Author's response to reviews

Title: A family-based education programme for obesity: a three-year study.

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Running head

A sustainable therapy for obesity.

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ABSTRACT

Background: The epidemic of obesity is increasing in all countries. In particular, the number of controlled studies focusing on children obesity, with a long follow-up is still limited. Even tough Behavioural Therapy showed some efficacy, it requires a prolonged teamwork that is not always available in public health facilities. In addition, Behavioural Therapy is not always accepted. We describe a new intensive and sustainable family-based therapeutic education programme for children obesity.

Methods: Controlled clinical study. The therapeutic education programme involved overweight and obese children/adolescents and their families; it consisted of only three clinical and educational sessions, carried out by a single physician. Further sessions were carried out every six months the first year and then every year. Children’ Body Mass Index % (BMI%) and BMI z-score, measured at baseline and after a three year-follow-up, were compared.

Subjects: 85 overweight children (45 males and 40 females, mean age of 10.43±3) with an average BMI% of 54.72 ± 19.6%. Controls included 105 matched children, treated with traditional dietary approach.

Results: After a follow-up of 2.7±1.1 years, 72.9% children belonging to the study group reduced their BMI% compared to 42.8% of controls. Weight reduction was good in moderately obese children and better in severely ones; in addition, compared to controls, a smaller percentage (11.8% vs. 25.7%) of children of the study had a BMI% increase >10%, while their drop-out rate fell to 2%.
**Conclusions**: the results indicate the efficacy and sustainability of the therapeutic education programme that was completely carried out by a single pediatrician in three times; in addition, it met with an elevated participants’ acceptance, suggesting a convenient therapeutic solution when Behavioural Therapy is not available or teamwork is poor.

**Key Words**: Pediatric obesity, Therapy, Children, Adolescent, Family-based treatment, Therapeutic Patient Education.
**Introduction**

During the past twenty years, the prevalence of pediatric obesity has risen significantly in Italy [1], as it has worldwide, causing alarm in both medical and political circles.

To date, proposed therapeutic approaches for obesity have met with little success. In fact, according to a recent Cochrane Library review [2], standard effective therapy for obesity is not yet available. In children, in particular, many authors affirm that current treatments remain largely unsuccessful [3]. Simple dietetic interventions have a high percentage of failure or drop-out [4]. Even though behavioural therapy seems to provide some results, the few clinical studies with long follow-up in adults show that, within 2-3 years, they usually miss the target of weight reduction [5]. When considering children between 5 and 12 years of age, some authors report successful results following family-based multiprofessional behavioural treatment programmes [6-8]. Although these are considered the gold-standard therapy for obese children, they require a number of professional resources and a prolonged teamwork, that are not always available or accessible in public medical facilities [9-10].

In the attempt to overcome these problems, we devised a “intensive” therapeutic education programme (TEP), including only the essential learning content and involving the active engagement of both children and their families [11].

We report the results of a clinical study involving 85 consecutive children, referred by primary care physicians to our endocrinology unit, over a three-year period, compared to those obtained in 105 children that followed a traditional
dietetic therapy.

**Study population**

Our therapeutic education programme was started in March 2000 at the Pediatric Department of Ferrara Hospital. Eligible children included Caucasian overweight and obese children and adolescents, aged 3 to 18 years. Children with secondary obesity and psychiatric problems were excluded. Informed consent was obtained from children’s parents/caregivers before enrolment.

Body height, expressed in 0.1 cm intervals, was measured by a Harpenden’s stadiometer, while body weight, expressed in 0.1 kg intervals, was determined by a medical balance beam scale. Height and weight were used to calculate Body mass indexes (BMI) (kg/m^2). Percentage overweight (BMI%) was calculated by the following formula: (BMI–BMI at the 50th BMI percentile)/BMI at the 50th BMI percentile x100. Body mass indexes standardized (z-BMI) for mean (M) and standard deviation (z-BMI=[BMI−M]/SD) were determined for each child and evaluated according to the Italian reference curves published by Luciano [12].

Most heights and weights were measured in the laboratory; self-reported values, as assessed by family pediatrician, were accepted [13], when children and families were unable or, due to different reasons, didn’t want to attend assessment sessions.
We included in the study children with values of BMI \( \geq 85^{\text{th}} \) percentile. According to the cut-off proposed by CDC and WHO [3] we divided them into the following two degrees: first degree, overweight children, with a BMI ranging from the 85\(^{\text{th}}\) to the 94\(^{\text{th}}\) percentile, and second degree, obese children, with a BMI \( \geq 95^{\text{th}} \) percentile. Obese children with a BMI \( \geq 99^{\text{th}} \) percentile were considered as “severe” [14].

Participants’ BMI, BMI\% and z-BMI were recorded at baseline and after the follow-up period in order to assess their evolution and to make a comparison [15].

Stages of puberty were assessed according to Tanner [16], from stage 1 (not started puberty) to stage 5 (ended puberty).

From March 2000 to March 2003, 87 families of obese or overweight children gave their consent to enter the educational programme.

A follow up of at least 1 year (range 1-5.6 years, mean 2.7±1.1) was observed for 85 children (45 males and 40 females; 47 in pre-pubertal stage and 38 in pubertal), 2 children dropped-out due to serious family problems. The age of children ranged from 3.1 to 18.3 years (mean 10.43±3), the mean BMI\% was 54.72±19.6\%. At the beginning of the programme, 7 out of 85 children were overweight and 78 obese, 52 of them severely obese.

Controls were 105 overweight or obese children (47 males and 58 female, aged 4.5-15.5 years, mean 10.19±2.8) treated with traditional dietetic therapy (DT), following a preliminary endocrinologist consultation and receiving a standard dietetic and physical activity advice. They have been followed in the same period at the Pediatric Department of Ferrara Hospital by another physician in
collaboration with their family pediatricians. They were matched as to age, gender and follow-up.

Their mean BMI% was 41.78±19.4. At baseline 24 children were overweight and 81 obese, 35 of them severely obese. The average baseline value of BMI% of the study group was higher compared to control-group (mean 54.7 vs 41.8%).

**Therapeutic education programme**

We named our programme “The Balloon Game” [11], recalling the action of reshaping a toy balloon in a longer rather than larger way. We made it with the aim of exchanging the feelings of shame and guilt usually linked to obesity, for those of fun and blamelessness of an amusing game.

In agreement with the reported evidence [8, 17-19], our therapeutic education programme includes three steps, carried out by a single skilled pediatrician:

1. Initial assessment and educational session (individual family group). During this first session, taking about one hour, the pediatrician assesses children’s eating behaviour, physical activity, psychological condition (including self-esteem and body-image), knowledge and beliefs about obesity and its treatment. The physician also explores the point of view, the eating behaviour and the life-style of children’s family members (parents or caregivers). Then the pediatrician fosters their motivation to enter the therapeutic programme, encouraging them to change their eating behaviour, physical activity pattern and home environment, placing the focus on well-being and a healthier and more pleasant way of living
rather than on weight loss. Even if not obese, also family members are warmly invited to improve their eating style and physical attitude.

2. Therapeutic education session for parents/caregivers (in small groups). During this session, taking about two hours, after carrying out a brainstorming about the concept of “obesity”, the pediatrician discusses participants’ knowledge and beliefs. Then, with the aid of simple explanations and illustrations, gathered in a little self-help book, the physician explains the importance of parents and friends as models for children behaviour. He/she then teaches them some basic self-monitoring skills and the correct self-assessment of daily food and caloric intake, according to different situations and individual needs. Additionally, basic positive reinforcement techniques, (that do not include food or money) are proposed and families are taught how to change their external environment (e.g., how to reduce access to high-fat and low-nutrient dense foods, how to shop and cook healthier foods, how to increase access to physical activity while avoiding behaviours that prompt inactivity, such as TV watching, playing computer games, etc.), just as in behavioural therapy. At the end, all participants complete a questionnaire, investigating their learning, opinions and feelings about the session.

3. Second assessment session (individual family group). After 2 months, the pediatrician meets again with each children and their parents/caregivers for about 40 minutes, to provide them with information about the obesity-related risk of the child. The physician also gives them a positive feedback for every behavioural or BMI% improvement. He/she then assesses their knowledge and
self-management skills and explores barriers and problems encountered during the first phase of the programme.

He/she finally proposes to each children and family group a personalized follow-up schedule that includes:

- A clinical assessment every six months for children with a low risk of obesity-related complications (physical, psychological or social), a negative family history for obesity and related complications, normal laboratory data and satisfactory clinical results (improved life-style and/or BMI% decrease).

- A clinical assessment every four months for teenagers, severely obese children and those without initial satisfactory results or high risk of obesity-related complications.

- An educational session every two weeks during the first three months for children with body-image dissatisfaction or “emotional eating”.

With the exception of children searching medical advice for personal problems, after the first year, the follow-up schedule includes a clinical assessment every year. Drop-out families receive a phone call every year to reinforce their motivation of resuming follow-up programme and to take note of their self-reported anthropometrical measures (as assessed by their family pediatrician) and life-style changes.

During follow-up, the pediatrician asks parents about the increase in physical activity and the adoption of a healthier eating behaviour by the children and the
family group. Finally, by the help of a short questionnaire, he asks their advice to improve the therapeutic education programme.

After three years, the pediatrician assesses children’ quality of life by the help of a brief questionnaire about emotional, social and school functioning, he/she explores both the difficulties and gratifications that they encountered. Finally, he/she openly probes the children on the temptation to leave the programme.

**Statistical analysis and results evaluation**

In consideration of the natural history of obesity, we scored clinical outcome as follows:

Positive: when a BMI% reduction was observed (Normal-weight: z-BMI <85th percentile at follow-up)

Negative: when a BMI% increase was observed (≥10% from baseline)

Weight variations were expressed as a difference between mean BMI, BMI% and z-BMI at baseline and at the last follow-up.

Statistical processes were carried out using SPSS v.8.0. (SPSS Inc, Chicago IL, USA), and Statgraphics v.4.0 (STSS, Inc. Rockville, MD, USA), specifically employing ANOVA-RM, as a basic procedure for data analyzing, once the method feasibility was verified by distribution tests and Levene’s test of variance equality. The treatments (i.e. our TEP and DT) plus gender and obesity-degree, all together or separately, represented the ‘between factors’ while the before and
after treatment times always played the role of the ‘within factor’, i.e. that to be matched paired.

Student-t and $\chi^2$ tests were employed as well to verify possible age and follow-up time-span differences relative to interval-measures or the number of cases involved, respectively. Linear regressions were also employed to search for weight variation trends versus some parameters like follow-up time-span, age variation, etc. An $\alpha$-error of 5% was set as the study significance threshold.

Results

Figure 1 and Table 1 summarize the results of two therapies after follow-up.

Following TEP, 72.9% (62) of children had positive results and 8.2% (7) became normal-weight. In this group, as a whole, the BMI% decrease was 9.32±15.3%, while it was 4.86±9.2% (baseline 26.97±5.1%) in the overweight children and 9.72±15.7 (baseline 57.22±18.5%) in the obese. The number of obese children decreased by 16.5% (14), that of severely obese children by 19% (16) (Table 2). Negative results were observed in 11.8% (10), (60% females, aged 3.1-15.5 years, mean 9.34±3.7), only among obese children, with two new severely obese at follow-up.

In the control group, 42.8% (45), of children obtained positive results and 7.6% (8) became normal-weight after the follow-up time. All children had an average BMI% increase of 1.89±13.3% (the overweight children increased by 1.36±9.8%, and the obese children by 2.04±14.3%). The number of obese children
decreased only by 2.85% (3), while that of severely obese children remained unchanged. Negative results were observed in 25.7% (27): 5 overweight and 22 obese children (59% females, aged 5.25-14.1 years, mean 8.98.24±3.1), with 4 new severely obese at follow-up.

The BMI% at baseline showed a positive correlation with age (linear regression p<0.05) in children of two groups. After follow-up, BMI% of pre-pubertal children (baseline 53.84±18.3%) decreased by 5.48±13.9% (z-BMI reduction of 0.41±0.9), while in pubertal children BMI% (baseline 55.82±21.3%) decreased by 14.07±15.8% (z-BMI reduction of 0.45±0.7). The BMI% reduction, i.e. the weight-reduction, positively correlates (p<0.01) with the stages of puberty, ranging from 1 to 5.

Positive children number in the study group (TEP) was significantly higher (p<0.01), while negative children number remained significantly lower in respect to the DT group (p<0.02). At follow-up the z-BMI and BMI of negative children increased less in the study group, than in the DT group (Figure 2).

In particular, a significant decrease in z-BMI was observed after TEP with respect to the values observed after DT (Figure 1a), whether for children when considered altogether or for obese children only (p<0.05). Average BMI was substantially unchanged after TEP, while a significant increase after DT was observed (p<0.05) (Figure 1b).

On the other hand no significant difference was found between male and female children, notwithstanding the males reported a higher overweight degree both at baseline and at follow-up time.
Usually families refuse to enter the programme because they do not like to take part in training groups and/or in a follow-up programme. Despite the low compliance for obesity treatment and the very high drop-out rate in pediatric age [4, 20], periodical phone calls reduced the drop-out rate in the study group. 22% of children received only telephone follow-up.

Initial questionnaires, investigating children’ opinion and feelings about therapeutic education show a good acceptance and a high level of satisfaction. Final questionnaires, after a 3-year follow-up, show an improvement in life style of children without worsening their quality of life (Table 3).

**Discussion**

The stability of clinical outcomes after a 3-year follow-up seems to confirm the efficacy of our therapeutic education programme. In addition, “The Balloon Game” did not seem to cause any adverse effect, such as growth delay, additional psychological disturbances or eating disorders.

The therapeutic education programme was conceived to contend with three main problems: 1) the growing number of obese children seeking advice in our Department, 2) the lack of human resources and the need to take under control costs in public healthcare facilities, 3) the extremely low parent awareness and compliance with therapy [20, 22].

Furthermore, obese children frequently experience some psychological discomfort such as poor body-image, low self-esteem and binge-eating
disorders[23-25]. Early-onset overweight is an important risk factor that requires a very attentive and skilful person-centred approach.

We developed an “intensive” and reasonably simple one-man therapeutic strategy (i.e., carried out by a single skilled pediatrician), in the attempt to devise a possible alternative to multi-professional teamwork, that sometime is not available or that may be unpleasant for many families. Anyway, children who had clinically evident psychological problems (10% of the original group) were sent to a standard multidisciplinary treatment.

Five female children (5.6%) with “body-image dissatisfaction” or “emotional eating” received bimonthly behavioural therapy.

Observed overweight reduction was good in obese and severely obese children, but smaller among overweight children, perhaps because our programme did not stress the attainment of an ideal-weight, but the simple adoption of a healthier behaviour and life-style. Adolescent children, who usually are at higher risk of drop-out and of treatment failure [3], showed a larger overweight reduction than pre-pubertal children; they also had an improved lifestyle at follow-up.

A higher prevalence of negative results was observed in younger and female children. A rapid weight gain pattern during early childhood (“adiposity rebound”) and sexual development in females are risk factors for obesity for many reasons (genetic predisposition, life-long changes in the appetite regulating centres, etc.) [26]. Therefore, early therapeutic interventions aimed at controlling weight gain in early childhood, even if they are often refused, should be carefully considered in order to assure lasting results [9].
After TEP, negative children were significantly fewer than those undergoing DT (11.8 vs. 25.7 %) (p<0.05). The same occurred with severely obese children, decreasing of 19% after TEP and remaining unchanged after DT (p<0.01) (Table 2), with a consequent lower expected risk of metabolic syndrome and related cardiovascular outcomes [27].

Our results seem similar to those obtained in more expensive and intensive trials, usually working only with selected and well-motivated families [6, 7, 28].

A major problem was that only 31% of all obese children’ families coming to our Department, mostly the more severe, accepted our educational programme. In order to increase their motivation and participation we are now planning to involve family pediatricians of our district, so that they promote the TEP and its goals among children. A recent study of Quattrin [9] shows that families and pediatricians usually refer children to nutritional medical facilities for being underweight rather than overweight; indeed, in Italian rural mentality, “well nourished” children are still considered “healthy” children. However, it is also possible that some pediatricians might consider worthless current therapeutic approaches to obesity.

Our approach, based on the commitment and autonomy of children and their caregiver [29], led to high rates of satisfaction and better treatment results. The first aim of our programme is helping children to find a healthier lifestyle, thereby preserving the quality of life. Indeed, therapeutic education is “designed to enable a children (and families) to manage the treatment of their condition and
prevent avoidable complications, while maintaining or improving quality of life” (OMS, 1998) [30].

Conclusions

Our TEP showed some promising results. The growing number of obese children (82%) asking for treatment at our Department, together with the decrease in their total drop-out rate (from 44 to 36%), and in the number of non-responders and severely obese children after the introduction of the TEP (Table 2), seem to confirm our positive results.

A key value of our TEP consists of its ability to make use of participants’ motivation to reinforce an enduring commitment. Indeed, seizing their initial, transient willingness to face the problem of obesity, TEP enables children and their families to steadily adhere to a “sustainable and acceptable” treatment. In the same time, requiring active attitude and participation, TEP makes children and their families able to cope with obesity in a more aware and independent way.

A further key value of TEP is represented by its sustainability, also for healthcare professionals. In fact, it has been completely carried out by a single, skilled pediatrician. Thus, it might represent a feasible and realistic therapeutic solution both in hospital or primary care facilities where behavioural therapy is not available or when, due to different reasons, teamwork is poor.
List of abbreviations used

TEP: Therapeutic Education programme

DT: Dietetic Therapy

BMI: Body Mass Index

Competing interests

All authors declare that they have not competing interests.

None of the authors had financial or personal interest in any company or organization sponsoring the research.

Authors’ contributions

TR contributed to the conception, design and conduct of the study and to the interpretation of the data, as investigator and corresponding author, she had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. MR contributed to the conception of the study, critically interpreting the meaning of its results. PS contributed to data collection, organization, analysis and their interpretation. GG provided to design of the study and advice on the statistical analysis of the data.

The authors warrant that their contribution is original and that they has full power to make this grant. The authors confirm that the manuscript is not under consideration for publication elsewhere. Each author has been involved in the
conception and design of the study, or the analysis of the data and has participated in the writing of the manuscript. All authors have seen and approved the submitted version.

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Figure legends

Figure 1ab:

z-BMI (a) and BMI(b) changes from baseline to follow-up by TEP and DT.

Detailed legends

TEP: Therapeutic Education Programme

DT: Dietetic Therapy.

(p < 0.05)
Figure 2ab:

z-BMI(a) and BMI(b) changes from baseline to follow-up in Negative children, by TEP and DT.

Detailed Legend

Abbreviation: TEP: Therapeutic Education Programme. DT: Dietetic Therapy.

Negative children: non–responder children

Negative after TEP: number 10

Negative after DT: number 27.
Table 1. Baseline and changes of anthropometric measures after follow-up of Therapeutic Education Programme and Dietetic Therapy.

<table>
<thead>
<tr>
<th>MEASURED PARAMETER</th>
<th>AT BASELINE</th>
<th>AFTER A 3 YEAR FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Therapeutic Education Programme (n.85 children)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>27.53 (4.3)</td>
<td>0.08 (2.8)*</td>
</tr>
<tr>
<td>BMI%</td>
<td>54.72 (19.6)</td>
<td>-9.32 (15.3)</td>
</tr>
<tr>
<td>z-BMI</td>
<td>2.55 (0.8)</td>
<td>-0.43 (0.8)*</td>
</tr>
<tr>
<td><strong>Dietetic Therapy (n.105 children)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>25.11 (4.2)</td>
<td>+2.22 (2.8)*</td>
</tr>
<tr>
<td>BMI%</td>
<td>41.78 (19.4)</td>
<td>+1.89 (13.3)</td>
</tr>
<tr>
<td>z-BMI</td>
<td>2.13 (0.7)</td>
<td>-0.02 (0.5)*</td>
</tr>
</tbody>
</table>

*Significant differences (p<0.05) between TEP and DT for BMI and z-BMI.

Abbreviation: BMI: Body Mass Index; z-BMI : standardized BMI.

Data are given as mean (SD).
Table 2 Different children distributions by obesity degrees from baseline to follow-up of TEP and DT.

<table>
<thead>
<tr>
<th>OBESITY DEGREE</th>
<th>Therapeutic Educational Programme (TEP)</th>
<th>Dietetic Therapy (DT)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up</td>
</tr>
<tr>
<td>overweight</td>
<td>n. 7</td>
<td>n. 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(+8.2%)</td>
</tr>
<tr>
<td>obesity</td>
<td>n. 78</td>
<td>n. 64</td>
</tr>
<tr>
<td>(including severe obesity)</td>
<td></td>
<td>(-16.5%)</td>
</tr>
<tr>
<td>severe obesity</td>
<td>n. 52</td>
<td>n. 36</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(-18.8%)*</td>
</tr>
</tbody>
</table>

**High significant frequency difference (p < 0.01) between TEP and DT.

Detailed legends

TEP: Therapeutic Education Programme

DT: Dietetic Therapy.
Table 3. Questionnaires results assessing treatment quality, life-style and life-quality, as perceived by children and their parents.

<table>
<thead>
<tr>
<th>Time</th>
<th>Assessed issue</th>
<th>Good</th>
<th>Bad</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Therapeutic Education</strong></td>
<td>• Appropriateness</td>
<td>n.89 (99%)</td>
<td>n.1</td>
</tr>
<tr>
<td><strong>Session</strong></td>
<td>• Completeness</td>
<td>n.89 (99%)</td>
<td>n.1</td>
</tr>
<tr>
<td>n. 90</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1st year</strong></td>
<td>• Effectiveness of therapeutic education and self-help book</td>
<td>n.52 (93%)</td>
<td>n.4</td>
</tr>
<tr>
<td><strong>clinical assessment</strong></td>
<td>• Satisfaction</td>
<td>n.52 (93%)</td>
<td>n.4</td>
</tr>
<tr>
<td>n. 56</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3rd year</strong></td>
<td>Improvement in</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>clinical assessment</strong></td>
<td>• Eating behaviour</td>
<td>n.39 (98%)</td>
<td>n.1</td>
</tr>
<tr>
<td>n. 40</td>
<td>• Physical activity pattern</td>
<td>n.35 (88%)</td>
<td>n.5</td>
</tr>
<tr>
<td></td>
<td>Good Life Quality</td>
<td>n.39 (98%)</td>
<td>n.1</td>
</tr>
</tbody>
</table>