

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Family-based behavioural intervention program for obese children: a feasibility study
AUTHORS	Marie Teder, Evalotte Mörelius, Per Bolme, Maria Nordwall, Joakim Ekberg and Toomas Timpka

VERSION 1 - REVIEW

REVIEWER	Melanie Henderson McGill University Department of Epidemiology, Biostatistics and Occupational Health Montreal, Qc CANADA No conflict of interest to declare.
REVIEW RETURNED	07/09/2011

THE STUDY	While I appreciate the tremendous efforts put forth by the authors in this project, I have several concerns. Firstly, the study design was sub-optimal: the appropriate design to evaluate the efficacy of an intervention is a randomized controlled trial. This study may serve as a feasibility study, in order to pursue with the full fledged RCT, but doesn't really answer whether the intervention was effective thoroughly. In this regard, as there was no randomization and no control group, one cannot refer to "intention to treat" analysis. In the methods section, the actual assays used to measure glucose, insulin and lipids need to be described. The authors refer to the oral glucose tolerance test being "calculated according to the WHO" - this is meaningless. What did they calculate? From the OGTT, one can obtain fasting measures of insulin and glucose, 2hr-post load measures, as well as measures of insulin sensitivity or beta-cell function. Also, the data can be used to categorize individuals as normal glucose tolerant, IGT or IFG, etc. The authors need to clarify how they used the data from the OGTT, as well as the methodology of the OGTT.
RESULTS & CONCLUSIONS	Need to state which growth curves used for calculation of BMI Z-score (eg. WHO). There were 26 families that participated, with 1 family dropping out. However, in the results table, at the 36 month follow-up, there are only 23 families. The authors need to discuss the 3 families not included, as loss to follow-up is an important selection bias in observational studies. In some instances, the results of the study are somewhat over-stated. Again, this is much more of a feasibility study - While the authors do acknowledge that the results may not be attributable to the intervention per se, the discussion of the results needs to reflect this more. The small sample size must be discussed in the limitations section and ITT removed from the strengths section. Finally, it may be interesting to discuss measures of physical activity or diet, if available. To provide the reader with proof that these

	measures actually did change following the intervention would provide further strength to the study conclusions.
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REVIEWER	Marja Kalavainen Clinical Dietitian Department of Pediatrics Kuopio University Hospital Finland No conflict of interests
REVIEW RETURNED	05/10/2011

THE STUDY	<p>Minor comments</p> <p>It would be useful to have a table describing the participants. The children kept the diary of their habits. Did they keep the diary every day or occasionally? How did the youngest children (8 years) manage to keep the diary? If everything was confidential in children's groups, how did the parents get informations about changes in children's habits?</p> <p>When was the intervention performed?</p> <p>The English language should be revised (e.g. some separate words have been compounded, and some clumsy expressions). The size of the fonts was not uniform. In results section, the first sentence should be rewritten. It was also unclear whether cholesterol (p less than 0.01) referred to total cholesterol.</p> <p>Major comments</p> <p>Detailed description of the measurements of weight, height and waist circumference should be included in the text.</p> <p>How was z-BMI calculated, e.g. was the LMS method used and was it calculated by a calculator or manually?</p> <p>What kind of t-test was used? Were the variables tested for normality?</p> <p>One of the drawbacks was that the participants pubertal status was lacking. The pubertal status has a major impact on the lipid and insulin levels, which should be included in the limitations of the study.</p> <p>Reinehr et al. 2007, Reinehr et al. 2010 and Kalavainen et al. 2011 should be included in the references and discussed.</p>
RESULTS & CONCLUSIONS	<p>My main concerns about the credibility are the measurements of height, weight and waist circumference, the calculations of z-BMI and the statistical methods. They should be described in more detail in order to allow the the reliable assessment of of the methods. In addition, the authors write in the discussion section that the reason for increased glucose values at 12 months follow-up was that the children reached pubertal age. However, as the children were at baseline 8-11.9 years old, many of them can have been pubertal already at the beginning of the intervention. The impact of puberty on children's metabolism should be discussed.</p> <p>The authors conclude that their findings "are better than other studies". However, their have not includes in the discussion the studies by Reinehr et al. Furthermore, in the Finnish study (Kalavainen et al. 2011), the decrease in z-BMI was as high as 0.3 in the control group when assessed three years from the beginning of the intervention. In addition, the comparisons of the results between obesity treatment studies must be done very cautiously because of different study designs, outcome measures and the length of follow-up.</p>
GENERAL COMMENTS	The objective of the study is very important and the setting very

	interesting. If the authors will perform a RCS, the costs of the treatment should be included. In addition, a longer follow-up than one year is needed.
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VERSION 1 – AUTHOR RESPONSE

Summary of Changes Made to the manuscript

“Assessment of a Family-based Behavioural Intervention Program for obese children”

We thank the reviewers for their thorough and thoughtful comments and suggestions. We have endeavored to use them to strengthen the manuscript.

Reviewer 1= BMJ Open Editorial Office, Reviewer 2 = Editor-in-chief

Reviewer 3 = Melanie Henderson, Reviewer 4 = Marja Kalavainen

	Reviewer #3	
Rev #3 a	While I appreciate the tremendous efforts put forth by the authors in this project, I have several concerns. Firstly, the study design was sub-optimal: the appropriate design to evaluate the efficacy of an intervention is a randomized controlled trial.	We agree that the appropriate design to evaluate the efficacy of an intervention is a RCT but this study is rather a pilot study.
Rev #3 b	This study may serve as a feasibility study, in order to pursue with the full fledged RCT, but doesn't really answer whether the intervention was effective thoroughly. In this regard, as there was no randomization and no control group, one cannot refer to "intention to treat" analysis.	The manuscript has been changed according to the comment. We have removed from the text that this is an "intention to treat" analysis.
Rev #3 c	In the methods section, the actual assays used to measure glucose, insulin and lipids need to be described.	The required information has been added to the manuscript. Page 10-11, lines 188-192.
Rev #3 d	The authors refer to the oral glucose tolerance test being "calculated according to the WHO" - this is meaningless. What did they calculate? From the OGTT, one can obtain fasting measures of insulin and glucose, 2hr-post load measures, as well as measures of insulin sensitivity or beta-cell function. Also, the data can be used to categorize individuals as normal glucose tolerant, IGT or IFG, etc. The authors need to clarify how they used the data from the OGTT, as well as the methodology of the OGTT.	We have removed that the oral glucose tolerance test was performed according to the WHO guidelines. Page 10, line 188. We have clarified the OGTT in the data collection part of the manuscript on page 10, line 187.

Rev #3 e	Need to state which growth curves used for calculation of BMI Z-score (eg. WHO).	The z-BMI was calculated using the Swedish growth chart and Box transformation formula indicated by Karlberg et al 2001. This reference has been added on page 10, line 180.
Rev #3 f	There were 26 families that participated, with 1 family dropping out. However, in the results table, at the 36 month follow-up, there are only 23 families. The authors need to discuss the 3 families not included, as loss to follow-up is an important selection bias in observational studies.	The examinations drop-out is now explained in the results on page 11, line 208 and in the discussion part on page 14, line 264.
Rev #3 g	In some instances, the results of the study are somewhat over-stated. Again, this is much more of a feasibility study. While the authors do acknowledge that the results may not be attributable to the intervention per se, the discussion of the results needs to reflect this more.	The comments that the intervention was effective are removed. We have the same opinion; it is a good choice to use the term feasibility study. We have extended the discussion about this topic on page 15, line 289.
Rev #3 h	The small sample size must be discussed in the limitations section and ITT removed from the strengths section.	The sample size is now discussed as a limitation of the study on page 13, line 236. The mentioning of ITT has been removed from the manuscript.
Rev #3 i	Finally, it may be interesting to discuss measures of physical activity or diet, if available. To provide the reader with proof that these measures actually did change following the intervention would provide further strength to the study conclusions.	We regret that we have not measured physical activity, for example with a pedometer. Neither have we measured dietary habits.
	Reviewer #4	
	Minor comments	
Rev #4 a	It would be useful to have a table describing the participants.	A table describing the participants is added, table 1.
Rev #4 b	The children kept the diary of their habits. Did they keep the diary every day or occasionally? How did the youngest children (8 years) manage to keep the diary?	The use of the diary is now explained in more detail on page 9 line 149.
Rev #4 c	If everything was confidential in children's groups, how did the parents get information about changes in children's habits?	The children were reassured that everything that was said was confidential within the child and the parental group. This clarifying sentence is on page 9, line 163 in the manuscript.

Rev #4 d	When was the intervention performed?	The intervention was performed between 2004 -2006. These data are now included in the manuscript under the title "The family-based behavioural intervention program" on page 8, line 132.
Rev #4 e	The English language should be revised (e.g. some separate words have been compounded, and some clumsy expressions).	The English language has been revised again.
Rev #4 f	The size of the fonts was not uniform.	The fonts have been corrected.
Rev #4 g	In results section, the first sentence should be rewritten.	In the first results section we have removed the word "significantly" in the sentence. The first sentence under the title "Clinical outcomes" is now "The primary outcome measure, the mean z-BMI, was reduced from 3.3 (SD 0.7) at baseline to 2.9 (SD 0.7) ($p < 0.001$) at the end point (12 months after completion of the program)". Page 12, line 217.
Rev #4 h	It was also unclear whether cholesterol (p less than 0.01) referred to total cholesterol.	We have added total cholesterol in the text under the title "Data collection" on page 11, line 190 "Results and Clinical outcomes" and on page 13, line 224.
	Major comments	
Rev #4 a	Detailed description of the measurements of weight, height and waist circumference should be included in the text. How was z-BMI calculated, e.g. was the LMS method used and was it calculated by a calculator or manually?	The description of the measurements of weight, height and waist circumference is clarified on page 10, line 176 and on page 10, line 180. A more detailed description is included. The z-BMI is calculated using the Swedish growth chart and Box transformation formula indicated by Karlberg et al. 2001. This reference has been added on page 10, line 180.
Rev #4 b	What kind of t-test was used? Were the variables tested for normality?	The text under "Statistical analysis" is clarified on page 11, line 197.
Rev #4 c	One of the drawbacks was that the participants pubertal status was lacking. The pubertal status has a major impact on the lipid and insulin levels, which should be included in the limitations of the study.	Regrettably, puberty signs were not consistently investigated in this study. This fact is added and discussed at page 14, line 250.
Rev #4 d	Reinehr et al. 2007, Reinehr et al. 2010 and	Citation of Reinehr et al. 2007 on page

	Kalavainen et al. 2011 should be included in the references and discussed.	15, line 286. Citations of Reinehr et al. 2010 on page 5, line 83 and Kalavainen et al. 2011 page 14, line 264 have been added to the discussion.
Rev #4 e	My main concerns about the credibility are the measurements of height, weight and waist circumference, the calculations of z-BMI and the statistical methods. They should be described in more detail in order to allow the reliable assessment of the methods.	The credibility of to the measurements and the statistical methods are clarified under the title "Data collection" on page 10, and in the discussion on page 14, line 266.
Rev #4 f	In addition, the authors write in the discussion section that the reason for increased glucose values at 12 months follow-up was that the children reached pubertal age. However, as the children were at baseline 8-11.9 years old, many of them can have been pubertal already at the beginning of the intervention. The impact of puberty on children`s metabolism should be discussed.	The pubertal status of the children is discussed on page 14 line 248.
Rev #4 g	The authors conclude that their findings "are better than other studies". However, their have not includes in the discussion the studies by Reinehr et al.	The sentence "Our findings are better than other studies" is removed. Reinehr et al. 2007 is now discussed on page 15, line 286.
Rev #4 h	Furthermore, in the Finnish study (Kalavainen et al. 2011), the decrease in z-BMI was as high as 0.3 in the control group when assessed three years from the beginning of the intervention. In addition, the comparisons of the results between obesity treatment studies must be done very cautiously because of different study designs, outcome measures and the length of follow-up.	Kalavainen et al. 2011 is now discussed in the manuscript on page 14, line 264.

VERSION 2 – REVIEW

REVIEWER	Melanie Henderson, MD, FRCPC, MSc McGill University Department of Epidemiology, Biostatistics and Occupational Health Montreal, Quebec, Canada
	No conflicts of interest to disclose
REVIEW RETURNED	25/01/2012

THE STUDY	<p>Minor points: I would make the following suggestions for ease of reading:</p> <p>Line 112: "change physical activities" to physical activity</p> <p>Line 136: same comment</p> <p>Line 157: same comment</p> <p>Line 168: idem</p> <p>Line 140: change "individual talks" to "individual discussion sessions"</p> <p>Line 141: change the end of the line to "how to maintain them"</p> <p>Line 151: I am not sure what is meant by "then 1 week before each session".</p> <p>Line 196: I would change "based on that..." to "Given that variables were normally distributed, paired 2-tailed..."</p> <p>Line 240: replace "may have" with "might have"</p> <p>Line 271: "weight reduction" rather than "weight reductions"</p> <p>Line 294: "with evaluation of the long term outcomes" - I would propose to be more specific, for example with "evaluation of long term outcomes such as BMI and metabolic parameters"</p>
RESULTS & CONCLUSIONS	<p>Lines 208 to 210: It might be easier to add a footnote to Table 2, explaining the discrepancies in numbers from one column to the next.</p> <p>Table 2: it would be good to put reference values in square brackets [] and units in round brackets ()</p>
GENERAL COMMENTS	<p>Modifications made to the manuscript were nicely done. I would have liked to see the responses to the reviewers - were they submitted? In any case, I think this will be an interesting addition to current research.</p>

VERSION 2 – AUTHOR RESPONSE

Reviewer: Melanie Henderson, MD, FRCPC, MSc
 McGill University
 Department of Epidemiology, Biostatistics and Occupational Health
 Montreal, Quebec, Canada

Minor points: I would make the following suggestions for ease of reading:

Line 112: "change physical activities" to physical activity

Authors' reply: Thank you, the suggested change has been implemented in the manuscript.

Line 136: same comment

Authors' reply: The suggested change has been implemented in the manuscript.

Line 157: same comment

Authors' reply: The suggested change has been implemented in the manuscript.

Line 168: idem

Authors' reply: The suggested change has been implemented in the manuscript.

Line 140: change "individual talks" to "individual discussion sessions"

Authors' reply: The suggested change has been implemented in the manuscript.

Line 141: change the end of the line to "how to maintain them"

Authors' reply: The suggested change has been implemented in the manuscript.

Line 151: I am not sure what is meant by "then 1 week before each session".

Authors' reply: Thank you, we have clarified this sentence to "During the first 3 months they were encouraged to write in the diary every day, and thereafter once 1 week before each session".

Line 196: I would change "based on that..." to "Given that variables were normally distributed, paired 2-tailed..."

Authors' reply: The suggested change has been implemented in the manuscript.

Line 240: replace "may have" with "might have"

Authors' reply: The suggested change has been implemented in the manuscript.

Line 271: "weight reduction" rather than "weight reductions"

Authors' reply: The suggested change has been implemented in the manuscript.

Line 294: "with evaluation of the long term outcomes" - I would propose to be more specific, for example with "evaluation of long term outcomes such as BMI and metabolic parameters"

Authors' reply: The suggested change has been implemented in the manuscript.

Lines 208 to 210: It might be easier to add a footnote to Table 2, explaining the discrepancies in numbers from one column to the next.

Authors' reply: The suggested change has been implemented in the manuscript.

Table 2: it would be good to put reference values in square brackets [] and units in round brackets ()

Authors' reply: The suggested change has been implemented in the manuscript.