Author's response to reviews

Title: Weight maintenance treatment approach for adolescent obesity: case management via telephone counselling and SMS - study concept of the TeAM program

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Author's response to reviews: see over
Dear Dr. Backholder, dear Julie Anne Magtira,

Thank you very much for having reviewed our above mentioned manuscript and for giving us the opportunity to submit a revised version to the journal BMC Obesity. We submit herein the revised manuscript. According to the reviewer’s and editor’s comments and suggestions. As requested, all corrections and amendments are marked in the text. The point-to-point reply to all reviewer’s comments is listed below.

Please do not hesitate to contact us if you have any questions regarding this manuscript.

Sincerely,
Jana Markert
Associate Editor’s Comments:

The intervention proposed by authors is innovative and will likely be of interest to readers. However, the title and the aim of the paper, as it stands, is somewhat misleading. Although the aim of the manuscript is to 'present the design and baseline data of an innovative, low threshold weight maintenance program for obese adolescents utilizing the case management approach and new media', the paper appears to really focus on a feasibility study, rather than the actual proposed trial. The reviewers have provided useful comments and suggestions to improve the clarity of the manuscript.

We thank the associate editor for the important note. The title was changed (line 3, page 1) and all information referring to the planned RCT were summarized in one paragraph in order to distinguish them from the presented feasibility study (lines 236-264, pages 7-8).

In addition could the authors please add the year for the statistics in paragraph 1 of the background (‘obese individuals accrued medical costs approximately 30% higher than that of normal weight peers’).

The requested information was added (lines 64-65, page 3).

Reviewer 1:

Major Compulsory Revisions

1. There is no mention of the sample size that will be recruited for the RCT. Some calculations for the sample size should be included here to indicate how many subjects will be required to achieve a clinically significant difference in BMI-SDS during the trial.

The estimation of the sample size for the RCT was added according to the reviewers advice (lines 258-271, page 8).

2. When reporting methods and results of the feasibility study, this should be written in past tense as this feasibility study has been completed.

The feasibility study is not yet completed. Recruitment is finished (line 281, page 8).

3. More detail is needed regarding the Facebook page. Is this just to advertise the study?

Yes, this Facebook-Site is just to advertise the study, which has strictly
adhere to the requirements of the Ethics Committee of the University of Leipzig.

4. From your 'data analysis' it seems the only outcome that will be analysed for your RCT is the primary outcome (which I assume is BMI-SDS as it is not clear from your paper what the primary outcome is). You are however, collecting data on many other outcomes. How will these be analysed? For example, will analysis of co-variance be used adjusting for treatment site, case manager and gender?

So far planned data analysis of the RCT was added within the RCT-paragraph (lines 246-257, page 7). In the feasibility study, the percentage of adolescents who agreed to participate and who adhere to the intervention are explored (lines 234-239, page 7).

Minor Essential Revisions

1. Write in full the abbreviation 'BMI-SDS-reduction' where it is first used in your abstract.
   The full text of the abbreviation 'BMI-SDS' was added where it is first used in the abstract (lines 37-38, page 2).

2. 'TeAM was registered in the German Clinical Trials Register in 2012...' The tense was changed (line 102, page 4).

3. Does there need to be a space between 'AdiposityDiseases'? (Methods, third paragraph).
   No. The spelling is in accordance with the corporate design of the IFB AdiposityDiseases (line 116, page 4).

4. It is not clear why you mention the Clinical Trial Centre (KSL). Is this where the 'Integrated Research and Treatment Centre AdiposityDiseases' is located? (Methods, third paragraph).
   The KSL supports data analysis of the IFB-studies (line 121, page 4).

5. 'Thus, the difference between both groups reflects the impact of the intervention...' (Methods, sixth paragraph).
   The missing letter 's' was added (line 155, page 5).

6. A major source of bias in a RCT of a lifestyle intervention program is the participant’s awareness of their allocated group (i.e. control versus active treatment). Awareness of their health condition and willingness to participate are rare sources of bias as both groups are usually aware of their health condition are consenting to participate before randomisation, if you see what I mean. Therefore, I do not think this sentence is relevant and should be removed (Methods, sixth paragraph).
We thank the reviewer for the valuable comment. You are absolutely right by saying that persons aware of their health condition are consenting to participate. This information and potential source of bias is included in the manuscript (lines 150 and 156, page 5).

7. 'To remind the participant, his/her tasks are sent to the participant’s mobile phone via short message service (SMS) text messages.' (Methods, twelfth paragraph). It is also not clear how these task messages are ‘tailored’? An additional sentence was added (line 210, page 6) in order to make the tailoring of the SMS clearer. Two sample SMS were now presented within the manuscript (lines 212-217, page 6).

8. 'Reminders are generated by an internet-based SMS platform.' (Methods, twelfth paragraph).
Done. (line 222, page 7).

9. '...indicates the utility of systematic appointment reminders one day ahead of a counselling date to encourage participant’s attendance at their counselling session.' (Methods, twelfth paragraph).
The sentence was completed according to the reviewers suggestion (lines 221, page 7).

10. 'In the calculation of SDS values, changes over time according to age and sex are taken into account.' (Methods, thirteenth paragraph).
This sentence now is changed according to the reviewers suggestion and is included within the new created paragraph about the planned RCT (line 248, page 7).

11. You need to state somewhere what your primary outcome is (I assume it is BMI-SDS).
The primary outcomes of the feasibility study are acceptance and adherence. The primary outcome of the planned RCT will be change in BMI-SDS. An additional paragraph assembling all information regarding the planned RCT was created (lines 243-271, pages 7-8), making the differences between feasibility study and efficacy study (RCT) clearer.

12. Define abbreviations ‘IFB’ and ‘GCP’ (Methods, fifteenth paragraph), and ‘ICH-GCP’ (Methods, sixteenth paragraph).
They are now written in full according to the reviewers suggestion (lines 115, 120 and 129-130, page 4).

13. ‘Descriptive analyses of baseline data were performed using R software version 2.15.0’ (Methods, fifteenth paragraph).
The tense was corrected (line 277, page 8).

14. Suggest deleting the first sentence of the results and then include at the
beginning of the second paragraph 'Of the 38 adolescents recruited for the feasibility study, 14 were boys and 24 were girls.' (Results, first paragraph).
In order to explain the difference between recruited participants and collected data we decided to leave the first sentence, and hope this will find the approval of the referee(line 281, page 8).

15. It is stated that 38 adolescents were included in the feasibility study, yet the results are based on n=35 participants. Did the other three participants drop out of the study? This need to be made clear at beginning of the results. The respective rehabilitation hospital did not provide baseline data for three participants. This was made clearer at the beginning of the results (lines 282-283, page 8).

16. Table 1 is poorly presented. Define + parents as a footnote to the table. Indicate the frequency, number and nature (e.g. task reminder, counselling session reminder) of SMS text messages sent to participants in Table 1. We thank the referee for the valuable advice. Presentation of table 1 was changed according to the comments made by reviewer 1: Frequency of counselling interviews and SMS were added, as well as the nature of SMS sent to the participant (page 15).

17. The authors also need to be clearer in the methods (probably under session content) as to what is covered in the anamnestic, mental hygiene, physical activity and nutrition sessions. Are there any guidelines underlying the goals set with adolescents for their nutrition, mental health or physical activity? For example, clinical treatment guidelines for managing obesity in paediatric populations, or national public health guidelines for physical activity or nutrition.
We thank the reviewer for the valuable advice. The missing information was included into the methods section (lines 198-201, page 6).

Discretionary Revisions

1. The statement 'All candidates are addressed directly' is not clear here. I think you mean the adolescents were addressed directly, rather than through their parents. Due to word limitations, it may be best to leave this out of your abstract.
The mentioned sentence was left out. Another four words were added within the abstract to express the same fact more precisely (lines 42, page 2).

2. From when does this data refer to '....obese individuals accrued medical care costs approximately 30% higher...'; e.g. in 2010? (Background, first paragraph).
The missing information was added (lines 63-64, page 3).
3. '...is in- and/or out-patient...' (Background, first paragraph).
   The missing hyphen was added.

4. 'The design of the TeAM-study is a randomized controlled trial. Reporting of this trial is in accordance with the 2010 CONSORT Statement (25).' (Methods, first paragraph).
   The sentence was divided into two shorter ones (lines 100-101, page 4).

5. Use lower case for 'follow-up', i.e. '...medical practices (post intervention assessment, follow-up assessments)' (Methods, third paragraph).
   Done.

6. The term 'reconvalescent care' is not so common in public health literature. May the term 'treatment' or 'weight loss treatment' or 'obesity therapy' be used instead?
   The term 'reconvalescent care' was replaced by the term 'in-patient treatment'.

7. 'To ensure the quality of the counselling and adherence to the study manual...' (Methods, seventh paragraph).
   The dispensable 'the' was canceled (line 175, page 5).

8. Table 2

   (a) Suggest changing the title of table 2 to 'Baseline characteristics of participants from the feasibility study (N=38)'.

   (b) Could use N (%) rather than 'Numbers (%)'.

   (c) Be consistent in use of decimal places.

   (d) Capitalise outcome measures 'Duration of reconvalescent care' and 'Presence of co-morbidities'.

We thank the referee for the important comment. In accordance to the comments of both referees table 2 was revised. It is now presented by intervention groups to demonstrate differences in baseline characteristics (page 16).
Reviewer 2:

Major Compulsory Revisions

1. Introduction: When referring to weight loss maintenance interventions in adults, individual studies are quoted, when there are a multitude of systematic reviews in this area.
   The references #12 and #13 were replaced by systematic reviews (line 80, page 3 and lines 386-390, page 10).

2. Methods: The description of the intervention sessions is inadequate. Table 1 provides little detail
   We thank the referee for the valuable advice. Presentation of table 1 was changed according to the comments made by reviewer 1: Frequency of counselling interviews and SMS were added, as well as the nature of SMS sent to the participant (page 15).

3. Methods: The sample size should be justified in the methods.
   The estimation of the sample size for the RCT was added according to the reviewers advice (lines 258-271, page 8).

Minor essential revisions

1. Methods: Participant eligibility. Do participants need to have been successful in the weight loss program to be eligible to participate in this weight loss maintenance intervention.
   There exists no anticipated weight change which needs to be achieved during inpatient obesity treatment. Stratification of the randomization in the planned RCT gives the possibility to account for differences in the outcome of inpatient treatment.

2. Methods: The paper states that participants are randomly assigned to groups, but then states that participants are allocate to groups consecutively. This is a contradiction.
   The referee is correct in pointing out that the description of the randomization method is misleading. We have revised that passage (lines 148 and 152-153, page 5).

3. Methods: SMS: Examples of the text messages sent to participants would strengthen the paper.
   Two examplarily SMS were added (lines 212-217, page 6).

4. Methods: Greater detail on the study endpoints, particularly for the primary outcomes of ‘acceptance’ and adherance is required
The requested information was added (lines 235-241, page 7).

5. Methods: Statistical analysis: Insufficient detail of statistical methods provided.
The detailed description of the statistical methods planned to be used in the RCT were added according to the reviewers advice (lines 248-257, page 7).

6. Tables & Figures: Table 2 could be presented by intervention groups to demonstrate any differences in baseline characteristics. Figure 1 offers very little to the publication.
   We thank the referee for the important comment. In accordance to the comments of both referees table 2 was revised. It is now presented by intervention groups to demonstrate differences in baseline characteristics (page 16). Figure 1 is left out of the manuscript.

Editorial comments:

«Please include a Section Heading in your Competing Interest Section.»

The section heading was added (line 328, page 9). The section is now located between the ‘Conclusions’ and ‘Author’s contributions’.