, behavioral, and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviors that once had greater value. A central descriptive characteristic of the dependence syndrome is the desire (often strong, sometimes overpowering) to take psychoactive drugs (which may or may not have been medically prescribed), alcohol, or tobacco. There may be evidence that return to substance use after a period of abstinence leads to a more rapid reappearance of other features of the syndrome than occurs with nondependent individuals

**Diagnostic guidelines**

A definite diagnosis of dependence should usually be made only if three or more of the following have been present together at some time during the previous year:

- A strong desire or sense of compulsion to take the substance;
- Difficulties in controlling substance-taking behavior in terms of its onset, termination, or levels of use;
- A physiological withdrawal state when substance use has ceased or have been reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- Evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses (clear examples of this are found in alcohol- and opiate-dependent individuals who may take daily doses sufficient to incapacitate or kill nontolerant users);
- Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects;
- Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.

**Diagnostic criteria for research**

Three or more of the following manifestations should have occurred together for at least 1 month or, if persisting for periods of less than 1 month, should have occurred together repeatedly within a 12-month period:

- A strong desire or sense of compulsion to take the substance;
- Impaired capacity to control substance-taking behaviour in terms of its onset, termination, or levels of use, as evidenced by the substance being often taken in larger amounts or over a longer period than intended, or by a persistent desire or unsuccessful efforts to reduce or control substance use;
- A physiological withdrawal state when substance use is reduced or ceased, as evidenced by the characteristic withdrawal syndrome for the substance, or by use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- Evidence of tolerance to the effects of the substance, such that there is a need for significantly increased amounts of the substance to achieve intoxication or the desired effect, or a markedly diminished effect with continued use of the same amount of the substance;
- Preoccupation with substance use, as manifested by important alternative pleasures or interests being given up or reduced because of substance use; or a great deal of time being spent in activities necessary to obtain, take or recover from the effects of the substance;
- Persistent substance use despite clear evidence of harmful consequences as evidenced by continued use when the individual is actually aware, or may be expected to be aware, of the nature and extent of harm.

*From the treatment of addiction to the treatment of obesity: some suggestions.* If morbid obesity can be described as an addiction, some suggestions to improve the actual long-term outcome of the available treatments may come from the approaches/strate-

gies used in the treatment of substance-related disorders. Volkow and Wise, in their recent paper for *Nature Neuroscience*,<sup>36</sup> share this vision: "some of the behavioral interventions that are beneficial in the treatment of addiction are also helpful in the

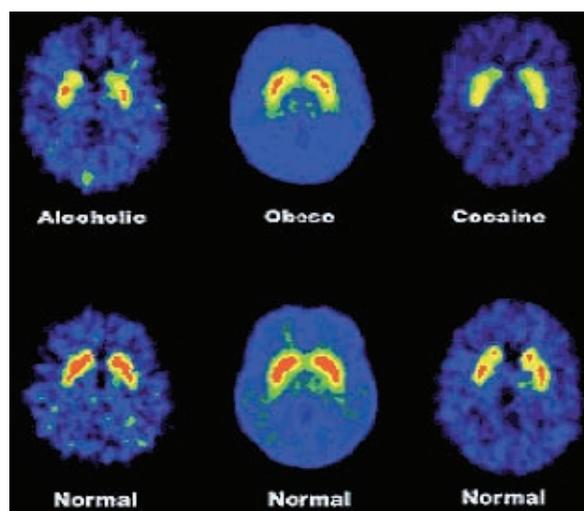


FIG. 1. Dopamine (DA) D2 receptors in addiction and obese patients (adapted from NIDA News Release, 2001)

treatment of obesity.” In particular, their main suggestions are two:

- Treatment requires continuous care, with different approaches to target the different phases (e.g., abstinence, relapse) of the disease
- Treatment programs may require, at least in some stages, the participation of the medical community

Below we will try to deepen these points, relating them to the actual approaches used in the treatment of obesity.

*Different levels of type and intensity of care.* A key lesson coming from the treatment of addiction is the need to tune the treatment to the specific needs of the patient. The Patient Placement Criteria for the Treatment of Substance-Related Disorders (PPC) is a validated assessment prototype that stages addictive disease, provides guidelines as to the type and intensity of care, and systematizes the care of clients and patients who suffer from addictive disease.<sup>37</sup> The use of the PPC, now in its second edition (PPC-2R), is mandated in many states across the United States, and its use has spread to over 30 countries across the globe. The main features of the PPC-2R are both different levels of care and the choice of multifactorial assessment dimensions. According to the PPC-2R, addiction can be addressed through the following levels of care (for a detailed description, see Table 2):

- Level 0.5, Early Intervention
- Level I, Outpatient Treatment

- Level II, Intensive Outpatient/Partial Hospitalization
- Level III, Residential/Inpatient Treatment
- Level IV, Medically-Managed Intensive Inpatient Treatment

Within these levels of care, a decimal number (ranging from 0.1 to 0.9) expresses gradations of intensity. For example, a III.1 level of care provides a benchmark for intensity at the minimum description of Level III care. If we compare this approach with the one used in the standard treatment of obesity we can find significant differences. As summarized by Wing,<sup>38,39</sup> the typical behavioral treatment of obesity is delivered to groups, based on outpatient setting, involving weekly meetings whose main goal is the self-monitoring of eating. Even one of the most influential new approaches to the treatment of obesity—the cognitive-behavioral protocol detailed by Cooper et al.<sup>31,32</sup>—does not focus on the level of care. This protocol is divided in two phases: Phase 1, whose main goal is weight loss (30 weeks); and Phase 2, whose main goal is weight stability (14 weeks). In both phases the level of care is based on outpatient treatment, independently from the severity of the patient. Related to the definition of different levels of care is the concept of unbundling: uncoupling various treatment services from one another to provide a more patient specific treatment experience. Most obesity treatment providers are program-centric. This means that the patient is fit into the program, rather than vice versa. This issue is however addressed by the Cooper protocol<sup>32</sup>: “Flexibility is also required when implementing the treatment itself. The therapist should personalize the treatment, applying those techniques that are relevant to the individual patient and at a rate that matches their progress.”

*Multidimensional assessment and focus.* The PPC-2R defines areas of inquiry or domains of difficulties that must be assessed for a 360 degree view of the client or patient. These areas of inquiry are called *Dimensions* (Table 3). The PPC-2R defines six dimensions:

- Dimension 1: Acute Intoxication and/or Withdrawal Potential
- Dimension 2: Biomedical Conditions and Complications
- Dimension 3: Emotional, Behavioral or Cognitive Conditions and Complications
- Dimension 4: Readiness to Change (formerly “Treatment Acceptance/Resistance”)

TABLE 2. PPC-2R LEVELS OF CARE

**Level 0.5: Early Intervention**

Early intervention constitutes a service for specific individuals who, for a known reason, are at risk of developing dependence-related problems or for those for whom there is not yet sufficient information to document a dependence syndrome.

**Level I: Outpatient Treatment**

Outpatient services are designed to treat the individual's level of clinical severity and to help the individual achieve permanent changes in his or her dependence behavior and mental functioning. To accomplish this, services must address major lifestyle, attitudinal and behavioral issues that have the potential to undermine the goals of treatment or inhibit the individual's ability to cope with major life tasks without the addictive behavior.

**Level II: Intensive Outpatient Treatment/Partial Hospitalization**

Intensive Outpatient Treatment is an organized outpatient service that delivers treatment services during the day, before or after work or school, in the evening or on weekends. For appropriately selected patients, such programs provide essential education and treatment components while allowing patients to apply their newly acquired skills within "real world" environments.

Level II programs can provide comprehensive biopsychosocial assessments and individualized treatment plans, including formulation of problem statements, treatment goals and measurable objectives—all developed in consultation with the patient.

**Level III: Residential/Inpatient Treatment**

Residential/Inpatient Treatment encompasses organized services staffed by designated addiction treatment and mental health personnel who provide a planned regimen of care in a 24-hour live-in setting. Such services adhere to defined sets of policies and procedures. They are housed in, or affiliated with, permanent facilities where patients can reside safely. They are staffed 24 hours a day. Mutual and self-help group meetings generally are available on-site. The defining characteristic of all Level III programs is that they serve individuals who need safe and stable living environments in order to develop their recovery skills. Such living environments may be housed in the same facility where treatment services are provided or they may be in a separate facility affiliated with the treatment provider. More in detail, Level III encompasses four types of programs:

Level III.1: Clinically Managed Low-Intensity Residential Treatment

Level III.3: Clinically Managed Medium-Intensity Residential Treatment

Level III.5: Clinically Managed High-Intensity Residential Treatment

Level III.7: Medically Monitored Inpatient Treatment.

**Level IV: Medically Managed Intensive Inpatient Treatment**

Medically Managed Intensive Inpatient Treatments provide a planned regimen of 24-hour medically directed evaluation, care and treatment of mental and substance-related disorders in an acute care inpatient setting. They are staffed by designated addiction-credentialed physicians, including psychiatrists, as well as other mental health- and addiction-credentialed clinicians. Such services are delivered under a defined set of policies and procedures and has permanent facilities that include inpatient beds.

Level IV programs provide care to patients whose mental and substance-related problems are so severe that they require primary biomedical, psychiatric and nursing care. Treatment is provided 24 hours a day, and the full resources of a general acute care hospital are available. The treatment is specific to mental and substance-related disorders; however, the skills of the interdisciplinary team and the availability of support services allow the conjoint treatment of any co-occurring biomedical conditions that need to be addressed.

- Dimension 5: Relapse, Continued Use or Continued Problem Potential
- Dimension 6: Recovery/Living Environment

During the patient assessment, specific problems and priorities are identified as justifying admission to a

particular level of care. The addressing of those problems and priorities determines when a patient can be treated at a different level of care or discharged from treatment. It is important to note that assessment is not used only at the start of the treatment: as the patient moves through treatment in any level of service,

TABLE 3. PPC-2R DIMENSIONAL CRITERIA

**Dimension 1: Acute Intoxication and/or Withdrawal Potential**

Assessment considerations include: What risk is associated with the patient's current level of acute intoxication? Is there significant risk of severe withdrawal symptoms or seizures, based on the patient's previous withdrawal history, as well as the amount, frequency, chronicity and recency of discontinuation of (or significant reduction in) substance use? Are there current signs of withdrawal?

**Dimension 2: Biomedical Conditions and Complications**

Assessment considerations include: Are there current physical illnesses, other than withdrawal, that need to be addressed because they create risk or may complicate treatment? Are there chronic conditions that affect treatment?

**Dimension 3: Emotional, Behavioral or Cognitive Conditions and Complications**

Assessment considerations include: Are there current psychiatric illnesses or psychological, behavioral, emotional or cognitive problems that need to be addressed because they create risk or complicate treatment? Are there chronic conditions that affect treatment? Do any emotional, behavioral or cognitive problems appear to be an expected part of the addictive disorder, or do they appear to be autonomous? Even if connected to the addiction, are they severe enough to warrant specific mental health treatment? Is the patient able to manage the activities of daily living? Can he or she cope with any emotional, behavioral or cognitive problems?

**Dimension 4: Readiness to Change**

This is based on the concept that an individual's emotional and cognitive awareness of the need to change and his or her level of commitment to and readiness for change indicate his or her degree of cooperation with treatment, as well as his or her awareness of the relationship of alcohol or other drug use to negative consequences.

**Dimension 5: Relapse, Continued Use or Continued Problem Potential**

Assessment considerations include: Is the patient in immediate danger of continued severe mental health distress and/or substance use? Does the patient have any recognition or understanding of, or skills in coping with, his or her addictive or mental disorder in order to prevent relapse, continued use or continued problems? How severe are the problems and further distress that may continue or reappear if the patient is not successfully engaged in treatment at this time? How aware is the patient of relapse triggers, ways to cope with cravings to use, and skills to control impulses to use or impulses to harm self or others?

**Dimension 6: Recovery/Living Environment**

Assessment considerations include: Do any family members, significant others, living situations, or school or work situations pose a threat to the patient's safety or engagement in treatment? Does the patient have supportive friendships, financial resources, or educational or vocational resources that can increase the likelihood of successful treatment? Are there legal, vocational, social service agency or criminal justice mandates that may enhance the patient's motivation for engagement in treatment? Are there transportation, child care, housing or employment issues that need to be clarified and addressed?

his or her progress in all six dimensions should be continually assessed. Such multidimensional assessment ensures comprehensive treatment. This is not the case for many obesity treatments. As detailed by Wing,<sup>39</sup> most behavioral treatments are only based on the different facets of the eating experience: self monitoring of eating, behavioral goals related to eating and exercise, nutritional knowledge, and relapse prevention. Nevertheless, different studies are showing that differences in the six dimensions identified by PPC-2R have a significant role in weight maintenance after a therapy. Byrne et al.<sup>40</sup> identified specific psychological factors which characterized the "re-

gainers" but not the maintainers (Dimensions 3, 4, and 5): failure to achieve weight goals and dissatisfaction with the weight achieved; the tendency to evaluate self-worth in terms of weight and shape; a lack of vigilance with regard to weight control; a dichotomous (black-and-white) thinking style; and the tendency to use eating to regulate mood. In a later study, Byrne et al.<sup>41</sup> identified two prospective predictors of weight regain: one cognitive factor (dichotomous thinking) and one historical variable (maximum lifetime weight). Following these data, the Cooper protocol<sup>32</sup> introduced a broader approach targeting:

- The distinction between weight loss and weight maintenance
- The potential obstacles to the maintenance of the weight maintenance: unrealistic weight goals, body image concerns and patients' primary goals
- The behavioral and cognitive skills needed for effective weight control

*Functional analysis and skill training.* If we analyze the cognitive behavioral treatment of addiction, we can find two main goals<sup>42,43</sup>: functional analysis and skill training. On one side, therapist and patient do a functional analysis for each instance of substance abuse during treatment: they identify the patient's thoughts, feelings, and circumstances before and after the substance abuse. In the first phase of the treatment this is used to assess the determinants, or high-risk situations, that are likely to lead to substance abuse (e.g., to cope with interpersonal difficulties, to experience risk or euphoria not otherwise available, etc.). In the second phase of the treatment, functional analyses help in identifying the situations or states in which the individual still has difficulty coping. On the other side, the treatment trains abusers unlearn old habits associated with substance abuse and learn or relearn healthier skills and habits. By the time the level of substance use is severe enough to warrant treatment, patients are likely to be using it as their single means of coping with a wide range of interpersonal and intrapersonal problems. For this reason, the treatment<sup>42</sup> has to train patients in:

- *Developing coping skills:* to help patients recognize the high-risk situations in which they are most likely to use substances and to develop other, more effective means of coping with them
- *Changing reinforcement contingencies:* to identify and reduce habits associated with a substance-using lifestyle by substituting more enduring, positive activities and rewards
- *Fostering the motivation for abstinence:* to do a decisional analysis which clarifies what the individual stands to lose or gain by continued substance use
- *Fostering management of painful affects:* to recognize and cope with urges to use substance
- *Improving interpersonal functioning and enhancing social supports:* to help patients in expanding their social support networks and build enduring, substance-free relationships

The cognitive-behavioral treatment of obesity has included both functional analysis and skill training

in its protocol. Nevertheless these approaches are missing in some behavioral treatments and in most behaviorally oriented group psycho-educational interventions.

*Proposed Approach: Experiential Cognitive Therapy*

Experiential-Cognitive Therapy for Obesity is a relatively short-term, integrated, patient oriented approach that focuses on individual discovery.<sup>44-46</sup> It shares with the cognitive-behavioral approach proposed by Cooper et al. the use of a combination of cognitive and behavioral procedures to help the patient identify and change the maintaining mechanisms.<sup>32</sup> However, it considers morbid obesity as a peculiar form of addiction. So, as in the cognitive-behavioral treatment of addictions,<sup>47</sup> the two main goals are the functional analysis of the maintaining mechanisms and the required skill training (relapse prevention). Moreover, the proposed approach contains the following four distinctive elements none of which, alone, is unique to this approach:

- *It is based on different types and intensity of care.* If needed, as evaluated through the Patient Placement Criteria, the patient can enter, for some time, a medically managed intensive inpatient treatment.<sup>37</sup> In this view, the choice between an inpatient or outpatient treatment, and between individual or group sessions, is a critical part of the therapeutic strategy.
- *Its focus on the body experience,* a major reason patients want to lose weight.<sup>48</sup> Differently from the Cooper protocol, the experience of the body is not addressed only as potential obstacle to the acceptance of weight maintenance.<sup>32</sup> This approach suggests a functional vision of the body considered only as an intentional object, an image, a mental representation. We do not agree with this vision. Following the emerging "embodied cognition" approach,<sup>49-52</sup> we consider body image as an integral part of the subjects' identity. As noted by Gallagher,<sup>53</sup> the body experience is not neutral but it places constraints on intentional consciousness: "changes or distortion introduced at the level of body schema result in changes or distortions in intentional consciousness."
- *Its focus on the empowerment process.* Following the Cooper protocol, we consider a critical goal of the therapy the ability of the patient in defining a realistic target weight range, in monitoring eating behaviors and in managing the frustration related to weight fluctuations. However, differently from the Cooper protocol, we do not con-

sider these abilities as behavioral skills only. Here we agree with the DiClemente position,<sup>54</sup> which describes them as part of a broader individual dimension, defined "control self-efficacy": "an individual's ability to control the addictive behavior in a variety of provocative situations." Bandura<sup>55,56</sup> proposed the concept of self-efficacy as an explanation of behavior and behavior change. People tend to avoid activities they believe exceed their coping abilities and undertake those they consider themselves capable of handling. Efficacy expectations influence the decision to attempt a behavior, the length of time it will be attempted, and the effort, which will be involved.<sup>55</sup> Low efficacy expectations in the face of obstacles will result in persons experiencing serious doubts or giving up, while high efficacy expectations will result in greater efforts being extended to achieve desired results. Following this approach, the main strategy to raise self-efficacy is "empowerment", the process of helping people feel a sense of control over their lives. Within this process, there are three critical dimensions<sup>57</sup> to address:

- *Perceived control*: includes beliefs about authority, decision-making skills, availability of resources, autonomy in the scheduling and performance of work
- *Perceived competence*: reflects role-mastery, which besides requiring the skillful accomplishment of one or more assigned tasks, also requires successful coping with non-routine role-related situations
- *Goal internalization*: this dimension captures the energizing property of a worthy cause or exciting vision
- *The use of virtual reality (VR)*. VR helps the therapist in providing the two above features of our approach: body experience treatment and empowerment. The use of a VR treatment makes it possible to use the psycho-physiological effects induced by the virtual experience on the body schema for therapeutic purposes.<sup>58,59</sup> Moreover VR has the right features to support empowerment, since it is a special, sheltered setting where patients can start to explore and act without feeling threatened.<sup>60</sup>

*Role of virtual reality.* What is virtual reality (VR), and what is its role in our approach? According to Rubino et al.,<sup>61</sup> McCloy and Stone,<sup>62</sup> and Székely and Satava,<sup>63</sup> VR can be described as: "a collection of technologies that allow people to interact efficiently with 3D computerized databases in real time using their natural senses and skills."<sup>62</sup>

However, if we shift our attention on behavioral sciences, VR is defined as "an advanced form of human-computer interface that allows the user to interact with and become immersed in a computer-generated environment in a naturalistic fashion."<sup>64</sup> These two definitions underline two different visions of VR. For physicians and surgeons, the ultimate goal of VR is the presentation of virtual objects to all of the human senses in a way identical to their natural counterpart.<sup>63</sup> For clinical psychologists and rehabilitation specialists, the ultimate goal is different. They use VR to provide a new human-computer interaction paradigm in which users are no longer simply external observers of images on a computer screen but are active participants within a computer-generated three-dimensional virtual world.<sup>65</sup> Using VR in this way, the patient is more likely not only to gain an awareness of his/her need to do something to create change but also to experience a greater sense of personal efficacy. As emphasized by social cognitive theory, performance-based methods are the most effective in producing therapeutic change across behavioral, cognitive, and affective modalities.<sup>66</sup> The proposed experiential approach based on the interaction with virtual reality environments could help patients in discovering that difficulties can be defeated, so improving their cognitive and behavioral skills for coping with stressful situations.

This feature of VR has been extensively used in different clinical psychology treatments,<sup>60,67-74</sup> and it is expected to increase in the future: according to a recent positioning paper on the future of psychotherapy,<sup>75</sup> the use of VR and computerized therapies are ranked, respectively, third and fifth out of 38 psychotherapy interventions that are predicted to increase in the next 10 years.

At the same time, however, immersive VR can be considered an "embodied technology" for its effects on body perceptions.<sup>76</sup> In practically all VR systems, the human operator's normal sensorimotor loops are altered by the presence of distortions, time delays, and noise.<sup>77</sup> Such alterations, that are introduced unintentionally and usually degrade performance, affect body perceptions, too. The somesthetic systems has a proprioceptive subsystem that senses the body's internal state, such the position of limbs and joints, and the tension of the muscles and tendons. Mismatches between the signals from the proprioceptive system and the external signals of a virtual environments alter significantly body perceptions.<sup>78</sup> As noted by Gallagher,<sup>53</sup> "[different] studies indicate that changes in various aspects of body schemata have an effect on the way subjects perceive their own body, that

is, changes in body schemata lead to changes in body images." Following this vision we are using the changes in body experience produced by VR to facilitate the changes in body image. In particular, we applied within a VR environment some elements (for a detailed description of the VR component, see Thompson et al.<sup>30</sup> of the protocol for body image disturbances defined by Cash.<sup>79,80</sup> As showed by previous experimental research, VR is effective in producing fast changes in body experience<sup>81</sup> and in body dissatisfaction.<sup>74,82,83</sup>

## METHODS

This paper presents a Phase III randomized controlled trial in which we verified the efficacy of our approach (Experiential Cognitive Therapy–Experiential CT) in treating severe obese patients (BMI > 40) with a documented history of failures. In the trial, we compared its effect with nutritional (NT) and cognitive-behavioral (CBT) approaches.<sup>84</sup>

More in detail, the present study evaluated, in a randomized design: (1) the comparison of the effectiveness of three different inpatient approaches in the treatment of morbid obese patients: experiential-cognitive therapy, cognitive-behavior therapy, and a nutritional groups; (2) the assessment of differential effects of the three treatments; and (3) the comparison of the medium-term (6 months) effects of the three treatments.

In previous studies, a preliminary version of this approach was tested on clinical and non-clinical subjects in Phase I and Phase II trials.<sup>82,83,85–87</sup>

### Patients

Three hundred consecutive patients seeking treatment at the Obesity Unit of the Istituto Auxologico Italiano, Verbania, Italy (a medically managed intensive inpatient Unit) were seen for screening interviews for admission to the study. Criteria for participation in the study included the following: (1) women aged 18–50 years; (2) a BMI > 40; (3) no other concurrent severe psychiatric disturbances (psychosis, depression with suicidal risk, alcohol or drug abuse); (4) no concurrent medical condition not related to the disorder; (5) one or more failures in following an obesity treatment; and (5) written and informed consent to participate.

Of these, 84 either did not fulfill inclusion criteria or were excluded for other reasons (e.g., time constraints, involvement in other treatments). All patients meeting the inclusion criteria were then

randomly assigned to the waiting-list group and to the one of the three treatment conditions, all conducted on an inpatient basis (Fig. 2).

The randomization scheme was generated by using the Web site Randomization.com—<www.randomization.com>.

After randomization, five patients rejected participation in the study: two in the CBT group and one in the ECT group refused the treatment because in their opinion a psychological intervention was not required. Two in the NT groups left the hospital for family and work reasons. A chi-square analysis did not find any significant differences in the rejections between the groups.

Finally, 211 patients (mean age:  $36.13 \pm 9.04$  years; mean weight:  $110.69 \pm 14.81$  kg; mean height:  $1.62 \pm 0.06$  m; mean BMI:  $42.16 \pm 5.01$ ) entered the treatment phase. The majority (54%) had graduated from upper secondary school, were employed at the time of the study (71.2%) and were not married.

The study received ethical approval by Ethical Committee of the Istituto Auxologico Italiano and received, by the Current Controlled Trials Organization, the following official trial number—"ISRCTN59019572—VEPSY Updated."

### Procedures

In the initial interview, prospective participants were provided with detailed information about the study and the treatments. All patients included in the study were randomly assigned to the waiting-list group and to the one of the three treatment conditions described below, all conducted on an inpatient basis. The duration for all treatments was 6 weeks, and treatments were administered by two chartered clinical psychologists and one chartered psychotherapist under the supervision of a senior chartered psychotherapist. The three therapists were balanced among the three conditions. In accordance with informed consent, assessments were obtained before treatment, at posttreatment, and 6 months after the end of treatment.

*Nutritional groups.* In the NT condition, the subjects entered only 5 weekly nutritional groups held by dieticians based on the LEARN manual,<sup>88</sup> whose goal was to provide practical guidelines for the self-monitoring of eating and lessons on nutrition (e.g., stressing gradual weight loss with the caloric restriction achieved largely by reductions in fat intake), plus a low-calorie diet (1,200 kcal/day) and physical training (30 min of walking two times a week as a minimum).

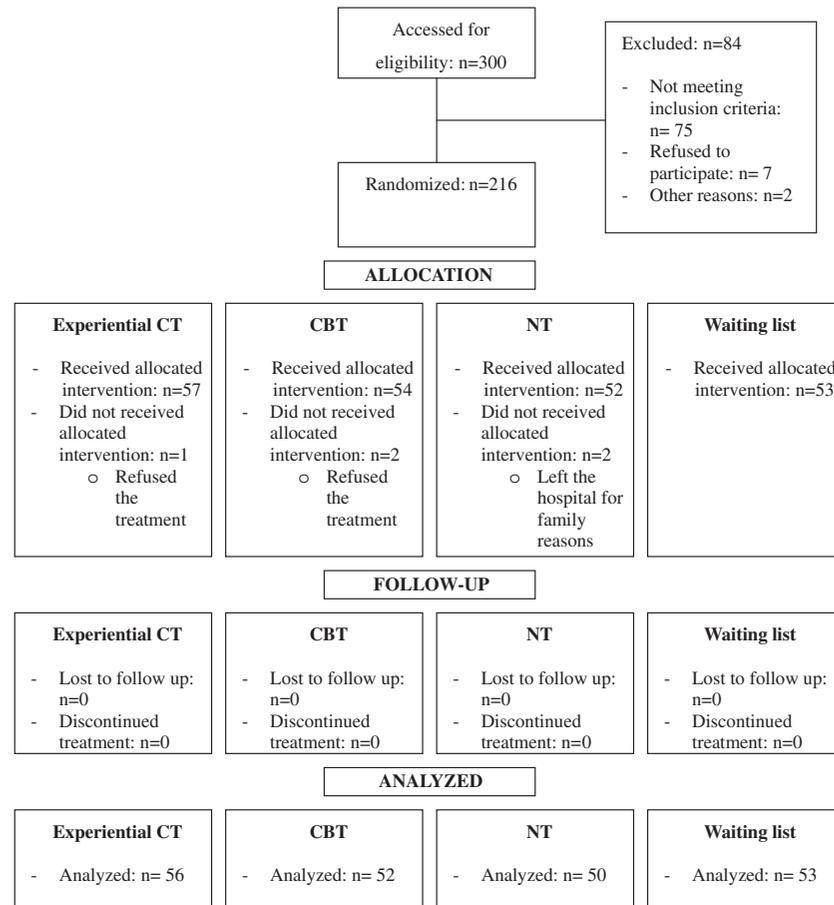


FIG. 2. Consort Flowchart for Randomized Trial

*Cognitive-behavioral therapy.* CBT involved the same treatment proposed in the first condition plus 15 additional sessions over 6 weeks. Therapists followed a detailed manual that outlined the content of each session. This manual was based on the cognitive-behavioral treatment approach described by Cooper et al.<sup>31,32</sup> It was developed during a year of intensive pilot work and adapted to the inpatient setting. Patients were taught to self-monitor their food intake and eating patterns and thoughts, as well as the circumstances and environment surrounding eating (e.g., whether eating alone or with others, speed of eating, and place of eating). Patients were also taught to identify problems in eating, mood, and thinking patterns and to gradually develop alternative patterns. In particular, after the first week the patients entered five weekly group sessions aimed at addressing weight and primary goals, and 10 biweekly individual sessions aimed at establishing and maintaining weight loss, addressing barriers to weight loss, increasing activity, addressing body image concerns and supporting weight maintenance.

*Experiential Cognitive therapy.* Experiential CT involved the same treatment proposed in the first condition plus 15 additional sessions over 6 weeks. In particular, after the first week, the patients entered five weekly group sessions aimed at improving motivation to change and assertiveness, and 10 biweekly virtual reality sessions. Experiential CT treatment was based on a detailed protocol describing the contents of each of the 15 sessions.<sup>84,89</sup> For the VR sessions, the Virtual Reality for Eating Disturbances Modification (VREDIM) was used (Figs. 3 and 4).

VREDIM is an enhanced version of the original Virtual Reality for Body Image Modification (VEBIM) immersive virtual environment, previously used in different preliminary studies on non-clinical subjects.<sup>58,90</sup> VREDIM was developed using the VIRTOOLS Dev 3 virtual reality development toolkit by Virtools SA (Paris, France). It runs on a PC-based workstation (Pentium-4, 3.0 Ghz, 512 Mb Ram, Nvidia 6800 GT Graphic Card with 128 MB Video Ram). Immersion is provided by a Sony Glasstron PLM-S700 head-mounted display includ-



FIG. 3. A VREDIM session

ing a InterTrax 2 head tracker (InterSense Inc., Bedford, MA).

VREDIM is composed of 14 virtual environments, used by the therapist within a 60-min session with the patient. The environments present critical situations related to the maintaining/relapse mechanisms (Home, Supermarket, Pub, Restaurant, Swimming Pool, Beach, Gymnasium) and two body image comparison areas. Through the VR experience, the patients practice both eating/emotional/relational management and general decision-making and problem-solving skills. By directly practicing these skills within the VR environment, the patient is helped in developing spe-

cific strategies for avoiding and/or coping with these.

In the sessions, we used the "20/20/20 rule." During the first 20 min, the therapist focuses on getting a clear understanding of the patient's current concerns, level of general functioning, and the experiences related to food. This part of the session tends to be characterized by patients doing most of the talking, although therapist guides with questions and reflection to get a sense of the patient's current status. The second 20 min is devoted to the VR experience. During this part of the session, the patient enters the virtual environment and faces a specific critical situation (e.g., Kitchen, Supermarket, Pub,



FIG. 4. Two VREDIM situations: Supermarket and Kitchen

Restaurant, Gymnasium). Here the patient is helped in developing specific strategies for avoiding and/or coping with it. In the final 20 min, the therapist explores the patient's understanding of what happened in VR and the specific reactions—emotional and behavioral—to the different situations experienced. If needed, some new strategies for coping with the VR situations are presented and discussed. To support the empowerment process, the therapists follow the Socratic style: they use a series of questions, related to the contents of the virtual environment, to help clients synthesize information and reach conclusions on their own.

The first session is used to assess any stimuli that could elicit abnormal eating behavior. Specifically, the attention is focused on the patient's concerns about food, eating, shape and weight. This assessment is normally part of the Temptation Exposure with Response Prevention protocol.<sup>91</sup> At the end of the first VR session the therapist uses the miracle question, a typical approach used by the solution-focused brief therapy.<sup>92,93</sup>

According to this approach the therapist asks the patient to imagine what life would be like without her/his complaint. Answering this question in writing the patient constructs her/his own solution, which then guides the therapeutic process.<sup>94</sup> According to deShazer,<sup>94</sup> this approach is useful for helping patients establish goals, that can be used to verify the results of the therapy. Using VR to experience the effects of the miracle, the patient is more likely not only to gain an awareness of her need to do something to create change but also to experience a greater sense of personal efficacy.

The next nine sessions are used to assess and modify:

- *The expectations and emotions related to food and weight:* This is done both by integrating different cognitive-behavioral methods: Countering, Alternative Interpretation, Label Shifting, Deactivating the Illness Belief
- *The strategies used to cope with difficult interpersonal and potential maintenance situations:* This is done both by using the Temptation Exposure with Response Prevention<sup>59,91</sup>—and by working on these three empowering dimensions<sup>57</sup>: *perceived control, perceived competence and goal internalization.*
- *The body experience of the subject.* To do this, the virtual environment integrates the therapeutic methods (Table 2) used by Butter and Cash<sup>95</sup> and Wooley and Wooley.<sup>96</sup> In particular in VREDIM we used the virtual environment in the same

way as guided imagery<sup>97</sup> is used in the cognitive and visual/motorial approach.

*Assessment.* Subjects were assessed by one of three independent assessment clinicians who were not involved in the direct clinical care of any subject. They were two M.A.-level chartered psychologists and a Ph.D.-level chartered psychotherapist. All the subjects were assessed at pretreatment and upon completion of the clinical trial.

Height was measured before treatment with a stadiometer, and weight was assessed with the participant in lightweight clothing with shoes removed, on a balance beam scale. The following psychometric test was obtained at entry to the study and at the end of the follow-up phase (6 months after the end of the therapy):

- Italian version of the Eysenck Personality Inventory–EPI.<sup>98</sup>

Moreover, the following psychometric tests were administered at each assessment point:

- Italian version<sup>99</sup> of the Dieter's Inventory of Eating Temptations.<sup>100</sup>
- Italian version<sup>101</sup> of the State-Trait Anxiety Inventory–STAI<sup>102</sup>
- Italian version<sup>103</sup> of the Weight Efficacy Life-Style Questionnaire–WELSQ.<sup>104</sup>
- Italian version<sup>105</sup> of the Body Satisfaction Scale–BSS.<sup>106</sup>
- Italian version<sup>107</sup> of the Body Image Avoidance Questionnaire–BIAQ.<sup>108</sup>
- Contour Drawing Rating Scale–CDRS,<sup>109</sup> a set of 9 male and female figures with precisely graduated increments between adjacent sizes

#### *Statistical analysis*

The pretest-posttest design is a frequently encountered repeated measures design in psychology that requires special attention. In such a design, measurements are taken before and after an intervention of some sort. Often, as in this paper, two or more groups of people will participate (e.g., a treatment group and a control group), and the researcher is interested in determining whether one group's posttest scores changed from the pretest significantly more than another group's posttest scores. Researchers in the behavioral sciences tend to use one of three statistical analyses<sup>110,111</sup> here:

- A repeated measures ANOVA with time as the *Within* variable and group as the *Between* variable
- An analysis of covariance (ANCOVA) on the gain scores (the gain score for a person is simply the posttest score minus the pretest score) using the pretest scores as covariates
- An ANOVA on the gain scores

Which analysis is the most appropriate? The first approach, the repeated measures ANOVA, is probably the most frequently used, but it is the least parsimonious. Because performing a one-way ANOVA on gain scores is more efficient, this procedure is always better than the repeated measures ANOVA.<sup>112</sup> The question then becomes when to use an ANOVA versus an ANCOVA on gain scores.

As clearly stated by different authors for a randomized design, where there is random assignment to treatment groups and the pretest group means can be assumed to be the same, the ANCOVA provides a more powerful analysis of the group effect.<sup>112</sup> For a technical discussion, see Huck and McLean,<sup>110</sup> and Maxwell and Delaney.<sup>113</sup> To verify this assumption, before the pre/post comparisons, individual one-way analyses of variance (ANOVA) were conducted to identify pre-treatment differences among groups in demographic characteristics, clinical variables (weight) and the psychological variables (the results of the assessment phase).

Differential effects of the treatments were determined using post-hoc analyses. In particular, to reduce the risk of type I errors, we used the LSD post-hoc procedure with an adjusted Experiment-wise Error Rate (EER): 0.05 for each variable in a three-group analysis and 0.025 for each variable in a four-group analysis.<sup>114</sup>

## RESULTS

Before beginning analyses of the treatment effects, pretreatment characteristics of groups were compared. As a check on the random assignment to conditions, ANOVAs of the pretreatment differences among the conditions and the waiting list group were carried out on all the clinical and psychological variables. None of the tests was significant at  $p = 0.05$ .

### *Pre- and post-treatment analysis*

The oneway ANCOVA on the pre- post-treatment differences showed a significant group effect ( $F = 177.596$ , d.f. = 3, 206,  $p < 0.000$ , effect size = 0.72) on the primary outcome variable of weight reduction. In particular, post hoc analyses showed a significant difference between the waiting list group and the three treatments ( $p < 0.000$  for all the treatments). While no significant differences were found in the waiting list group between the pre- and post-measurements, all the treatment groups were able to obtain significant weight reductions (Table 4). Post-hoc analyses did not revealed significant differences among the three treatments, even if the weight reduction for the CBT group was slightly higher.

For all the psychological variables, the ANCOVAs on the pre-post treatment comparison showed a significant group effect. More in detail, State-Trait Anxiety Index (STAI) significantly decreased in all the treatments without differences between them, while no significant changes are evidenced in the waiting list condition (Table 5). The same trend was found for the Eating Behavior characteristics (DIET and WELSQ) and Body Satisfaction (BSS, BIAQ, and CDRS). In general, the reduction is higher, though non-significant, for the Experiential CT group.

TABLE 4. MEANS AND STANDARD DEVIATIONS FOR THE CLINICAL OUTCOME MEASURES IN EACH TREATMENT CONDITION AT PRE- AND POST-TREATMENT

Measure weight (kg)	Waiting list		ECT		CBT		NT	
	M	SD	M	SD	M	SD	M	SD
Pre	111.4	15.3	112.1	15.6	108.0	12.1	110.0	15.2
Post	112.2	14.9	105.0	14.3	100.5	11.3	103.2	14.5
Follow-up			99.6	15.5	99.7	14.5	104.3	14.7

TABLE 5. MEANS AND STANDARD DEVIATIONS FOR THE SIGNIFICANT PSYCHOLOGICAL OUTCOME MEASURES IN EACH TREATMENT CONDITION AT PRE- AND POST-TREATMENT

Measure	Waiting list		ECT		CBT		NT		ANCOVA			
	M	SD	M	SD	M	SD	M	SD	F	df	P	
STAI												
Pre	44.10	11.34	39.04	10.72	41.12	11.39	41.36	12.09	13.0	3, 206	0.000	
Post	44.69	11.91	33.47	8.2	34.93	10.21	34.73	10.12				
DIET Tot												
Pre	52.12	14.01	48.59	13.77	50.12	14.07	51.87	12.94	22.70	3, 206	0.000	
Post	52.36	13.49	32.55	15.46	30.95	16.02	36.40	16.34				
WELSQ												
Pre	122.8	35.01	125.9	35.89	125.0	38.73	117.8	34.12	24.02	3, 206	0.000	
Post	123.7	34.74	163.8	27.90	165.8	29.07	156.4	38.20				
BSS Tot												
Pre	55.90	12.32	51.37	14.80	58.76	12.39	51.4	13.81	11.31	3, 206	0.000	
Post	55.77	13.57	42.14	13.71	49.43	12.38	42.49	17.43				
BIAQ Tot												
Pre	32.19	8.69	30.12	7.62	32.69	7.76	32.29	8.72	6.73	3, 206	0.000	
Post	31.71	8.89	25.84	8.35	27.86	6.24	26.56	8.89				
CDRS Tot												
Pre	1.83	0.39	1.70	0.61	1.97	0.48	1.79	0.42	3.52	3, 206	0.016	
Post	1.79	0.37	1.55	0.56	1.63	0.34	1.56	0.35				

#### Follow-up analysis

We applied one-way ANCOVAs to the pre/follow-up weight differences (Table 4). The analysis showed a nonsignificant group effect. Moreover, no significant differences in the pre/follow-up reduction were found between Experiential CT group and CBT group, even if the weight reduction for the Experiential CT group was slightly higher. In all the groups the pre/follow-up weight reduction is strongly significant ( $p > 0.000$ ), even if, for the NT group the follow-up weight is higher than the weight at the end of the therapy.

We then used a Chi Square analysis to compare within the three groups:

- The number of subjects who reached a 10% weight reduction in relation to the initial weight
- The number of subjects who maintained or improved the weight reduction achieved after the treatment
- The subjects with a weight equal or higher than the initial one

In all three analyses, we found a significant difference between the three conditions (Table 6), with Experiential CT as best condition and NT as worse condition.

We also compared Experiential CT and CBT groups only. We found that in Experiential CT, compared with CBT:

- 25% more subjects achieved a 10% weight reduction (Chi Square = 2.913;  $df = 1$ ;  $p = 0.088$ )
- 11% more subjects were able to maintain or improve the weight reduction (Chi Square = 3.492;  $df = 1$ ;  $p = 0.062$ )
- 8% less subjects reached a weight equal or higher than the initial one (Chi Square = 3.150;  $df = 1$ ;  $p = 0.076$ )

We then analyzed the psychological outcome. The ANCOVAs found significant group effects for the following variables (Table 7): the Neuroticism EPI scale ( $F = 4.091$ ,  $df = 2,159$ ,  $p < 0.019$ , effect size = 0.05); the Total Score ( $F = 8.001$ ,  $df = 2,159$ ,  $p < 0.000$ , effect size = 0.09) and the Head ( $F = 9.911$ ,  $df = 2,159$ ,  $p < 0.000$ , effect size = 0.11), Torso ( $F = 4.004$ ,  $df = 2,159$ ,  $p < 0.02$ , effect size = 0.05), Limbs ( $F = 3.202$ ,  $df = 2, 159$ ,  $p < 0.043$ , effect size = 0.04) BSS scales; the WELSQ Total Score ( $F = 4.603$ ,  $df = 2,159$ ,  $p < 0.011$ , effect size = 0.06); the Total Score ( $F = 4.515$ ,  $df = 2,159$ ,  $p < 0.012$ , effect size = 0.05), and the Clothing ( $F = 6.750$ ,  $df = 2,159$ ,  $p < 0.002$ , effect size = 0.08), Eating Restraint ( $F = 4.859$ ,  $df = 2,159$ ,  $p < 0.009$ , effect size = 0.06), and Social Activities ( $F =$

TABLE 6. WEIGHT FEATURES AT 6-MONTH FOLLOW-UP IN THE THREE EXPERIMENTAL CONDITIONS

<i>Feature:</i>		<i>Subjects who reached a 10% weight reduction in relation to the initial weight</i>		
Treatments		<i>Yes</i>	<i>No</i>	<i>Total</i>
ECT		42	14	56
CBT		31	21	52
NT		6	44	50
	Chi square = 44.803		df = 2	p = 0.000
<i>Feature:</i>		<i>Subjects who maintained or improved the weight reduction achieved after the treatment</i>		
Treatments		<i>Yes</i>	<i>No</i>	<i>Total</i>
ECT		52	4	56
CBT		42	10	52
NT		21	29	50
	Chi square = 36.985		df = 2	p = 0.000
<i>Feature:</i>		<i>Subjects with a weight equal or higher than the initial one</i>		
Treatments:		<i>No</i>	<i>Yes</i>	<i>Total</i>
ECT		55	1	56
CBT		47	5	52
NT		35	15	50
	Chi square = 19.155		df = 2	p = 0.000

5.132,  $df = 2, 159$ ,  $p < 0.007$ , effect size = 0.06) BIAQ Scales.

More in detail, using post-hoc analyses we found that Experiential CT obtained significantly better improvements than both CBT and NT in the *Neuroticism* EPI scale, in the *Head, Torso* and *Total* Score of the BSS, and the BIAQ Total Score. Further, Experiential CT was significantly better than CBT in the *Eating Restraint* BIAQ scale; and significantly better than NT in the WELSQ Total Score, in the *Social Activities* BIAQ scale and in the *Limbs* BSS scale. No other significant differences were found.

## CONCLUSION

For many, including the three patients in our sample who refused any psychological treatment, obesity is just a problem of energy input and expenditure. This explains why, in contrast to the efforts to document the physical consequences of obesity, much less is known about the neurological and psychological correlates of excess weight.

On the neurological side, Volkow et al.<sup>22,35,36</sup> showed the strict similarities between obesity and addiction. Their conclusions are very clear: "Although each condition has its own interface with brain mechanisms of motivation, the motivational mechanisms themselves largely overlap. In each case, neuroadaptations resulting from excessive in-

take may make the ingestive behavior more compulsive. The guidelines for prevention and treatment of the two disorders are remarkably similar." Nevertheless, the treatment of obesity is still unconnected from that of addiction: it differs in length, continuity of care, levels of care, and clinical focus.

On the psychological side, the situation is similar. Most people share the belief that the best way to improve one's body image is to lose weight: I go on diet to have a better body. However, recent studies have questioned this belief: dietary intervention, even if accompanied by significant weight loss, may be ineffective in reducing total body dissatisfaction.<sup>25,26</sup> Moreover, different studies have shown that both adolescent and adults with elevated scores on dieting scales are at increased risk for future onset of obesity.<sup>27-29</sup> Finally, radical weight-control behaviors, such as vomiting and laxative abuse, have predicted increases in body mass over time.<sup>28</sup>

Apparently, people go on diets to increase body satisfaction, but the reduced effectiveness of this approach produces more radical weight-control behaviors, which in the long term lead to obesity.

These findings argue for the potential benefits of treatment strategies for improving appearance satisfaction for obese individuals, despite the success of their weight-management efforts.<sup>30</sup> Unfortunately, most obesity researchers have not yet added

TABLE 7. SIGNIFICANT GROUP DIFFERENCES FOR THE PSYCHOLOGICAL OUTCOME MEASURES AT 6-MONTH FOLLOW-UP

Measure	ECT		CBT		NT		ANCOVA		
	M	SD	M	SD	M	SD	F	df	p
EPI neuroticism									
Pre	10.63	5.01	8.88	5.00	9.67	4.66	4.091	2, 159	0.019
Follow-up	13.99	5.59	10.79	5.13	11.31	5.91			
BSS—head									
Pre	13.92	8.66	15.45	6.63	13.20	6.75	9.911	2, 159	0.000
Follow-up	11.13	6.11	14.36	5.27	15.02	7.69			
BSS—torso									
Pre	18.82	5.29	21.43	5.37	19.20	5.50	4.004	2, 159	0.02
Follow-up	15.80	5.87	19.26	3.88	18.16	6.09			
BSS—limbs									
Pre	18.80	5.06	21.88	4.53	19.02	5.28	3.202	2, 159	0.043
Follow-up	16.11	5.52	19.31	4.71	18.33	5.86			
BSS—total									
Pre	51.37	14.80	58.76	12.39	51.40	13.81	8.001	2, 159	0.000
Follow-up	43.04	14.83	53.40	10.46	51.51	16.57			
WELSQ									
Pre	125.9	35.89	125.0	38.73	117.8	34.12	4.603	2, 159	0.011
Follow-up	158.9	35.06	155.6	36.09	136.8	40.01			
BIAQ—clothing									
Pre	12.28	4.76	13.40	3.98	13.20	4.29	6.750	2, 159	0.002
Follow-up	7.93	4.51	9.71	4.13	11.29	5.34			
BIAQ—eating restraint									
Pre	4.76	2.08	4.52	2.22	4.98	2.86	4.859	2, 159	0.009
Follow-up	5.41	2.00	6.52	2.92	5.38	2.69			
BIAQ—social activities									
Pre	8.79	4.55	9.64	3.91	9.73	4.34	5.132	2, 159	0.007
Follow-up	5.14	3.87	6.52	3.57	7.76	4.79			
BIAQ—total									
Pre	30.12	7.62	32.69	7.76	32.29	8.72	4.515	2, 159	0.012
Follow-up	23.95	6.88	29.10	9.30	28.69	10.94			

body image interventions to their programs. Only recently, Cooper et al. underlined the need to introduce, into cognitive-behavioral treatment of obesity, a specific module addressing body image concerns.<sup>31,32</sup>

A final key issue for obesity treatment is long-term weight maintenance, as shown by the disappointing results of many follow-up studies.<sup>33</sup> As stated by Cooper et al.,<sup>32</sup> an important problem in treatments is the lack of distinction between the objective of obtaining weight loss and the one of maintaining it. In particular, weight maintenance requires the ability of the patient to define a realistic target weight range, to monitor eating behaviors, and to manage the frustration related to weight fluctuations. Unfortunately, these dimen-

sions are usually not targeted by many obesity treatments, in particular by the behaviorally oriented group psycho-educational interventions that are still very popular today.

We presented an integrated approach to the treatment of morbid obesity that shares with the treatment of addiction a focus on maintaining/relapse mechanisms.<sup>47</sup> We labeled it “experiential cognitive therapy” for its focus on the direct experience of the patient. During the therapy, with the help of virtual reality, the patient experienced critical situations related to the maintaining/relapse mechanisms (Home, Supermarket, Pub, Restaurant, Swimming Pool, Beach, Gymnasium). Within the VR experience, patients practice both eating/emotional/relational management and

general problem-solving skills. Moreover, the therapy used the changes in body experience produced by VR to facilitate changes in body image.

This approach was compared, within a controlled clinical trial, with two other obesity treatments: psycho-educational nutritional groups and cognitive-behavioral therapy. For the trial, we chose a difficult patient sample: women with a BMI of >40 and a long story of failures. Typically for these patients, the only effective therapeutic approach is bariatric surgery.<sup>7</sup>

For this reason, the results of this trial are compelling. First, findings illustrate that a medically managed intensive inpatient obesity treatment, independent of the specific approach, can substantially decrease weight (5–10%; effect size: 0.72) and improve psychological well-being (effect size: 0.16/0.26) in a relatively brief period (6 weeks) even in a hard-to-treat population.

Second, our results suggest that the use of different strategies may improve the long-term outcome of therapy. Even if, after a 6-month follow up, we have found a non-significant group effect for weight differences, only in the NT group the follow-up weight is higher than the weight at the end of the therapy. This group lacked for specific strategies related to the maintaining/relapse mechanisms. Moreover, when we compared the number of subjects who reached a 10% weight reduction in relation to the initial weight, or the number of subjects who maintained the weight reduction achieved after the treatment, we found significant differences between the three conditions, with Experiential CT as best condition, and NT as worse condition.

More relevant differences can be found in the psychological profile. After a 6-month follow-up, Experiential CT, differently from the other approaches, was able to significantly improve both the level of body image satisfaction—measured through the BSS questionnaire—and self-efficacy—measured through the WELSQ questionnaire. This change produced a reduction in the number of avoidance behaviors as well as an improvement in the number of adaptive behaviors as showed by the DIET and BIAQ questionnaires.

These data suggest that Experiential CT can help in addressing two key issues for the maintenance of obesity: body experience and self-efficacy. As emphasized by social cognitive theory, performance-based methods are the most effective in producing therapeutic change across behavioral, cognitive, and affective modalities.<sup>66</sup> This was confirmed in a recent controlled trial<sup>115</sup> that used an experiential method—like role-playing—

to help addiction and PTSD patients to improve relapse prevention.

#### *Limitations and future direction*

This study has some strength, being the largest randomized controlled trial ever conducted to date on the effectiveness of a virtual reality-based psychological intervention. At the same time, however, it has some limitations. First is the short follow-up. Six months is a short period to investigate the real long-term impact of therapy in obesity. In particular this study does not clarify if an improvement in body image dissatisfaction can also foster weight maintenance. Second, the CBT treatment used in the study is a reduced (6-week) version of the Oxford outpatient<sup>31,32</sup> protocol. Obviously, major changes have been made to the original 44-week format, so we should take with caution the extension of these results to an outpatient setting. Third, we did not investigate the perceptual dimension of the body image changes. We decided to avoid the use of perceptual measurement tools like the adjustable light beam method<sup>116</sup> to reflect the recent theoretical shift in the body image literature from perceptual distortions to the body-weight self-schema.<sup>117</sup> Nevertheless, understanding if body image dissatisfaction in obesity is related to perceptual distortions is an interesting research area that could provide new insights for therapy.

Our results show the added value of ECT as integrated obesity treatment based on the experiential approach allowed by virtual reality. Longer follow-up data and multi-centric trials are required to investigate the possible effects of the behavioral and body image changes on the long-term maintenance of the weight loss.

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