Author's response to reviews

Title: Effects of a general practice guided web-based weight reduction program - results of a cluster-randomized controlled trial

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Author's response to reviews: see over
Response to the Reviewers

We thank the peer reviewers for their interest in our manuscript and the valuable comments. We tried our best to incorporate the suggestions into the revised version. As suggested by reviewer 2 we now follow the recommendations for presenting an eHealth study and its findings. We hope that you are satisfied with the actual version. Please find our point by point response in blue italics behind the single comments from reviewers.

Reviewer 1

1. The study actually tested the benefits of the web-based program + SMS + telephone reminders by the GP or a qualified practice nurse. It is well known that the GP's influence is remarkable and it is hard to differentiate the benefits of the web based program from the GP telephone calls. Bennett et al (ref 19) included a dietician consultation, while others did not include any further consultations. Is it possible to check the differences (within the intervention group) of patients who were contacted by the physician vs the nurse?

Response: We now state more explicitly in the abstract and discussion that we tested a combination of the program and reminders. Unfortunately, we do not have the data needed to investigate the influence of procedural aspects of the intervention on outcome.

2. A possible reason for the high drop-out in the intervention group (109-76) vs the control group (77-72) may be the 10euro compensation that were given to patients in the control group to encourage them to come to the follow-up visit. Nevertheless, the conclusions did not change even through an intention to treat analysis.

Response: Indeed, the different drop-out rate might be partly due to different incentives. However, other reasons (e.g. less documentation in the control group) could have a role, too. We added a short discussion of potential reasons in the limitations session.

3. I see the statistically significant age difference between the intervention and control groups as very important (46.5+-10.9 vs 50.9+-15.3yrs respectively). It is questionable if similar results would have been if the patients in the intervention group were older.

Response: We agree that the age difference between the groups could be a confounder. Therefore, age was included as a covariate in the multivariate analyses. These analyses suggest that the observed difference in outcome has not been influenced by the age difference. Yet we critically point to the problem in the discussion (limitations).
**Reviewer 2**

**Methods:**

1. The recruitment and selection procedure: How were the GP’s recruited? What was the exact procedure that the GP’s used for inviting participants into the study?

   *Response: We added and changed following passages in the methods section:*

   … At the beginning of the study, around 2,000 Bavarian general practitioners (GPs) received a fax by the Bavarian Association of General Practitioners with information about the research project. All interested GPs were sequentially registered for randomization. After giving written consent, the participating practices were randomized either to the interventional or the control arm. The sequence of randomization (allocation 1:1) was provided by a methodologist, who did not participate in the execution of the study, via the program Randomizer (www.randomizer.org). Randomization was concealed by using sequentially numbered, opaque sealed envelopes held by the study coordinator. Before starting recruitment of patients, physicians and practice nurses received detailed instructions by the research team on the study process (both intervention and control group) and on the coaching program (only intervention group).

   … Participating physicians were general practitioners in Bavaria, Germany. The GPs were requested to recruit overweight individuals of whom a weight reduction was recommendable. Individuals with a BMI > 25 were potentially eligible. Exclusion criteria were age younger than 18 year, insufficient German language skills, and lack of internet access.

   … After decision of the GP that the participation of a patient was recommendable for enrollment, an information form was given and discussed and a participation form had to be signed. At the same time the baseline data acquisition took place. All participants were asked to fill in a standardized questionnaire together with the GP. Baseline data of weight and waist circumference were measured in general practice; eating behaviour and physical activity were documented at the same time. Participants of the intervention group received a free web-code. The physician filled in a form together with the patient with detailed information about diabetes mellitus or hypertension (if necessary), dietary advices (like low cholesterol diet) and suggested physical activity. This form and the web-code are used by the patient for specification during the registration process of the internet program.

2. Sample size calculation. Based on a sample size calculation taking into account the cluster randomized design, how many general practices would have been needed for the study and how many participants per practice?

   *Response: The sample size calculation providing the requested details has been added to the statistics section.*
Sample size calculation was performed with G*Power 3 correcting for the cluster design (intra-cluster correlation coefficient = 0.05, average cluster size = 3) for two-sided testing ($\alpha = 5\%$ and a power of 80 %). Using these assumptions the calculated total sample size for primary outcome weight loss was 142 participants. Taking expected attrition into account we aimed at recruiting a total of 180 participants in about 60 general practices.

3. The contents and the theoretical basis of the intervention and what the participants needed to do, to go through the program.

Response: We added further details of the theoretical basis of the intervention.

...The coaching program is based on principals of the cognitive behaviour therapy – e.g. education, realistic goal-setting and individual resources – and in particular on the behaviour change theory targeted to reduce and maintain weight by using inexpensive Internet and mobile technologies in combination with existing health care resources of GPs. The content of the coaching program aims at achieving a lasting change of behaviour patterns with the help of individualized education, motivation, exercise guidance, daily SMS reminders, self-monitoring via Internet and, finally, through an active monitoring and approximately 3 telephone calls during the 12 weeks by the GPs or their respective staff.

The program is based on a concept developed by Prof. Dr. Pudel, Institute for Nutrition and Psychology Research Department at the University of Göttingen [12,13]. A weight loss plan including individual energy requirements supports each patient during the 12 weeks and assures an adequate nutrition including nutrients such as proteins, carbons and fat. The given dietary recommendations are based on current nutritional guidelines (German Nutrition Society - DGE). Additionally, the program was conceptualized for the nutritional needs of diabetics and hypertensive patients. This trial was the first evaluation of this intervention. There were no changes undertaken in regard of the content of this intervention during the whole observation.

4. What was the usual care in the control group?

Response: We added further details of the usual care group.

... Physicians assigned to the control arm were asked to change nothing in their usual way of counselling and to treat participants in the same manner as if they would have been non-participants. There was no structured documentation of the care provided.

5. The procedure for assessment of the anthropometric measures.

Response: We added further details of the procedure for assessment of the anthropometric measures
… Physicians of both groups were requested to document the anthropometric measures from the participants with their existing practice equipment. The physicians were advised to measure the weight in underwear without shoes and to measure the waist circumference corresponding to the standardised definition (measured with a tape around the abdomen located marginally above the upper hip bone). A follow-up investigation with the same measurements and documentation was performed in the general practices twelve weeks after inclusion.

6. The questionnaire for assessment of the dietary and physical activity Behaviours.
Response: We added further details of the questionnaire for dietary and physical activity behaviours.

… The evaluation of the self estimated eating behaviour (range from 1-5), conscious eating pattern (range from 0-2), frequent cooking (range from 0-2) and physical activity (range from 1-4) was conducted at baseline and after 12 weeks. A higher number on the scale refers to a more even or more conscious eating behaviour, more frequent cooking or more frequent physical activity.

7. The statistical procedures that were used and the rationale for using so many different analyses. Because the design was a cluster randomized design, multilevel analysis would have been required. It is a serious limitation of this study that no multilevel analyses were conducted.
Response: In the “statistics” section of our original submission we already described that the strongly variable cluster size (with 12 practices including only one patient) caused major numerical problems in the linear mixed model questioning the validity of multilevel analyses. Therefore, and because of the high number of practices with only 1 patient, we decided to use a simple t-test for the main analysis, with a GEE approach as secondary analysis in the sense of sensitivity analysis. We are aware that the t-test approach does not take account of the cluster randomization, but the t-test is simple, straightforward and appropriate for 1-patient-practices. In addition we performed multilevel analyses, however, due to the highly variable cluster size the interpretation of these analyses is hampered, too. We understand that it might be confusing to present too many different analysis methods. As this reflects our original decision we would prefer to keep the t-test for the main analysis. We propose to present in addition only one secondary analysis (generalized estimating equations), which accounts for cluster levels in addition to the results of the t-tests. We also added a phrase to the limitation section in the discussion pointing to this problem again.
Results:

8. What was the response rate among the GP’s who decided to participate and what was the response rate among the potential participants who were invited to participate?

Response: We added further details of the response rates from practitioners and participants.

…Originally 92 practices were interested to participate and were randomised. 16 practices withdrew early after randomization (7 GPs from the intervention and 9 GPs from the control group), 27 practices (14 GPs from the intervention and 13 GPs from the control group) did not recruit any participant for the study. Altogether, 186 patients were recruited (Figure 1).

9. The authors should report the results of the multivariate analyses in the paper and in the tables and not the results of the simple t-test analyses.

Response: We now also report the results of the GEE analyses in the text of the manuscript. See response to comment 7 for further details.

10. There were differences between the groups at baseline. How were these differences taken into account in the analyses?

Response: The baseline group differences were taken into account by using respective covariates in the GEE approach.

11. It would be helpful if results of a process evaluation were included in the paper. Now there is no indication at all as to how many people actually used the program, or which parts of the program were used in particular. This information would be important for interpretation of the results.

Response: We added further results of the documented process evaluation.

… On the average, participants in the intervention group completed 6.4 (SD 4.2) week modules of the web-based coaching program. The mean duration of the program use was 72.7 (SD 28.7) days. This means that some participants did not use the program continuously and interrupted the program use (e.g. because of vacation).

Discussion:

12. In the discussion section it seems that the authors consider their intervention program as being purely web-based, whereas in fact it is a combination of a web-based program accompanied by telephone counselling. This needs to be stressed more in the discussion section and the results of the study need to be compared to
really comparable studies. Based on the design of the study, the authors cannot draw conclusions about the effects of the web-based part only.

Response: This critical comment is clearly justified and has been also raised by reviewer 1 (point 1). Please see our answer there

13. The authors compare the results of their study to another study in which a weight loss of 2.6 kg was achieved and then suggest that the latter intervention was less effective than their intervention in which a weight loss of 2.5 kg’s was achieved. This postulation does not seem to be correct based on the figures that they present.

Response: This aspect has been justified. We now report and compare the mean group differences between the trials.

… Another randomized controlled trial by Rothert et al. [15] received a mean group difference of weight loss from 1.4 kg after a web-based intervention of 3 months. This individually tailored weight management intervention was conducted without any coach support which might explain the lower efficacy when compared to our trial.

14. The authors suggest the results of their study are internally confirmed, since they use a number of weight related outcomes (weight loss, BMI and waist circumference). This is, however, a bit misleading, since BMI is a measure that is strongly related to body weight and weight loss and can, therefore, not be seen as a fully distinct measure.

Response: We absolutely agree with you that the BMI is strongly related to the body weight. We deleted the reference to the BMI in this paragraph. Yet we think the simultaneous reduction of the waist circumference can be considered as an according affirmation.

15. A strong and unique point of this study is that the intervention was provided through GP’s. There is, however, hardly any discussion about the fact that the intervention was implemented in this specific setting and whether this would lead to better or longer lasting effects, or would attract other participants as compared to interventions implemented through other channels and in other settings. The implementation in this specific setting would warrant more discussion.

Response: We agree that the implementation of the intervention through GP’s is a unique setting and could be very beneficial to all involved parties.

… Therefore a web-based program was developed, which combines an individually tailored strategy for weight reduction with automated advice and feedback elements based on cognitive behavioural therapy, in addition to monitoring via internet and telephone counselling in general practice. Such a tool would facilitate the management of patients as
they receive support from their general practitioner (GP) during the weight reduction process guided by the web-based program. The aim of the study was to examine the short-term effectiveness of a web-based coaching program in combination with an accompanied telephone counselling regarding weight reduction in a primary care setting.

16. The authors mention as a strength of the study that it was a cluster randomized trial. This is not a specific strength, especially not, since the further design and the analysis plan was not designed to fit a cluster randomized trial. This is a severe limitation of the study, which should be stressed as such.
Response: Please apologize; the relevant part of the phrase was somewhat misleading. We deleted it. The analysis issue has been addressed above.

Tables:
17. Table 1: Why was there a part in the intervention that focused on letting people understand the effect of insulin and control of blood sugar or to understand the effect of salt on hypertension? This does not seem to be related to weight loss?
Response: The module to understand the effect of insulin and to control blood sugar was performed only for participants with diabetes mellitus type 2. The module to understand the effect of salt respective hypertension was performed for participants with hypertension. This individual information was requested within the first login during the pre-assessment of the internet program, so that the internet program was able to generate an individual content of coaching.
We added further information
… The physician filled in a form together with the patient with detailed information about diabetes mellitus or hypertension (if necessary), dietary advices (like low cholesterol diet) and suggested physical activity. This form and the web-code are used by the patient for specification during the registration process of the internet program.

18. Table 3: Indicate in the tables which type of analyses are presented
Response: In table 3 are complete-case analyses presented in use of student t-test.

Minor essential revisions:

19. Page 10, second last sentence needs to start with a capital.
Response: Done

20. Page 11, second paragraph: methodical needs to be methodological
Response: Done

21. Table 2: Chi quadrat needs to be Chi squared
Response: Done