

## Original Research Article

# Effects of self-conditioning techniques in promoting weight loss in patients with severe obesity: a randomized controlled trial protocol

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## ABSTRACT

**Background:** Obesity is a worldwide epidemic; most obese individuals who lose weight after lifestyle educative treatments, soon regain it. Our aim is to evaluate the effectiveness of a training to teach self-conditioning technique (self-hypnosis) added to standard care in determining weight loss compared with standard care in patients with obesity.

**Methods:** This randomized controlled open trial will recruit 120 obese patients (BMI 35-50 Kg/m<sup>2</sup>), aged 20-70 years. The control group will receive a traditional approach: diet + exercise + behavioral recommendations. The experimental group will receive self-conditioning techniques + traditional approach. Three individual sessions of hypnosis with rapid-induction techniques will be administered by trained personnel. All the participants of both groups will be assessed at three, six, nine and twelve months after randomization. The primary outcome is weight loss difference between groups at 12 months after randomization; secondary outcomes are changes in adherence to dietetic and exercise recommendations, appetite and satisfaction/well-being, waist circumference and body fat, blood pressure and blood metabolic and inflammatory variables.

**Conclusions:** The results of this trial will assess whether a self-conditioning approach, based on self-hypnosis, is able to help participants to modulate unhealthy patterns of eating and sustain weight loss in the long term.

**Keywords:** Hypnosis, Obesity, Randomized controlled trial, Weight loss

**Trial Registration:** The protocol of this study is registered at ClinicalTrials.gov (identifier: NCT02978105)

## INTRODUCTION

The ongoing obesity epidemics is currently a serious health concern.<sup>1</sup> Most lifestyle interventions fail over time, and people inexorably regain the lost weight after about 6-12 months.<sup>2-3</sup> Usually, overweight/obese

individuals resume wrong lifestyle habits, such as overeating, unhealthy diets, and physical inactivity.<sup>4</sup> Overeating often involves loss of control and compulsive behaviors;<sup>5</sup> habits, time of the day, social situations, convenience, hunger/taste, mood or stress and genetics are all factors which can determine the extent and type of

the meals, often overcoming known homeostatic mechanisms, including gastrointestinal and central nervous system satiation signals.<sup>6</sup> Both the emotional eating, i.e. the automatic tendency to eat in order to suppress negative thoughts and feelings<sup>7-9</sup> and the reward mechanisms by which obese individuals seek pleasure by foods are well described conditions, leading to a sort of food addiction.<sup>10</sup> These mechanisms are mediated by multiple areas in the brain that seem to be hyper-responsive to food and emotional stimuli in obese subjects.<sup>5,11,12</sup>

Psychological factors are often disregarded in the treatment of obesity despite growing evidence of their pathogenetic role.<sup>13,14</sup> In addition to traditional psychotherapeutic treatments, promising non-verbal interventions are increasingly used, such as the mindfulness technique.<sup>15</sup> This topic is receiving increasing research and clinical interest.<sup>16</sup> It is described as a state of self-regulated attention to a current experience with the goal of achieving a non-elaborative awareness of it.<sup>17</sup> Many studies have supported the benefits of mindfulness-based interventions to control some obesity-related behaviors, including binge eating, emotional eating, externally-induced eating, and to promote weight loss maintenance.<sup>18</sup>

Hypnosis has been considered either “a distinct state of consciousness” or a normal state with heightened suggestibility determined by social influence combined with a set of cognitive-behavioral skills.<sup>19</sup> The core components of hypnosis involve reduced awareness of external stimuli, increased responsiveness to hypnotic suggestions, deep relaxation, increased capacity to enhance mental representations, and absorption in hypnotic suggestions.<sup>20,21</sup> Suggestions may be verbal and non-verbal communications that can be used to influence mood, behavior, and habits.<sup>22,23</sup> Hypnosis has been used in medicine for different purposes: the control of acute and chronic pain, support during labor, smoking cessation, anxiety alleviation, treatment of conversion disorders, schizophrenia and insomnia, with mixed results.<sup>24-27</sup>

Indeed, hypnosis could be considered as another therapeutic possibility, like mindfulness, by increasing the ability to control emotional impulses.<sup>28</sup> Self-conditioning techniques borrowed from hypnosis (self-hypnosis) increase self-control and self-management of emotions, with the patient fully awake and conscious. Recent hypnosis techniques with a rapid-induction phase allow the patient to go into hypnosis in a few minutes. Therefore, trained subjects are able to repeat the experience in complete autonomy, in several moments, employing a short time of the day only.

It could be hypothesized that self-hypnosis could be applied before meal or snack times, and, in general, during each circumstance of irrational need of foods. Indeed, very often people begin their meals with the

stress and worries of the day, thus eating in less conscious way, often gorging, without being able to control themselves.

We will test whether a training to teach self-conditioning technique (self-hypnosis) added to traditional approach (diet, exercise and behavioral recommendations) will be effective in determining weight loss with respect to the traditional approach in patients with obesity.

**METHODS**

***Trial design and participant enrolment***

We planned the execution of a prospective, randomized controlled, open-label monocentric trial. It will be performed in patients with a BMI between 35 and 50 Kg/m<sup>2</sup> by comparing an experimental group, in which self-conditioning techniques will be added to usual care, to a control group who will be treated only with the traditional care, i.e. the combination of diet, exercise and behavioral recommendations.

The trial will be conducted at the Obesity Unit of the Unit of Clinical Nutrition of the “Città della Salute e della Scienza” Hospital of Turin (North-Western Italy).

The trial is registered at ClinicalTrials.gov (identifier NCT02978105) and has received ethical approval from the ethics committee of “Città della Salute e della Scienza” of Turin; all the procedures will be conducted in agreement to the principles of the Helsinki Declaration. All participants will provide written informed consent to take part to the study.

The trial will include participants recruited by nutritionists and dieticians from outpatients of the Obesity Unit with a body mass index (BMI) value between 35 and 50 kg/m<sup>2</sup>, with an age range 25-70 years, without any exclusion criteria as presented in Table 1.

**Table 1: Eligibility criteria.**

Inclusion criteria
<ul style="list-style-type: none"> <li>• Ability to give written informed consent</li> <li>• BMI between 35 and 50 kg/m<sup>2</sup></li> <li>• Age 20-70 years</li> </ul>
Exclusion criteria
<ul style="list-style-type: none"> <li>• Current or previous mental disorders and/or on any psychotropic drug</li> <li>• Insulin treatment</li> <li>• Candidates for bariatric surgery</li> <li>• Current (or discontinued for less than 6 months) treatment with anti-obesity drugs</li> <li>• Patients at risk of heart failure, edema, ascites (heart diseases, chronic liver diseases, nephrotic syndrome, renal failure)</li> <li>• Patients with untreated or uncompensated thyroid diseases</li> </ul>

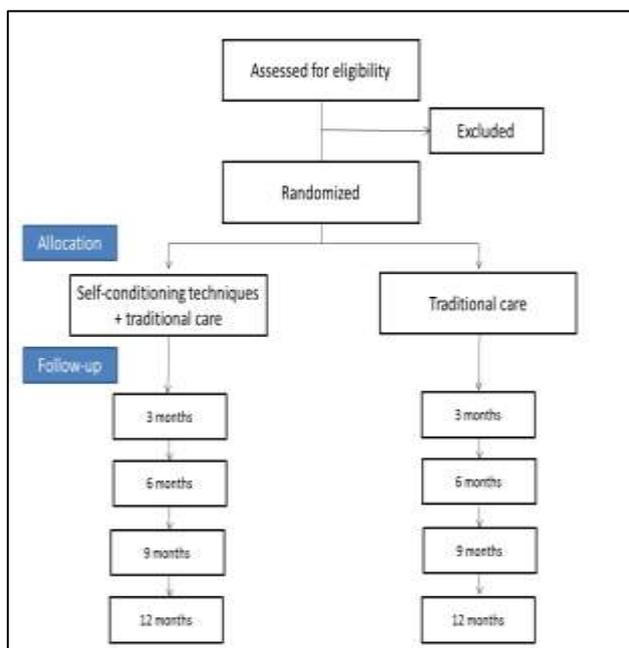
The subjects preliminarily identified in this way will be further submitted to the following questionnaires:

- The Hamilton rating scale for depression.<sup>29</sup>
- The Hamilton rating scale for anxiety.<sup>30</sup>
- The Binge Eating Scale.<sup>31</sup>

Only individuals who will satisfy all scores [respectively <8 (Hamilton depression scale), <17 (Hamilton anxiety scale) and <17 (Binge Eating scale)] will be enrolled, after obtaining informed written consent

### Outcomes

Patients who are eligible for the study will be randomized to one of the following arms: experimental arm (self-conditioning techniques + standard care) and control arm (standard care, i.e. diet + exercise + behavioral recommendations) as shown in Figure 1.



**Figure 1: Flow of the study.**

The *Primary* outcome is the difference between groups in weight loss at 12 months after randomization.

The *Secondary outcomes* are the variations in:

- Adherence to the diet (3-day food records)
- Physical activity level (Minnesota questionnaire)<sup>32</sup>
- Appetite (Satiety Labeled Intensity Magnitude scale)<sup>33</sup>
- Satisfaction and well-being (EuroQol (EQ)-5 questionnaire [Index and Visual Analog Scale (VAS)]<sup>34</sup>
- Waist circumference and body fat percentage
- Arterial blood pressure (and/or use of anti-hypertensive drugs)

- Fasting glucose, glycated hemoglobin (and/or use of hypoglycemic drugs)
- Fasting insulin and insulin resistance [index Homeostasis Model Assessment-Insulin resistance (HOMA-IR)]<sup>35</sup>
- Total cholesterol and HDL-cholesterol, triglycerides (and/or need for lipid-lowering drugs)
- Markers of inflammation [C-reactive protein (CRP)]
- Incident diseases and/or need for new drugs
- Evaluation the average weekly frequency use of self-conditioning in the experimental arm only.

### Randomization

The list of randomization, stratified by age (50; > 50 years), gender, BMI (40; > 40 kg/m<sup>2</sup>) will be generated by using a variable-length block procedure, masked to researchers who enroll the patients. The randomization procedure will be centrally run through an online procedure (available at: <http://www.epiclin.it>). At enrollment, a unique code will be assigned to each patient. After the randomization procedure, the patient will be assigned to the experimental or control arm, and the change of the arm to which the patient has assigned is no longer possible.

### Intervention and follow-up

The following recommendations will be provided to all the participants:

#### Diet

Personalized diet, with a caloric intake of approximately 1500±100 kcal/day (15-20% protein, 55-60% carbohydrates; 25-30% lipids);

#### Exercise

At least 20 minutes of brisk walking every day according to the criteria of the Borg scale (target rating 12-14)<sup>36</sup>

#### Behavioral recommendations

Verbal and written suggestions on how to put the exercise in daily activities and how to follow one's diet with the help of simple tips (i.e. don't buy foods on an empty stomach, do not do anything else when eating, lay your cutlery between mouthfuls, etc).

The use of anti-obesity drugs will be prohibited during the trial course. The experimental group will receive 3 individual sessions of hypnosis, performed by trained personnel (2 nurses and 1 medical doctor). To minimize the potential lack of fidelity, the health care providers will be assigned to the sessions by a scheduled rotation among sessions to ensure a balanced intervention for all the subjects, and the delivered intervention will be checked every session. Rapid-induction techniques will

be used, allowing the patient to go into a hypnotic condition in a few minutes.<sup>37</sup> The timing and the structure of the sessions are reported in Table 2 and Table 3, respectively.

The degree of susceptibility to hypnosis will be evaluated through the first part of the test of Spiegel (eyeroll) and by the changes in body parameters occurring during the hypnotic sessions.<sup>38</sup> This will be then correlated with the outcome achieved in the experimental group.

**Table 2: Time points of assessments.**

Study time-points (months)	0	0.5	1.5	3	3.5	6	9	12
Enrolment/Randomization	X							
Written informed consent	X							
Blood sample collection	X							X
Physical assessment	X			X		X	X	X
Dual Energy X-ray Absorptiometry	X							X
Dietary and exercise questionnaires	X							X
Hypnosis sessions (for experimental arm only)		X	X		X			
Recording of adverse events/compliance check				X		X	X	X

**Table 3: Technique of the hypnotic procedure.**

Session	Phase	
1	<b>Introduction to the session</b> (10 minutes)	<ul style="list-style-type: none"> <li>-greetings and mutual presentations (the hypnotist, after listening to a few sentences and having observed the subject, chooses the best suited method of hypnosis induction for each subject)</li> <li>-information about what medical hypnosis is and its potential application as an amplification of personal resources to manage self-control</li> <li>-Spiegel test to assess the degree of subject’s susceptibility to hypnosis</li> </ul>
	<b>Hypnotic induction</b> (10 minutes)	<ul style="list-style-type: none"> <li>-induction by a technique of attention focusing (fixing a point or focusing the attention on a part of one’s body)</li> <li>-ratification of what is happening</li> <li>-phase of full-body relaxation</li> <li>-phase of slow breathing</li> <li>-imagining pleasant images and thoughts and creating an ideal "safe place" in which the subject can take refuge whenever he/she feels the need to. In this imaginary place, the subject can feel stronger, more determined, self-controlled and fit, efficient and dynamic. In particular, he/she will be able of doing things that previously create some difficulties, such as appearing in public without shame, climbing stairs, sit down at table with the knowledge of what he/she is about to eat, refrain from gorging, etc.</li> <li>-anchor phase: the subject receives a self-conditioning signal (i.e. joining the thumb with index, or making the fist with the thumb folded inside the hand, etc.) by which he/she can rapidly fall under hypnosis in complete autonomy</li> <li>-anchor verification stage: the subject is trained to come in and go out from hypnosis alone when desired</li> </ul>
	<b>Instructions for use</b> (10 minutes)	<ul style="list-style-type: none"> <li>-information on how to use the anchor signal to enter into hypnosis and on all possible applications of self-hypnosis</li> <li>-instructions on how hypnosis should be used before each main meal for about three minutes (10 seconds to enter, 2 minutes and a half of “safe place” thinking, with muscle relaxation and mental well-being and 30 seconds to exit)</li> <li>-instructions on how self-hypnosis can be used in case of food compulsion</li> </ul>
2-3	<b>Reinforcement sessions 1 and 3 months after the first session</b> (20-30 minutes)	<ul style="list-style-type: none"> <li>-participants’ reporting of difficulties, problems, barriers and benefits with self-hypnosis (5 minutes)</li> <li>-check of the subjects’ skill of going into hypnosis</li> <li>-a new image will be evoked relative to the subjects’ power to face difficulties (a metaphorical climb on top of a mountain by overcoming natural obstacles) (10 minutes). The same suggestions described above will be evocated.</li> <li>-instructions for correcting mistakes and overcoming the barriers and problems encountered (5-15 minutes)</li> </ul>

The hypnotic sessions have a common core, but the method of hypnosis induction will be individualized on the basis of participant characteristics. Hypnosis will be induced with a technique based on focus of attention and early ratification of the obtained effects.<sup>39</sup> Participants will be taught how to get back in hypnosis by means of a signal: at the end of the induction hypnotic session, an “anchor” (a symbolic signal) will be given to each participant. At any time, by repeating this anchor the subject will be able to go into hypnosis again in complete autonomy (self-hypnosis), also repeatedly during the day.

The acquired ability to go back in and exit from hypnosis by oneself will be checked-out in real time. Instructions on how to apply self-hypnosis before every meal and every attack of food compulsion will be given.

The hypnotic induction session will last 10 minutes and will be focused to provide the patient with a tool to help him to maintain self-control towards food. All the subjects enrolled in the trial will be assessed at three, six, nine and twelve months after randomization as seen in Table 2.

### **Quality control**

The acquired skill of the patients of the experimental arm will be checked by the hypnotists during each session, by evaluating some body parameters:

- One or more typical changes (i.e. Muscle inertia with inability to move a body part, levitation, catalepsy)
- The characteristic physical appearance of the subject (variation of facial expression, movements of eyelids and eyeballs, swallowing, changes in respiratory rate, vasodilation, reduced muscle tone)
- Alteration of consciousness (the patient reports well-being, partial detachment from reality, time warp, realistic images and conceived situations).

The hypnotic condition will be reached if all the above reported conditions occur simultaneously. Furthermore, the patients’ skill will be tested by asking them to show the effectiveness of the anchor signal and by reevaluating the quality of the above described changes after self-induction during each session. In the second and third sessions, participants of the experimental arm shall report the efficacy and persistence over time of his/her skill to go into hypnosis, the adherence to behavioral prescriptions received and the effectiveness in getting a sense of well-being. If a low hypnotizability is detected, the patient will still be encouraged to run the procedure before each meal and food compulsion attack.

### **Endpoints and measurements**

The evaluated endpoints and the corresponding measurements are reported in Table 4.

### **Blinding**

Because of the nature of the intervention, blinding participants and health professionals will not be possible. Personnel who perform the laboratory analyses and collect data will be blinded to the arm assignment.

### **Drop-out**

The following will be considered as dropouts:

- Subjects who will withdraw from the study before 12 months for any reasons (change of residence, dissatisfaction/intolerance with the recommendations provided, etc.)
- Subjects taking slimming products/drugs
- Subjects using techniques to lose weight other than those recommended (e.g. very low calorie diets, or highly unbalanced diets, etc).

### **Safety**

Adverse events and compliance with the study protocol will be monitored during each visit. Participants will be instructed to inform the researchers if adverse effects occur. These cases will be then communicated to the statisticians, who will monitor the safety of the study.

### **Sample size**

The sample size has been calculated in relation to the primary outcome. Available data on patients with clinical characteristics similar to those required for patient enrolment were used to calculate the sample required. The parameters used were:

- 2 tailed  $\alpha$ -error = 0.05
- $\beta$ -error = 0.10
- Average baseline weight = 120 Kg (SD= 15 Kg)
- Expected weight reduction at 12 months = 10 Kg (Effect size = 0.67)

With these assumptions 48 patients per arm are needed; this number was increased to a total of 120, in consideration of the possibility of drop-outs.

### **Statistical analyses**

Statistical analysis will be conducted in agreement with the intention to treat principle. Demographic and baseline characteristics will be described for the entire study cohort. Discrete variables will be summarized by frequencies and percentages. Continuous variables will be summarized with standard measures of central tendency and dispersion (mean and standard deviation or median and interquartile range). The analysis of the primary endpoint will be based on the comparison between the two arms of the weight change from baseline

to 12 months after randomization. The averages of within-subject weight differences will be compared between the two arms by a linear regression model, including the weight values at baseline. As sensitivity analysis, additional potential confounding detected at

baseline will be included in the regression model. In the experimental arm, the weight difference from baseline by degree of susceptibility to self-hypnosis will be also assessed. The same methods will be employed in the analyses of the secondary outcomes.

**Table 4: Primary and secondary endpoints.**

Primary endpoint	Measurement
Weight loss at 12 months	Mechanical column scale (SECA Model 711, SECA, Hamburg, Germany), with the participants wearing light clothes and no shoes
Secondary endpoint	
Adherence to the diet	3-day food record
Level of physical activity	Minnesota questionnaire [32]
Appetite	Satiety Labeled Magnitude Intensity scale [33]
Life and health quality	EuroQol (EQ)-5D [Index and Visual Analog Scale (VAS)] questionnaire [34]
Body fat %	Dual-energy X-ray absorptiometry (DXA)
Waist (cm)	Plastic tape meter immediately above the iliac crest
Arterial blood pressure (mmHg)	Two measurements by a mercury sphygmomanometer in a sitting position after at least 10 min rest
Fasting blood glucose (mg/L)	Enzymatic method with hexokinase (Roche Diagnostic, Germany)
Glycated hemoglobin (mmol/mol)	Non-porous ion-exchange high performance liquid chromatography (HPLC) (G8 Analyzer, TOSOH, USA)
Insulin ( $\mu$ U/mL)	Enzyme immunoassay (Siemens, Germany)
Insulin resistance (Homeostasis Model Assessment Insulin resistance index)	[35]
Total cholesterol (mg/dL)	Enzymatic colorimetric assay (Roche Diagnostic, Germany)
HDL cholesterol (mg/dL)	Enzymatic colorimetric assay (Roche Diagnostic, Germany)
C-reactive protein (mg/L)	Particle-enhanced turbidimetric immunoassay (Roche Diagnostic, Germany)
Triglycerides (mg/dL)	Enzymatic colorimetric assay (Roche Diagnostic, Germany)
Diseases incidence and/or new drugs	Interview
Evaluation (in the experimental group only) of the average weekly frequency of use of self-hypnosis	Interview

## DISCUSSION

Influencing a person to change his/her behavior is very difficult, since changes in internal motivations are required.<sup>40</sup> The role of hypnosis as an effective tool for producing behavioral changes in patients with overweight/obesity has been evaluated by old studies, most of which with methodological limits, such as a low number of participants, the lack of a control group, the high percentage of dropouts, the heterogeneity of patients, the short-term follow-up, variations in procedures and different measures of response.<sup>40-44</sup> Overall, the use of hypnosis seems to provide some additional benefit increasing over time when added to a weight reduction program, but the results are still highly controversial. Indeed, the need for more rigorous research has been emphasized by all the reviews on this topic.<sup>40-44</sup>

A rapid induction technique of hypnosis has developed some years ago.<sup>37,39</sup> This allows to administer behavioral and awareness recommendations in a hypnotic context in

a short time interval, making this method easily applicable for trained patients in everyday life.

This approach seeks to maintain over time the change to a healthy lifestyle, since most overweight/obese patients are not able to keep these habits at the end of educational interventions.

The results of this randomized clinical trial will determine if a self-conditioning approach, based on self-hypnosis, is able to help participants to disadopt unhealthy patterns of eating and sustain weight loss in the long term.

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*Conflict of interest:* None declared

*Ethical approval:* The study was approved by the ethics committee "Comitato Etico Interaziendale AOU Città della Salute e della Scienza di Torino" (Approval Number: CS/273)

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