Author's response to reviews

Title: Translational research: Are community-based child obesity treatment program scalable?

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Version: 3 Date: 4 June 2015

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Dr Mota
Journal Editorial Office
BioMed Central

Dear Dr Mota,

Thank you for the opportunity to revise our manuscript (MS: 2905182651645470 Translational research: Are community-based child obesity treatment programs scalable?) following peer review.

We have addressed each of the reviewer’s comments in the attached document, and changes in the manuscript are in yellow highlight.

We note the additional Editorial request for copyediting, which recommends that we copyedit the paper to improve the style of written English. Our apologies, but we are native English-speakers and have asked several colleagues to read the manuscript who commented that they felt the manuscript is clearly written. Where a reviewer has not understood a sentence we have revised the sentence to be clearer.

We would like to thank the reviewer’s for their considered comments, and feel that their suggestions have been most useful and contributed to the manuscript.

I look forward to your response.

Kind regards

Louise Hardy
- Comment 1

This study investigated the outcomes of translating a small successful efficacy child obesity treatment program (MEND) in the real world. The study is appropriate for this journal. The topic is relevant given the importance of translational research for progressing public health and translating evidence from efficacy trials into practice. However, my biggest concern involves the lack of a control group. A major limitation of uncontrolled trials is the absence of a randomly selected comparison group, making these trials unsuitable for fully evaluating the efficacy of a new treatment/intervention. Uncontrolled trials are intrinsically weak evaluative designs, as secular trends or sudden changes make it difficult to attribute observed changes to the intervention. There is also evidence to suggest that the results of uncontrolled before and after studies may overestimate the effects of interventions. The fact that the intervention have demonstrated efficacy through a previous randomized controlled trial (MEND) does not ensure the efficacy (internal validity) of the present study; the efficacy of one study depends on its own design... Therefore, the lack of a control group should be clearly added as a limitation of the study.

Author reply

We appreciate your comment. We would like to emphasise that Go4Fun is an example of implementation science and hence cannot be a traditional RCT. In terms of research, at some point it is imperative to move from RCT designs and translate the intervention through (uncontrolled) replication and scaling up. (see Nutbeam D, Bauman AE: Evaluation in a nutshell: a practical guide to the evaluation of health promotion programs, vol. 2nd. North Ryde: McGraw-Hill Australia Pty Ltd; 2006.)

For example, MEND has also been scaled up in the UK. Their research findings also indicate that MEND can be delivered by non-obesity specialists (see Smith LR, et al. Assessing the short-term outcomes of a community based intervention for overweight and obese children: The MEND 5-7 programme. BMJ Open 2013;3:e002607. doi:10.1136/bmjopen-2013-002607). The findings in these publications are also based on uncontrolled delivery of the program.

The primary purpose of our paper is also to evaluate the outcomes of the program in an uncontrolled, real world situation, in Australia.

The replication and scaling of interventions with demonstrated efficacy is critical to the public health response to the high prevalence of obesity, as current specialised treatment is not adequate to treat obese folk. In order to assist with the reading of the paper and context that the findings are not based on and RCT design we have changed the terms ‘pre-post to ‘before’ and ‘after’ program.

To this end, in order to ensure it is clear that the study is a pre-post design, the following sentence has been added to the Methods section (line 96);

A pre-post non-controlled design was used to report the outcomes of the Go4Fun program implemented between 2009 and 2012.

Comment 2: Methods, Outcome measures (first paragraph): Were outcomes measures (both first and last) measured by the same trained facilitator? Please clarify. Different facilitators measuring (pre and post) the same participants may introduce bias.

Author reply

Thank you and we agree this is an important point of clarification. We have checked and revised the text with the following (line 141);

One trained facilitator at each LDH collected outcome measures at the first and last session of the program.

Comment 3: Figure 1: Please check the unit/values in the abscissa axis (most of these BMI values are not possible/real). On the other hand, the caption states that figure 1 represents “BMI distribution curves of completers (attended ≥75% of sessions)”, whereas in the second paragraph of the Results section the authors write: “In Figure 1, the pre and post BMI distribution of all children attending #1 session...”. Please clarify or eliminate the figure.

Author reply

Thank you for pointing out this significant typographical error; we have now corrected the values on the x-axis. Similarly, we have corrected the text in the results to reflect that the distribution curves are based on children who attended 75% of the Go4Fun sessions. The amended text now reads; (line 238)

Figure 1 graphically shows the left shift in the BMI distribution curves of completers before and after participating in the program (p < .001).

Comment 4: The small differences in mean change values between Children attending #1 sessions and Children attending ≥75% sessions are unexpected to me (i.e. waist circumference, BMI z-score, WtHtr, etc.). Maybe the mean attendance rate in the attending #1 sessions children group was close to 75% (15 sessions)... Including this rate would help to understand the differences. Please give further explanation.

Author reply

Thank you. Following your comment we have revised the presentation of the results as we felt they were somewhat confusing.

We have included both mean number of sessions attended for all participants, and those attending ≥75% sessions and <75% of sessions in Table 1.

Table 2 now only presents the outcomes of all children who participated (which includes adjusting for the number of sessions attended).

Table 3 now presents the mean outcome changes for children attending <75%, mean change for attending ≥75% sessions, and the mean difference between those two groups.

We feel that this presentation of the findings is clearer.

MINOR ESSENTIAL REVISIONS

Comment 5: Abstract: a full stop is lacking in the conclusions (behaviours The findings).
Author reply

Thank you we have correct this typographical error.

---Comment 6 Introduction: a full stop is lacking at the end of the second paragraph.

Author reply

Thank you we have correct this typographical error.

---Comment 7 Methods, participants: please clarify ages, ¿7-13 or 6-15 yrs.? please check first paragraph in the Results section.

Author reply

Thank you. The eligibility age criterion was 7-13-years, however a small number of children age 6, 14 and 15 years participated. The following text has been added to the Methods section. (line 110)

Children were eligible for the program if they were aged 7-13 years, however a small number of children whose birthdays were close to the age criteria were included in the program (age 6.2-6.9 years n=70 and 14.0-14.8 years n=19).

---Comment 8: Methods, Outcome measures (second paragraph): please check if the reference [17] fits into the context.

Author reply

This reference is from the original MEND papers, but we agree that it is not in context here as the paper was about only the physical activity questions. To this end we have removed it from the text.

---Comment 9: Methods, Outcome measures (second paragraph): typo (trial).

Author reply

Thank you we have correct this typographical error.

---Comment 10: Results (second and third paragraphs): some values in the text are repeated in tables 2 and 3. Please consider choosing the best way to present the results.

Author reply

We have removed the repetition as suggested in the text, and replaced the text for Table 2 and 3 with the following statement: (lines 225-238)

Table 2 shows the mean changes and odds ratios in program outcomes, adjusting for covariates (n=2,650; mean attendance=13.3 sessions). Overall, the mean changes in program outcomes were statistically significant and in the desired direction (all p<.001), with the exception of understanding nutrition labels, which showed a 77% reduction in ‘always’ understanding nutrition labels after attending the program (OR 0.23; 95%CI 0.20, 0.26). Medium effects sizes (d=.20-.38) were observed for change before and after the program in self-esteem, screen time, physical activity daily vegetable intake, and a strong effect size for change in unhealthy food index (d=.41). Tables 3 and 4 show the mean change in program outcomes according to program attendance (i.e., non-completers v completers).
Compared with non-completers, greater beneficial changes were observed among children who completed the program for BMI, BMI z-score, unhealthy food index, and the frequency of consuming sugar sweetened beverages, lollies/chocolates, potato chips and takeaways. Figure 1 graphically shows the left shift in the BMI distribution curves of completers before and after participating in the program (p < .001).

-Comment 11: Discussion, fifth paragraph: typo (values).

Author reply
Thank you we have correct this typographical error

-Comment 12: Table 1: please check non-completers % girls value.

Author reply
Thank you we have correct this typographical error (51.4%)

-Comment 13: Table 1: please check significant p values [different values vs Results section, first paragraph].

Author reply
Again, thank you for identifying these typographical errors; we have corrected the p-values in the first paragraph Results section

-Comment 14: Table 2 caption: the authors write: “attending >1 (n=2,650) and 75% of session”. Please correct (#1 and #75%). Same change (#75%) along the results section.

Author reply
We have revised Table 2, including the title which now reads;

Table 2 Mean changes in program outcomes for all child participants (n=2,812) †

-Comment 15: Table 2: please correct the second heading of the table (Children attending #1 sessions seems to be incorrect).

Author reply
Thank you. This was a typographical error, however as mentioned above we have revised the presentation of the results in Table 2, which now reports only change for all participants.

-Comment 16: Table 2: please check Daily serves of fruit and vegetables p values [different values vs text in the Results section].

Author reply

Author reply Thank you we have revised the results as suggested in comment 10 above so that we are not repeating findings in the text that are presented in Tables.

-Comment 17: Table 3: a bracket is missing in the figure caption.

Author reply
Thank you we have correct this typographical error.
-Comment 18: All the references need to be worked according to the journal rules.

Author reply We have formatted the references according to BMC Public Health guidelines.
Reviewer's report; Reviewer: João Valente-dos-Santos

1. GENERAL COMMENT

This paper has the potential to be of interest to readers. This is another output from the Go4Fun® program; details have been previously published on BMC Public Health (2014, 14:140 doi:10.1186/1471-2458-14-140). The present paper seeks to report the outcomes of the program on children's weight and weight-related behaviours. This is an interesting question in an important population, thus the authors should be commended for their effort. However, I believe that this paper can be improved on some counts. I have mainly focused my feedback on Major Compulsory Revisions and occasionally in Minor Essential Revisions and Discretionary Revisions. That said these limitations should be easy for the authors to address.

Author reply Thank you. We have addressed your queries and feel that they have contributed to improving the manuscript.

2. MAJOR COMPULSORY REVISIONS

INTRODUCTION

2.1. Translational research includes “several” areas of translation. One of the most interesting, from where I stand, concerns research aimed at enhancing the adoption of best practices in the community. Therefore, cost-effectiveness of prevention and treatment strategies are definitively an important part of translational science. However, the first paragraph of the introduction section could be rewritten to make it more focused in the topic under discussion. Be concise without indulging on general reasoning around the impact of Australian national policies.

Author reply Thank you and we agree. We have revised the Introduction section, and removed the reference to Australian policies in the first paragraph as requested and the repetition in some of the other paragraphs. The closing paragraph now reads; (Line 80)

MEND is a UK community-based child obesity treatment intervention [8-11] designed to be scalable and delivered by a range of health professionals. The program has been translated into the Australian context as Go4Fun® and assessing its effectiveness is critical to the success of examining comprehensive population approaches to childhood obesity treatment and prevention. For policy makers, information on whether scaled-up interventions are viable across a variety of communities and circumstances is important to ensure best practices for the community are adopted. The process evaluation and details of the Go4Fun® program sessions have been published [12]. The aim of this paper is to report the programs' outcomes following scaling-up across New South Wales (NSW), Australia’s most populous state (pop: 7.2mil). We hypothesised that children’s weight and weight-related behaviours would improve in the desired direction and the strength of improvements would be stronger among children who participated in ≥75% of the programs sessions.

2.2. Second paragraph: External and internal validity are not independent types of validity. The second helps to ensure confidence in the casual linkage between the programs and the outputs. There is probably the need to highlight these questions taking into account that several constraints are faced in community-based obesity programs.
Author reply

Thank you, we have included the following text (and extra reference) on internal validity in the Introduction: (line 75)

In terms of community-based obesity treatment programs, the external validity (i.e., generalizability to other populations and settings) and internal validity (i.e., change attributed to the intervention alone and not to an alternative factor) have received less attention resulting in a major knowledge gap in our understanding of how such interventions may work in the real world[6-8].

2.3. Fourth paragraph: It would be informative if you stated your hypotheses.

Author reply

Thank you, we have added a hypothesis as requested in the last paragraph of the Introduction;

We hypothesised that children’s weight and weight-related behaviours would improve in the desired direction and the strength of improvements would be stronger among children who participated in ≥75% of the programs sessions.

METHODS

2.4. In the methods, under the topic “outcome measures”, in addition to “… July 2009 and October 2012”, let the readers know if the design was controlled for seasonal variation. For example, sedentary behaviour may range from higher levels in the Fall to lower values in the Spring. If seasonal variation was not controlled, the limitations should be assumed in the manuscript which continues a very valuable contribution.

Author reply

Thank you for this comment, we coded season according to program dates and have re-examined the data including season as a covariate as suggested. Please note that the program was run in New South Wales in Australia where there is less seasonal variation than in some European or North America countries.

2.5. How was stature, body mass and waist circumference assessed? I would be delighted to have some technical error of measurement on anthropometry. Meantime, the relevance of WHtR should be part of the introduction, not in the methods section.

Author reply

The facilitators were trained by MEND Australia, in measuring anthropometry, and anthropometry was directly measured (i.e., not self-reported). To this end, while the facilitators are trained to collect this information, MEND Australia does not have any information on inter- and intra-rater reliability assessments to ascertain any technical error of measurement. Their rationale is that Go4Fun is a community program, not a research study, and the primary aim of Go4Fun is to assist parents choose/navigate healthy lifestyle options.

To this end, we have added the following text in the Discussion, as requested. (line 296)

Similarly, the reliability of facilitators’ anthropometric measurements is not assessed so the level of measurement error is unknown.
We considered your suggestion to move the relevance of the WtHtr to the Introduction, but felt it did not fit nicely. To this end, we removed the relevance as suggested, but left the reference for the cut point.

2.6. The well-known variation in the tempo and timing of biological maturity for boys and girls of the same chronological age necessitates the use of an accurate measure of maturation in research involving children and adolescents. The biological maturity of the child will confound the results and has a large independent impact on adiposity, fitness and cardio-metabolic risk. I would argue that it is essential to control for these influences. You can include a measure of biological maturation, parallel to the anthropometric description of the sample (e.g., Moore et al., 2014). - Moore, S. A., et al., Med Sci Sports Exerc. 1014. doi: 10.1249/MSS.00000000000000588. Maturity-related effects should also be briefly mentioned in the discussion. If the authors cannot do this, then it needs to be acknowledge as a limitation. Maturity-related effects should also be briefly mentioned in the discussion.

Author reply

Thank you and we do agree that the assessment of pubertal status is an important element when assessing changes in weight and some weight-related behaviours. However, as you will be aware, in large community based programs it is not feasible, and in this case not ethically acceptable, to have program facilitators undertake pubertal assessment.

Thank you too for the Moore reference. We considered but decided against using their algorithm to calculate maturity onset. Our rationale was that the algorithm has not been extensively tested, especially among different ethnic groups (Australia is a multi-cultural country) and that the sample was not large enough to rigorously assess variation in prediction error due to early- and late-maturing children. Moore et al’s sample did not comprise overweight/obese children and, given the strong links between obesity and early onset of puberty, we felt that the algorithm was not suitable to apply to our sample.

Rather, we have added the following text to the Discussion as suggested. (ine 296)

Children’s pubertal status was not collected because of the invasiveness of such measures in a community-based program and may have confounded our results given maturation has a large independent impact on adiposity, fitness and cardio-metabolic risk.

2.7. I recommend that the authors provide a little more detail regarding the process of survey procedures and multilevel modelling. Although I am quite familiar with some of these statistical techniques, and believe that the authors have used this technique appropriately, I think that those unfamiliar with these methods would struggle to understand or replicate the analytical process. For example, when you account for the clustered design of the program in the multilevel models, they accommodate within-individual variance \( \text{var}(\sigma_{ij}) \) for the \( i \)th assessment in the \( j \)th individual; the between-individuals intercept variance \( \text{var}(\mu_j) \); and, also the between-individuals slope variance \( \text{var}(\beta_{ij}) \). So, in multilevel modelling each individual has their own trajectory, with intercepts and slope coefficients varying between individuals. Therefore, we controlled for independent inter-group effects while simultaneously controlling for the effects of age, sex, area level of socio-economic disadvantage, area level of remoteness, and the number of sessions attended, within each individual. If this was the way, or not, please clearly state that.

Author reply
We have provided more detail on the process of survey procedures and multilevel modelling as requested. The change in the analysis section is as follows:

For continuous variables mixed models were used to estimate the mean values and 95% confidence intervals (CIs) at each time point (before and after the program) controlling for age, sex, season, area level of socio-economic disadvantage (SEIFA, quintiles), area level of remoteness (ARIA+), and the number of sessions attended. Participant was modelled as a random factor to account for the paired before and after values on the same participant. Programme ID was also modelled as a random factor to account for the cluster design of the study. The mean change in outcome between before program attendance and after the program was assessed using a linear mixed model with change as the dependent variable and controlling for baseline as well as the factors above but with only Programme ID as a random factor.

2.8. Multilevel model technique allows the number of observations and temporal spacing between measurements to vary among subjects, thus using all available data. It is assumed that the probability of data being missing is independent of any of the random variables in the model. As long as a full information estimation procedure is used, such as maximum likelihood for normal data, the actual missing mechanism can be ignored. Was maximum likelihood estimation used for the models? For discrete response multilevel models, maximum likelihood estimation is computationally intensive, and therefore quasi-likelihood methods were implemented in several statistical packages. If so please clearly state that.

Author reply

The continuous models were run using proc mixed in SAS which uses residual maximum likelihood estimation. Proc glimmix was used for the generalised linear mixed model analysis which uses residual pseudo-likelihood. Text has been added to the manuscript to describe the estimation methods used.

2.9. How did you checked for heteroscedasticity? Heteroscedasticity can result in biased parameter estimates and standard error estimates that are either too large or too small. Consequently, heteroscedasticity can increase Type I-error (be overly optimistic about parameters being statistically different from zero) or increase Type II-error (be overly pessimistic about parameters being statistically different from zero). One approach to detecting violations of homoscedasticity is to examine plots of residuals versus predicted values for evidence that residuals increase as a function of the predicted value. However, heteroscedasticity can also be a result of a violation of the linearity or normality assumptions, and it may also be remedied by addressing those violations.

Author reply

Thank you, this is a very good point. We did examine the plots of the residuals from both the multilevel models and univariate approaches where we examined the relationships between each outcome and factor independently and were satisfied we could run the models.

RESULTS
2.10 The authors make a point, in Figure 1, that pre and post BMI distribution of all children attending #1 session shows a slight left shift in the distribution curves following participation in the program. The authors should make a clearer case as to whether or not the left shift is or not statistical significant.

Author reply

We have re-done the Figure so that it is now based on the BMI distribution curves of completers (attended ≥75% of sessions) at baseline and program completion (n=1,486), and the following text has been added to the Results

Figure 1 graphically shows the left shift in the BMI distribution curves of completers before and after participating in the program (p <.001).

2.11. Table 1, 2 and 3: Reporting only the P-values for an analysis is not adequate for readers to fully understand the results. Magnitude-based inference is far superior to the traditional approach of null-hypothesis significance testing. This approach allows for conclusions about sample-based effects (e.g., Batterham & Hopkins, 2006; Hopkins et al., 2009). - Batterham, A.M. & Hopkins, W. G. (2006). Int J Sports Physiol Perform. 1:50-57. 2006. - Hopkins, W.G., et al.. Med Sci Sports Exerc. 41:3–12, 2009. I am fully aware of the criticism of Welsh and Knight (2015) to the use of magnitude-based Inferences, but I am also aware of the mistakes of that statistical review. - Welsh, A. H., & Knight, E. J. Med Sci Sports Exerc, 47(4): 874-884. 2015. However, if the authors do not believe that magnitude-based inference can be specifically valuable in follow-up studies as it is a less conservative method, there are other alternatives. Instead of magnitude-based inference you can chose to report (partial) eta-squared statistics as a measure of effect-size, along with the traditional statistical significance and P-values. By doing so, you will provide a measure of effect-magnitude, but still within the traditional statistical framework. Moreover, you can do the square root of eta-squared and interpret it as a correlation. Something like: The effect size correlations (ES-r) were estimated using the square root of the ratio of the F-value squared and the difference between the F-value squared and degrees of freedom (Rosnow and Rosenthal, 1996). Coefficients were interpreted as follows: trivial (r < 0.1), small (0.1 < r < 0.3) moderate (0.3 < r < 0.5), large (0.5 < r < 0.7), very large (0.7 > r > 0.9), nearly perfect (r > 0.9 and perfect (r = 1) (Hopkins et al., 2009). - Hopkins W G , Marshall S W , Batterham A M , Hanin J . Med Sci Sport Exer 2009 ; 41 : 3 – 13 - Rosnow R L , Rosenthal R. Psychol Meth 1996 ; 1 : 331 – 340

Author reply

Thank you, we have calculated and inserted Cohen’s Ds into the Tables for continuous variables, as requested. The following text has been included in the analysis section:

Effect sizes were determined using Cohen’s d [17] and calculated using mean differences and standard errors from the mixed model where 0-0.2 is small, 0.2-0.4 is medium and 0.4+ is a large effect size.

In the results section:

Medium effects sizes (d’ = .20-.38) were observed for change before and after the program in self-esteem, screen time, physical activity daily vegetable intake, and a strong effect size for change in unhealthy food index (d=.41).
**DISCUSSION**

2.12. The discussion section, in general, is good and provides straightforward and transparent account of the findings of this study. A considerable effort to link the results of the currently study in relation to existing literature was performed. My recommendation would be that the authors spend a little more time discussing the potential practical implications of this research.

**Author reply**

Thank you for your comment. We have re-worked the Discussion as requested to include discussion on the potential practical implications of the findings. In particular, having undertaken the analysis for completer v non-completer, we have included the following paragraph in the discussion section; (line 265)

> We examined outcome differences between completers and non-completers to inform policy decisions on the program’s delivery. Greater beneficial changes in BMI and diet behaviours were observed among children who completed the program compared with children who did not complete the program. Although children who completed the program did not consistently demonstrate better outcomes on all weight-related behaviours, the fact that children who completed the program had a significantly higher probability of decreasing their intake of ‘extra’ foods (i.e., junk food) is highly relevant given the evidence shows that Australian children over-consume such food[23, 24]. Other research shows that parents believe that as long as children also eat ‘healthy’ foods then the frequent consumption of extra foods is acceptable [25]. Given the majority of Go4Fun sessions focused on diet (13/20), and completers attended almost 10 more sessions than non-completers this potentially indicates that improvements in food literacy require maximal program exposure in order for poor dietary behaviours to change.

3. **MINOR ESSENTIAL REVISIONS**

**INTRODUCTION**

3.1. NSW (i.e., New South Wales) - Not previously defined.

**Author reply**

Thank you we have spelt out the NSW acronym

3.2. At the end of the second paragraph “in the real world” – correct to “in the real world.”

**Author reply**

Thank you we have added a full stop at the end of the sentence.

**METHODS**

3.3. “Outcome measures” subheading is repeated twice under the methods section.

**Author reply**

Thank you we have deleted the first occurrence.
RESULTS

3.4. I would present the median number of participants per program, who completed the program, etc. and not the average.

Author reply

We have replaced the means with the median number of participants as suggested.

3.5. Table 1 is easy to follow but you do not explain what the "***" stands for.

Author reply

We have added the missing asterisk to the bottom of Table 1 so that it now reads;

*P-value difference between completers and non-completers;

DISCUSSION

3.6. Fourth paragraph: I am not a native English speaker but I found this sentence somewhat confusing: “This may reflect the current status of the range of different nutrition labels suggest that policy makers need to ensure nutrition labels are understandable by community members”.

Author reply

We have re-worded the sentence as follows to help non-English speakers’ readability as follows: (line 260)

This may reflect the current confusing status in Australia of different nutrition labelling formats (e.g., %RDIs, star rating, Pick the Ticks, traffic lights etc)[21] on food products and suggests that policy makers need to ensure nutrition labels are understandable by community members[22].

Conclusions

3.7. In this section the authors should address more possible take home message/s and avoid replicating statements already stated in other parts of the paper.

Author reply

Thank you and we agree the conclusion was repetitious. To this end we have redone the Conclusion as follows; (line 326)

Go4Fun® programs demonstrated small but beneficial changes in overweight and obese children’s weight and weight-related behaviours in the short-term. Completing the program was associated with greater improvements in diet, but not other weight-related behaviours. An important funding policy decision is to examine the current program format to determine the optimal number of sessions required to achieve desired outcomes. The outcomes provide promise that community-based child obesity treatment programs are an adjunctive intervention to tertiary obesity health service, but long term follow up is necessary. Go4Fun is a service delivery program, however strategies to minimise missing data would assist ongoing evaluation process.
REFERENCE LIST

3.8. Check the guidelines for the reference style. There are several inconsistencies.

**Author reply** We have formatted the references according to BMC Public Health guidelines.

4. DISCRETIONARY REVISIONS

4.1. **Keywords:** for indexing purposes, repeating a word used in the title (i.e., translational research) does not seams a robust approach.

**Author reply**

We have changed the keywords so that there is no repeating words from our title. The new key words are Community Health Services, behaviour change, public health