To Dr Lolu da-Silva,
Assistant Editor, BMC-series journals,                      Ferrara, 04 June, 2007

Dear Editor,

thank you for the careful revision of our manuscript: “A family–based educational approach to obesity: a three-year study”, to be considered for publication as a Research article in “BMC Pediatrics”.

We changed the text according to the reviewers' suggestions. We also provided a letter with a point-by-point answer to the reviewers' comments. We made the required changes to the manuscript's format and entered the references according to the standard style of your Journal (Microsoft Word Template). We also provided figures as separate files, after trimming them to optimise the space.

Yours sincerely,

on behalf of all authors

Dr. Rita Tanas, MD

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Dear Dr. Braet,

thank you for your careful revision of our manuscript. Of course, we do know your papers and share your opinion that, actually, prompted us to start and develop our therapeutic education program. In particular, we refer to your article “Long –Term Follow-Up of a cognitive Behavioural Treatment Program for Obese Children” (Behav Ther 2000; 31: 55-74), where you describe an advice-in-one-session, educational approach in the treatment of obese children. As to your remarks, please find here in our point-by-point answers.

Yours sincerely,
on behalf of all authors

Dr. Rita Tanas

MAJOR COMPULSORY REVISIONS

INTRODUCTION

1. The introduction section is too concise. It would benefit from a more detailed description of former research results on childhood obesity treatment. Providing numerical data (e.g.: what is unsuccessful? What is a high drop-out? what are successful weight losses?) would lead to a more thorough review of the literature. Also add shortcomings of these studies.

Answer. A more detailed description of former research results, with particular attention to therapeutic education, has been added to the introduction. It also includes the evaluation criteria of reported results and data about dropout.

2. The authors should fit TEP into the other current interventions for childhood obesity (eg description of the treatment model: what are the ingredients and how are they chosen?). Describe whether similar interventions were evaluated.

Answer. TEP is usually carried out according to a systemic approach and to some well-defined procedural steps (e.g., learner’ need assessment, identification of learning/therapeutic objectives, training, learning evaluation; TEP also implies the careful sharing of every phase of the educational process “with” the patient and his/her caregiver (in our case the child and his family) who are always involved in decision making.

3. Please provide a definition of treatment success and all dependent variables. What about weight stabilization? It is not clear if this was positive or negative. If the authors choose that a 10% weight increase is negative, this has to be motivated. In the result section, satisfaction is included as dependent variable as well. In the discussion, success is described as a healthier life-style.

Answer. See above, answer to point #1 (introduction) and, below, answer to point #1 (statistics and results). As reported in the revised text, we think that weight stabilisation can be considered as a good result in treatment of children and adolescent obesity. As to the choice of the 10% of weight increase in the evaluation of a negative result, it was an authors’ arbitrary decision. Since, in our experience, obese children between the age of 10 and 13 usually grow beyond the 10%, we adopted a BMI% increase >_10%, during the three years follow-up, as score for negative outcomes. About this Rudolf MC affirm that in UK “BMI increase with age at rates of up 0.1 SDscore per year, although we could not disentangle the secular trend from the age trend because of their co-linearity” (Rudolf MC et al Growth of primary school children: a validation of the 1990 references and their use in growth monitoring. Arch Dis Child 2000, 83:298-301). May be it is a little bit generous measure, but still in line with some current therapeutic policy (e.g. Neumark-Sztainer, ref. #16) in the prevention of unhealthy weight reduction behaviours.
4. We need a more solid narrative text leading up to a more explicit formulation of the hypotheses and the end of the introduction.

**Answer.** The text has been changed according to your suggestion.

**METHOD**

1. Please provide different paragraphs in the method section: information about the procedure must be deleted in the study population and moved to ‘procedure’. Information collected at the follow-up (see page 6) must be moved to the result section. Add also a paragraph ‘assessment or measures’.

**Answer.** The method section has been changed according to your suggestion.

2. More information on the assessment phase should be included, describing the measurements used (especially because on p. 9 is written that children with body-image dissatisfaction, emotional eating and binge-eating received additional sessions – how was this measured?).

**Answer.** The paediatrician who led the program was adequately skilled. She evaluated the possible occurrence of body-image dissatisfaction, emotional eating and binge eating on the base of a clinical evaluation and of her professional experience. When necessary, she sought the advice of the psychologist.

3. Design of the study: A more detailed description of the inclusion and exclusion criteria is needed. The authors describe in this section that children with secondary obesity and psychiatric problems were excluded. In the discussion section on page 14 however, the authors state that children who had clinically evident psychological problems (10% of the original group) were sent to a standard multidisciplinary treatment. This is confusing.

**Answer.** A more detailed description of the inclusion and exclusion criteria has been added. Children who had clinically evident psychological problems (10% of the original group) were sent to standard multidisciplinary treatment and excluded from the study.

4. Design of the study: How were participants assigned to either the TEP group or the DT group? Was it randomised?

**Answer.** This is not a randomised study; however, when the families call our centre asking for advice and consultation, they make a completely free and uninfluenced choice between different healthcare professionals.

5. Design of the study: On p. 6 – 7 the authors write that the TEP group and the DT group were matched as to age, gender and follow-up. Did the authors control for other potential baseline differences in order to check whether both groups are comparable? How do they control for motivation and psychological problems? (e.g. see page 14: some families were not allowed in TEP or were not willing to participate (69%) in the TEP-group).

**Answer.** No other potential baseline differences were controlled and cases having psychological troubles were excluded. The percentage of families that, despite their initial adhesion to our program, did not take part in it has been 69%.
6. Matching implicates a case-control study (for each case, a control case was selected). This means that we needed 85 controls instead of 105.

**Answer.** This is not a strict case-control study in that cases for the control group (DT treatment) have been recruited taking into account only their age, gender, parents BMI and follow-up time.

7. The description of the study population (p. 5 – 7) raises several issues of concern: description of the sample with regard to their ethnicity, socio-economic status and other related demographic characteristics should be presented in the text.

**Answer.** The study population was made only by Caucasian people of random socio-economic extraction. In particular, we decided of not assessing the families’ socio-economic status in the attempt of not endangering their privacy and fragile motivation.

8. The description of the study population: do the authors have any information about differences between the participants versus refusers in both groups? It is a relatively low response rate (as was described in the discussion section) and it would be helpful to characterize these families more completely. I do not understand how many children actually refuse to participate. Information in the discussion is different than those on page 6 (87 families gave their consent, and for 85 children the one year follow-up was observed, so the drop-out is 2/87?) and page 27 (90 families started, 56 were on the one-year FU and 40 were on the 3 year FU).

**Answer.** We don’t have any information about the differences between the people who accepted to participate and those who refused to. However, we have the impression that they were afraid to be involved in a therapeutic education program or to put themselves rather their “diet” under discussion. We missed the results of only two children out of 87 because they had a tragic mourning in their families. Questionnaires were filled only by families coming to our centre for control and not by telephone FU; 90 is a wrong number that included also 5 children/families that still had to reach a one-year FU; 85 refers to those who reached a one-year FU; 56 refers to children/families who came to our centre for control after one year and 40 to those who reached at least a three-year FU, came to our centre and filled the final questionnaire.

9. Percentage overweight (BMI%) means BMI/BMI at 50th percentile x 100. Why did the authors choose for another index?

**Answer.** We changed the text according to your suggestion about BMI%.

10. I notice a considerable age range (3-18 years). Do the authors found age-related differences?

**Answer.** We are still working on these data. The boys over twelve years are now directly taking part to the TEP that has been adapted to their needs. We tried to understand if there were some age-related differences in the results; taken together, they seem good at every age and weight reduction (BMI% variation between beginning and follow-up) positively correlates with age (p< .05) and stage of puberty (p<.01) at the beginning of the study.

11. Therapeutic Education Programme. How many therapists were involved? Did they use a standardized protocol? How many weeks were there between the sessions (on page 8 we see ‘after two months’: does that mean after intake or after session 2?) (specify exactly the number of weeks between session 1 and 2 and between 2 and 3)? Who decided that?

**Answer.** As reported in the section METHODS PROCEDURE describing our intervention, the entire TEP program was carried out by a single skilled educator-paediatrician. As to the adopted protocol, see above, (introduction) answer to point #2 and reference #42 (W.H.O. working group. World Health Organization, Regional Office for Europe. Therapeutic Patient Education. Continuing
education programs for healthcare providers in the field of prevention of chronic diseases. Geneva, 1998). After the first assessment (session #1), families that accepted to adhere to the program usually took part to the group education session within a month (session #2 was normally repeated every month). The second assessment (session #3) was usually carried out within two months from session #2.

12. Therapeutic Education Programme. On which theoretical or empirical grounds was the follow-up schedule based?

**Answer.** FU was scheduled by the educator-paediatrician on the base of W.H.O. working group indications (see reference #42) and according to the availability and needs of families.

13. Programs. The authors should elaborate this section by adding a description of the DT. What are similarities and differences between TEP and DT? This is especially important for the appraisal of potential overlap between both conditions. Are both condition checked on treatment integrity? Do the therapists had contact with each other? How to avoid contamination of the treatment approach?

**Answer.** Of course, there are many similarities between TEP and DT, such as information content and biological parameters evaluation. However, compared to DT, besides information, TEP transfers to families specific skills in order to enable them to the self-management not only of their diet but also their life-style and physical activity. Moreover, TEP periodically includes both a self-evaluation by the family and a shared paediatrician and family evaluation of the results. The therapists of our centre have been working together for many years and, of course, this might cause contamination; yet, this is a very common situation in many other centres. Originally, in our intention, this program was meant to find out a sustainable and efficient solution for healthcare personnel treating obese children/adolescents, mainly in centres where human resources are scarce or inadequate to face the ever increasing number of people seeking advice for weight related problems.

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**STATISTICS AND RESULTS**

Several issues should be clarified:

1. p. 10: A negative outcome was scored when a BMI% increase was observed (>= 10% baseline): the use of this criterion should be justified.

**Answer.** There are no acknowledged criteria to assess a negative outcome. Since, in our experience, obese children between the age of 10 and 13 usually grow beyond the 10%, we adopted a BMI% increase>10%, during the three years follow-up, as score for negative outcomes. About this Rudolf MC affirm that in UK “BMI increase with age at rates of up 0.1 SDscore per year, although we could not disentangle the secular trend from the age trend because of their co-linearity” (Rudolf MC et al Growth of primary school children: a validation of the 1990 references and their use in growth monitoring. Arch Dis Child 2000, 83:298-301.

2. p. 11: baseline information has to be moved to the description of the participants in the method section.

**Answer.** The information has been moved as requested.
3. p. 11: When making comparisons between the number of children that decreased, please add $X^2$ analyses.

**Answer.** $X^2$ analyses have been added to the results section. The $X^2$ test was statistically significant among obese children that decreased, while no significant differences were observed among those who normalized their weight. See Tables #2 and 3 for details.

4. p. 11: What is meant by ‘that to be matched paired’?

**Answer.** The procedure employed in the analysis of the data, i.e. the ANOVA Repeated Measures, takes into account that feature when matching it during FU. Any way, to avoid possible misunderstanding, we skipped any mention to the ‘within’ matching phase of the computing method.

5. Information on the conducted t-tests and chi quadrate tests should be completed. Further, should it not be more solid to use a repeated measure analysis?

**Answer.** Student t-test was applied without obtaining significant results; so, we chose of not mentioning it in the ‘statistical methods’ section. As to the repeated measure analysis, it has been widely employed as the ‘carrying’ analysis procedure.

6. p 12: please put figure 1 and 2 in the right order. Is figure 1 referring to all children or, only those with positive evolution?

**Answer.** The citation order of figures has been rectified. Figure #1 refers to all children.

7. p. 12: ‘positive children number’ and ‘negative children number’ are confusing concepts.

**Answer.** The text has been made more clear.

8. p. 13: additional information on the evaluation and lifestyle questionnaires should be provided.

**Answer.** As requested, additional information about lifestyle has been added in the Method section: Intervention Descriptions The Therapeutic Education Program. The questionnaire includes fives questions about the subjective improvement of nutritional habit and four about physical activity and habit.

9. The use of linear regression is rather confusing. On page 11, the authors state that “Linear regressions were employed to search for weight variation trends versus some parameters like follow-up time span, age variation, etc. ” However, this was not clearly elaborated in the result section.

**Answer.** We changed the result section according to your suggestion, including only significant results. Linear regression was carried out to assess some age and growth related trends.

10. Table 1: Please add a row ‘Normal weight’, so that we can see how many children moved to that category at follow-up.

**Answer.** We changed table #1 according to your suggestion.
DISCUSSION

1. A major critique is that the authors should not generalize beyond the study findings. The section on practical implications should be done cautiously. Would it not be more ethical to conclude that TEP is effective for a subgroup of children with overweight and their families? For children with moderate overweight (specify criteria!), with no additional psychological problems, for well motivated families... Several criteria should be described; as such that TEP is implemented in first care and can have its specific target population. Children with severe overweight and with additional psychosocial and familial problems (the majority of the obese children) should be referred to multidisciplinary treatment programs. In that way TEP deserves its place next to 'the golden standard' instead of TEP taking the place of a well evidenced multidisciplinary treatment. We prefer this view to be implemented in the discussion section.

   Answer. We changed the discussion section according to your suggestion.

2. Furthermore, the limitations of the study should be acknowledged and suggestions for future research should be included.

   Answer. We changed the discussion section according to your suggestion.

3. No new data can emerge in this section (see page 16: 'growing number of obese children asking treatment', is not a relevant conclusion).

   Answer. We changed the discussion section according to your suggestion.
Dear Dr. Plachta-Danielzik,

thank you for your careful revision of our manuscript. Please find here in our point-by-point answers to your remarks.

Yours sincerely,
on behalf of all authors

Dr. Rita Tanas

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MAJOR COMPULSORY REVISIONS
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- The authors used as outcome parameter BMI% and BMI z-score. Both parameters indicate the variation of a BMI value from the 50th percentile (or mean). The z-score is the more common parameter and should be used. In addition the use of BMI-SDS would be better than BMI z-score because the BMI in children is not normal distributed.

Answer. The z-score has been employed to enable a better comparison between our study and the others, even if it may arise some problems of distribution. Nevertheless, we calculated SDS by means of an Italian reference (Cacciari et al 2006) and have now cited it in the text (table 1).

- Why do the authors used two different reference databases for BMI: Luciano et al. to calculate z-score and %BMI and Cole et al. for the obesity degrees? To compare z-score values and the prevalence of overweight the same reference database should be used.

Answer. For BMI, we adopted the reference databases of Luciano et al. We referred to Cole et al. only when considering evaluation of weight variations before and after TEP (see also reference #26).

- Changes in z-score should be always given in the results section.

Answer. The result section has been changed according to your suggestion.

- The scoring of outcome is unclear: BMI <85th percentile: according to which reference?

Answer. In medical literature there is not univocal consent about the definitions of “risk of overweight”, “overweight”, “obesity” and “risk of obesity”. However, we usually adopted a BMI > 85° (CDC 2000, WHO, Lobstein) to set the occurrence of “overweight”.

- The authors showed changes in BMI z-score and changes in BMI. Due to the high range in age of the children (and the different development of BMI during childhood) changes of BMI are misleading. Figure 1b and 2b should be skipped.

Answer. Fig. #1b has been changed and the #2b skipped according to your suggestion.

- The authors matched the control group according to age, gender and follow-up. It would be important to match for BMI, socio-economic status and weight status of the parents. These are the main determinants of childhood overweight and additionally influence the success of an intervention.
**Answer.** Unfortunately, we have been unable to match the control group for BMI. Moreover, we decided of not assessing the families’ socio-economic status in the attempt of not endangering families’ privacy and the fragile relationship with them. The parents’ BMI was similar in the two groups.

- Why did the authors write "he/she" when speaking about the physician. They wrote that it was only one person (?). Or was the TEP performed by several physicians? Then a cluster effect have to be proven.

**Answer.** In fact, the program has been entirely carried out by the same female physician. So, we changed the personal pronoun to “she” when referring to the physician.

- Not all children were measured at follow up. How many self-reported values were included? To which group did they belong?

**Answer.** As reported in the Results section, in the TEP group, the percentage of self-reported values was 22%.

- Drop out rate as well as a drop out analysis are missing.

**Answer.** The drop-out percentage in TEP group (who received a phone FU) has been 1,74%, while in DT group (who did not receive a phone FU) it has been 45,7%. Dropout data have been added in the result section and their implications are reported in the discussion.

- As stated in the discussion, girls had a higher prevalence of negative results than boys. This is not given in the “Results” section (e.g. in table 1 and 2).

**Answer.** The prevalence of negative results was 60% among girls, but the difference between sexes wasn’t statistically significant. These items are added in the Results section and in the Discussion.

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**Minor Essential Revisions**

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- table 2 should include number of children changing their obesity degree. Normal weight is missing. In TEP numbers of baseline and follow up are not the same (?). 

**Answer.** Table #2 has been changed according to your suggestions and remarks. A table #3 has been added including subjects who changed their obesity grade. Normal weights have been added to table #2. In TEP group, numbers of baseline and follow-up differ because Obesity includes also severely obese subjects.

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**Discretionary Revisions**

(which the author can choose to ignore)

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- Figure 2 is cited before fig. 1b is cited.

**Answer.** The citation order has been rectified.