Author’s response to reviews

Title: Case report. Stroke as an atypical initial presentation of giant cell arteritis

Authors:

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Author’s response to reviews:

Answers to the associate Editor:

1. Your recommendation that “in the case of vegetable consumption, sending additional support through SMS to parents may be worth the investment, and e-mail may be useful to improve fat meat and fat fish consumption”. is based on the results, but seems unexpected. Do you have any explanation for these findings, and are they in line with previous research? Without such, this sentence should be removed from the abstract and conclusion.

Indeed, we based our recommendation on our findings, but because of a lack of evidence in other studies on the specific food categories, we are not able to provide comparison with past research. We deleted the sentence as suggested, and modified the previous one to read:

[...]The use of SMS to support greater behavior change, in addition to Web-based communication, resulted only in a small significant positive change for vegetables, while the use of e-mail in addition to Web did not result in any significant difference.[…]

2. Table 2 suggests that many of the dietary intake variables you studied are not normally distributed. Hence, means and standard deviations should not be presented; and median and an appropriate measure of spread (e.g. interquartile range) should be shown instead.

We agree and now provide the median and interquartile ranges in table 2.
3. As reviewer #2 also pointed out, more details on the statistical modelling should be given (please see below). Whilst doing so, please also describe whether your statistical models met their assumptions, and how you examined this.

Generalized Linear Mixed Models (GLMM) are particularly useful for modelling continuous outcomes where there is some sort of dependency structure between observations. In our case, we worked with repeated measures (two measures per child). As linear model, GLMM assumes that the residuals are normally distributed. However, given the fact that in this kind of model (i.e. multilevel) there are residuals at different levels (first at the level of observations and second at the level of individual, as it is the case of this study) the assumption is that residual at each level are normally distributed. Thus, we checked the distribution for the first and second level residuals using QQ plots (see attached files and attached response to reviewers file)

We assessed normality of the residuals of first and second level and that for all items except fish, eggs and sugar drinks no clear violation of the assumption was found. For the other three items, it cannot be fully inferred that normality assumptions (and thus model adequation) were met, but this kind of model is sufficiently robust to handle small deviations from normality and homoscedasticity.

We added the following text in the manuscript, statistical methods: “Adequacy of the models was assessed by creating QQ-plots for the residuals of first and second level and that for all items (supplemental figures 1-4). Except for fish, eggs and sugar drinks no clear violation of the normality assumption was found”.

We also added the following text in the manuscript, study limitations: “Model adequation could not be fully ascertained for fish, eggs and sugar drinks, as normality of the first or second level residuals could not be fully assessed. Still, GLMM are sufficiently robust to handle small deviations from normality and homoscedasticity”

4. Please describe how height and weight data were collected in the study

We modified the text in the methods section as follows: “Gender, age, height and weight of the children were collected at baseline (BL) through a print survey completed by parents. Height and weight were used to calculate body mass index (BMI).”
5. The method section should also how data were stored and managed.

We added the following sentence in the methods section: “All data were entered in a database and double checked to limit data entry errors. The database was stored on the University server, accessible only to the research team.”

6. All tables and figures should explain the abbreviations used in e.g. a footnote.

We updated the tables adding the explanation of the abbreviations.

7. All statistics mentioned in the tables should be explained as part of each table. For example, the reader can only guess what the statistics in brackets in Table 3 represent.

We updated the information in the tables.

8. Was your trial registered? If so, please add the relevant information to the abstract and manuscript. Please consult the following page for further guidance: https://nutritionj.biomedcentral.com/submission-guidelines/preparing-your-manuscript/research

We have not registered our study with a trials registry because it does not include any medical or clinical intervention that meets the criteria for trial registration. If the Editorial Board deems the registration to be necessarily, we will immediately proceed with it.
Answers to reviewer #1:

This is an original piece of research examining the effects of social marketing of a healthy nutrition program. This is a very important topic as little is known about how we best engage parents in making changes to their children's eating behaviours using online interventions.

Minor comments:

1. It would be helpful for some audiences who are not familiar with the term 'social marketing' if you could define this on p4.

We added a definition and explanation of Social Marketing.

“Social Marketing is a framework that integrates Marketing principles with other approaches to promote healthy behaviors, with the final aim of benefiting society. Social Marketing focuses on behavior and integrates best practice, theory, research, and a deep population analysis to develop effective behavior change interventions [10].”

2. It would benefit the reader if you could add a few sentences about how you developed your social marketing approach (I could not locate the paper you referenced for this) with regards to which marketing concepts, behaviour change approaches and evidence (on existing beliefs, attitudes and behaviours) you integrated and whether you incorporated inputs from end-users.

We added a paragraph at the beginning of the methods section about the development of the intervention. Thank you also for letting us know about the problem of locating the paper. It seems that the webpage of the journal is down. We have added the paper as a supplemental file, for reference.
3. Future research: Can you say something about the use of apps for changing children's eating behaviours? The camera functionality is becoming a valid instrument for recording food data.

Thank you for the suggestion. We tested the communication channels used to communicate with parents, and therefore did not include a discussion regarding technologies that could be used to communicate with children to change their behavior. However, the camera and other technologies offer promising methodologies to measure food intake. However it was out of the scope to discuss assessment methods in this paper.

Answers to reviewer #2:

The paper reports on a study that included various forms of electronic prompts to augment an online social marketing campaign aimed at promoting healthy eating in children. As the authors note, such campaigns have been shown to be effective. Additionally, electronic prompts have also been shown to be effective at increasing program participation, although not necessarily in the type of intervention being tested here. So, this paper stands to add to the research community's understanding of the difficult problem of motivating parents to participate in an online health campaign aimed at children.

I believe the paper has potential, but there are a number of critical elements that need to be explained in more detail before a thorough and complete assessment of the paper's value can be made.

1. The paper needs a much clearer set of statements regarding the research hypotheses. There are at least three hypotheses being tested and these should be articulated and address separately.

We agree and we now list them as follows:
The following hypotheses were tested:

1) Healthy food consumption would increase in all groups

2) Unhealthy food consumption would decrease in all groups

3) The e-mail group would show greater improvement than the Web-only group

4) The SMS group would show greater improvement than the Web-only group

2. How does the study sample compare to the population of Ticino? Given the limited uptake of the program, the authors need to address selection of the sample.

We compared the age and gender distribution of our sample to the one of the whole Ticino population obtained from the cantonal office of statistics. For gender, no difference was found (girls were 50.4% in the current study and 48.8% in the population, p-value 0.427), while 6-year old children are over-represented and 11 and 12 year old children are under-represented in the sample (see table in response to reviewers file)

FAN Ticino

Age (years) Freq. % Freq. %
6 122 20.17 3006 13.69
7 94 15.54 2978 13.56
8 106 17.52 3147 14.33
9 91 15.04 3002 13.67
10 93 15.37 3306 15.06
11 57 9.42 3218 14.66
12 42 6.94 3299 15.03
We added a table comparing the two samples, and a sentence in the study limits section: “Also, the sample might not be fully representative of the Ticino child population: we compared the gender and age distribution of our sample to the corresponding distribution in the canton of Ticino, obtained from the canton’s statistical office (34). No differences were found regarding age; conversely, the study sample had a higher prevalence of 6-year olds and a lower prevalence of children aged 11 and older (Supplementary Table 1).”

3. Additional information on the social marketing campaign itself is needed to understand the program effects. For example, the paper (line 147) indicates that parents received tailored information. How was information tailored?

We provide more information regarding the program development as well as the tailoring in the methods section.

4. The authors need to provide data on individual's participation or interaction with the online SM campaign. Is there data in the number of times per week, numbers of weeks (of the 8 week intervention), number of minutes per interaction. In some way, information on the level of exposure to the campaign is needed.

We provided this information in the Results section. Other details about the exposure to the intervention are described in another paper that is under review and we will add that reference before publication. However, we did add the following text regarding some exposure details:

“The Website registered a total of 22’559 visits over the eight weeks of the intervention (34). It was visited by a total of 195 parents with 261 children (G1) 72 parents with 95 children; G2) 56 parents with 78 children; and G3) 67 parents with 88 children) (see Table 3). When children were asked whether they themselves visited the Website, 39% in G1, 30% in G2 and 39% in G3 answered that they did.
Table 3
Frequency and percentage of parents who visited the FAN Website and of children whose parents visited the Website.

<table>
<thead>
<tr>
<th></th>
<th>G1 Freq. (%)</th>
<th>G2 Freq. (%)</th>
<th>G3 Freq. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parents</td>
<td>72 (44.17%)</td>
<td>95 (43.58%)</td>
<td>56 (38.89%)</td>
</tr>
<tr>
<td>Children</td>
<td>163 (100%)</td>
<td>218 (100%)</td>
<td>144 (100%)</td>
</tr>
<tr>
<td>(n=195 parents)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>163 (100%)</td>
<td>218 (100%)</td>
<td>144 (100%)</td>
</tr>
<tr>
<td>(N=452 parents)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Parents Children Parents Children Parents Children

Visited the Website

(n=195 parents) 72 (44.17%) 95 (43.58%) 56 (38.89%) 78 (39.80%) 67 (46.21%) 88 (45.36%)
All
(N=452 parents) 163 (100%) 218 (100%) 144 (100%) 196 (100%) 145 (100%) 194 (100%)

P = Parents; C = Children;

5. Were a priori power calculations conducted? Given the lack of statistical significance, the authors must be able to support statistical conclusion validity and show that their findings are not the result of an under powered design.

Thank you for your comment. We did not perform any a priori power analysis, as there were no data available to perform the calculations; only a posteriori analyses were performed. We included the following text in the statistical methods:

“At the time of the study, there were no data available regarding food consumption among children in Ticino, nor information about possible effects of a social marketing campaign similar to ours on food consumption in children. Further, as this was an intervention at the cantonal level and in real-life setting, we could not limit our sample, nor we could make the intervention mandatory to participants. Hence, we could not conduct a power analysis prior to the study, and we had to rely on the available sample size to conduct the analyses. The sample size was
assessed post-hoc based on the results of the study and an alpha value of 5% and a power of 80% were used.”

The results of the power calculations performed a posteriori are presented in the discussion: "However, a possible limitation is the sample size. Indeed, the power calculations suggested that a much bigger sample size was needed to detect meaningful differences in food consumption change between three groups (e.g. for fruit, N=2544 per intervention group would be needed; for soft drinks N=3244 per group). This would require sampling approximately one fourth of the entire child population aged 6-12 of the canton, which would require considerable financial and logistic resources".

6. The statistical models need to be described in greater detail. The MLMs in particular, need to be more clearly elaborated as these models convey the main findings of the study. How were pre-and post-program data used? Are these difference-in-difference models? Were the models adjusted by the inclusion of covariates?

Our study focused on the differences (between groups) in the differences (before-after) in food intake. So we agree it is a difference-in-difference model. We ran linear mixed models applied on longitudinal data (where measurement occasions are nested within individuals) with a main effect (time) that measures the effect of the intervention on the control group (i.e. the Web only group) and an interaction term (time*group) which indicates whether the effect of the intervention varied in the interventions groups (SMS and e-mail groups) compared to the control one.

We did not adjust for any covariate. In this kind of model individual unobserved heterogeneity is modeled in terms of variance components.

We added the following text to make it more clear: “The models included a main effect (time) that measures the effect of the intervention on the control group (i.e. the Web only group) and an interaction term (time*group) which indicates whether the effect of the intervention varied in the interventions groups (SMS and e-mail groups) compared to the control one.”
7. Lines 244 and 245 refers to 'generalized linear models estimating the effect of the intervention. The term 'generalized' usually refers to a logistic, ordinal logistic, or probit type of model (i.e., a generalization of the linear model). What exactly is being modeled and reported. It is not clear.

Generalized can be used for linear mixed models too (if you choose the identity function as the link function and the distributional family is Gaussian. In our case, we used the Stata “mixed” command that is explicitly written for this kind of model (Gaussian family and identity function) and it is a bit more efficient than the meglm command where you have to select family and link. (https://stats.stackexchange.com/questions/142965/difference-between-multilevel-glm-and-mixed-linear-models-when-the-family-is-gau). The primary outcome is the average daily frequency of consumption of each type of food.

8. Additional consideration should be given to table preparation so that they can function without the aid of the surrounding text. In particular, table titles are brief and not clear enough to give the reader an understanding of their content. I encourage the authors to consider the following suggestions. If these additions are made, I would be pleased to review the paper again.

We edited the tables to make them more clear.