Viewpoint

Title: Prevention of childhood obesity - What type of evidence should we consider relevant?

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Abstract

Introduction. Two reviews, one by Summerbell et al and the other by Doak et al came to very different conclusions about the effectiveness of childhood obesity interventions. The aim of this commentary is to assess the extent to which inclusion and exclusion criteria, and definition of effective outcomes, explains discrepant results. **Methods:** Differences in results were compared by inclusion criteria and outcome definitions. The most important summary recommendations for inclusion/exclusion criteria were to exclude all non-peer review articles; to maintain a six month lower limit for duration of study; to include interventions from before 1990; to include pre-school age groups; to include pilot studies and to intervene in high risk communities. Authors did not reach consensus regarding inclusion of aims not specific to preventing weight gain and the manner of assessment of anthropometric measures. **Results:** Combining both reviews and applying agreed exclusion criteria leaves 30 interventions, 50% are positive. Excluding studies without an aim specific to preventing weight gain leaves 10/24 (42%) positive interventions. **Conclusion:** The differences in the results of these two reviews relates to the inclusion criteria and outcome assessments. These findings underscore the importance of the evidence considered in assessing interventions.

Introduction

The increasing prevalence of childhood obesity is continuing in most parts of the world (1), and the search for effective intervention strategies to curb this epidemic is urgent. Recent evidence that the epidemic is easing off in Swedish children suggests that it is possible to manage the problem (2). However, other countries such as Denmark show no leveling at all (3).

In recent years, several published literature reviews have considered whether obesity prevention programs in children are effective (e.g. 4-7) Two of these reviews, one by Summerbell et al (5) and the other by Doak et al (6) came to very different conclusions about the effectiveness of childhood obesity interventions. Summerbell et al (5) follows the Cochrane reviews method, a gold standard in systematic reviews. Doak et al (6) had a similar aim and was published only a year after the Summerbell et al (5) review. The Summerbell *et al*. (5) review included 22 studies with 4 (18%) categorized as effective. Doak *et al*. (6) included 24 studies with 17 categorized as effective (71%). Whereas the reviews share similar aims, only 10 of the studies included appeared in both reviews.

Initial inspection of the literature from both studies indicated differences in inclusion criteria and outcome definitions that may be summarized as: 1) non-peer review articles; 2) lower limits for duration of study; 3) choice of start date of search; 4) inclusion of pre-school age groups; 5) inclusion of aims not specific to preventing weight gain; 6) inclusion of pilot studies; 7) inclusion of studies targeting high risk children; 8) outcome by anthropometric measures not reported within the article and finally, 9) a major difference in what was accepted as an effective outcome.

We would also like to point out that here were differences in funding of the two reviews. The cost of updating of the Summerbell et al (5) review was provided in kind by the authors and their institutions, along with a small amount of funding from WHO. The Doak et al (6) review was funded by the Weight Management in Public Health Task Force of the European Branch of the International Life Sciences Institute (ILSI Europe) with food industry members on the task force. However, the task force had no influence on the selection of articles or interpretation of evidence.

The aim of the present commentary is to assess the extent to which key differences in inclusion and exclusion criteria, and definition of effective outcomes, can explain discrepant results. Furthermore, analysis of these differences will be used to identify a general set of inclusion and exclusion criteria that may contribute to the understanding of child overweight and obesity prevention programs. Using a single set of inclusion/exclusion criteria the interventions will be combined and the results compared to the initial studies. It is worth highlighting at this stage, that for many studies included in the two reviews, information needed for the review process was not reported in the published papers. Discrepancies in reporting of results by interventions studies contributed

to inconsistencies in the assessment of outcomes. The authors of both reviews have identified reporting as a key barrier. This issue highlights the need for journals to require standardized and comprehensive reporting criteria.

Differential inclusion and exclusion criteria

The two reviews included a total of 36 studies, with only 10 held in common. Fourteen of the studies included by Doak *et al*. (6) did not meet the inclusion criteria of the Summerbell *et al*. (5) review. Likewise, 12 studies included by Summerbell *et al*. (5) did not meet the inclusion criteria of the Doak *et al*. (6) review. These differences can be explained by the following eight differences in inclusion/exclusion criteria. For each of these 8 criteria, the first author from both reviews justifies their initial choices and a summary statement of the authors' decision is made with a conclusion based on majority opinion. The **authors' decision** is a summary statement, reflecting majority opinion of the four authors, and provides a general recommendation for future review writers. Furthermore, the **authors' decision** statement will also be the basis for the criteria for combining the results of the two reviews in our results section. Underlying the decisions about the inclusion criteria to apply are questions relating to the quality of the study design, power, sources of bias, and appropriateness of the comparisons for statistical analysis.

1. Inclusion of non-peer review articles: The Doak *et al*. (6) review included studies that were published and accessible, but did not specify that they had to be peer reviewed. The allowance of non-peer reviewed articles was made to consider the contribution of interventions that may have been published as book chapters or in another format. Only one study was included in the Doak *et al*. (6) review that was not peer reviewed, it was found to be effective. **Authors' decision:** inclusion of studies that are not published in a peer-reviewed journal introduces potential bias, as illustrated by the fact that the only intervention included on this basis was effective. Such studies should not be included.

2. Lower limits for duration of study: Both reviews divided studies into short and long term but only the Summerbell *et al*. (5) review specified a lower limit of 12 weeks and citing concerns about bias and weaknesses related to short term behavior change data. Two short-term studies of a duration of only 8 weeks were included in the Doak *et al*. (6) review – both were found to be effective. Assuming such very short term studies are more likely to be effective, they introduce a bias towards more effective results. However, these very short term studies do not contribute towards intervention models that are sustainable in the long run. Indeed, even 12 weeks may be too short. **Authors' decision:** It is concluded that the minimum duration of interventions should be set to at least 6 months.

3. Choice of start date for inclusion of studies. Studies published before 1990 were excluded from the Summerbell *et al*. (5) review. The rationale for this exclusion is that the environment and context in which interventions are carried out have changed. Interventions from before 1990 may or may not, be helpful to creating broad based public health interventions for today's environment. In contrast, the review by Doak *et al*. (6) had no exclusion by start date and included five studies from before 1990, 3 were found to be effective. The contribution of these interventions would be excluded. **Authors' decision:** It is concluded that pre-1990 publications may be included

4. Inclusion of pre-school age group: Interventions targeting children below the age of six were not included in the Doak *et al*. (6) review as, in some countries, children attending pre-schools are a select group, and because references used for determining overweight/obesity are not comparable to the older age group. Summerbell *et al*. (5) included 3 interventions targeting pre-school children, 1 was found to be effective. The exclusion of pre-school children may not be justified. While in a few countries, pre-school attendance may be a select group preschool attendance is increasingly widespread and in some countries even universal. As the obesity epidemic advances, school based interventions may need to target children at younger ages. **Authors' decision:** Pre-school studies can be included provided BMI-for-age is used.

5. Inclusion of aims not specific to preventing weight gain: Summerbell *et al*. (5) did not include studies if the stated aim was other than preventing weight gain. Allowing for a more liberal inclusion criteria based on aim raises difficult questions about which interventions should be included, such as interventions focused on bone density or dental health, which are not likely to relate directly to obesity. Furthermore, strength training interventions are more likely to result in (muscle) weight gain compared to controls, raising challenging issues with the BMI outcome measures. Doak *et al*. (6) included a number of interventions such as those with an aim to increase physical activity or to reduce cardio-vascular disease, as these were found to be indistinguishable from the interventions aimed to prevent obesity. The components of these interventions would not be different had overweight/obesity prevention been listed amongst the aims. Six such interventions were included in the Doak *et al*. (6) , 4 were found to be effective. **Authors' decision:** The inclusion of interventions that focus on improving obesity related behaviors is justified provided that overweight/obesity was an aim or sub-aim. However, whether interventions, that do not include overweight/obesity as an explicit aim sub-aim, should be included, is still debatable. On the one hand, the collection of adiposity data can be taken to imply a sub aim of obesity prevention. On the other hand, only studies with positive findings for these not-specified outcomes of obesity will be reported, and hence will likely introduce publication bias - in support of this of the 6 studies presented in the commentary that had different outcomes than obesity 5 were positive. However, it is likely that many more interventions will exist that would

not have reported because a non-significant result for obesity was obtained.

6. Inclusion of pilot studies: Results from pilot studies were included in the Summerbell *et al*. (5) review. The Doak *et al*. (6) review excludes pilot studies because pilot studies lack the power to show effective results. Thus inclusion of these studies may bias the conclusion towards a finding that interventions are not effective. The Summerbell *et al*. (5) review chose to include pilot studies because power calculations are generally rarely presented up front in studies. Excluding pilot studies based on the lack of power would also require similar considerations to be made because other studies may be under-powered as well. In total 6 studies were classified as pilot studies, none were found to be effective. **Authors' decision**: Pilot studies can be included provided they are peer-reviewed.

7. Inclusion of preventions targeting high risk children: Interventions targeting high risk children, such as the children from high-risk communities, were not included in the Doak *et al*. (6) review as the focus was on primary prevention that could be implemented on a large scale eg. community. Two studies were included in the Summerbell *et al*. (5) review that were targeted interventions focusing on children from high risk communities, neither was found to be effective. **Authors' decision:** The exclusion of studies on obesity prevention programmes from communities at risk may not be justified as extra attention may be necessary to prevent obesity in high risk groups, particularly as the obesity epidemic is most evident in low income communities. Thus, interventions targeting high-risk communities should be included in future reviews whereas interventions targeting high-risk *individuals*, such as children of obese families, may be considered excluded.

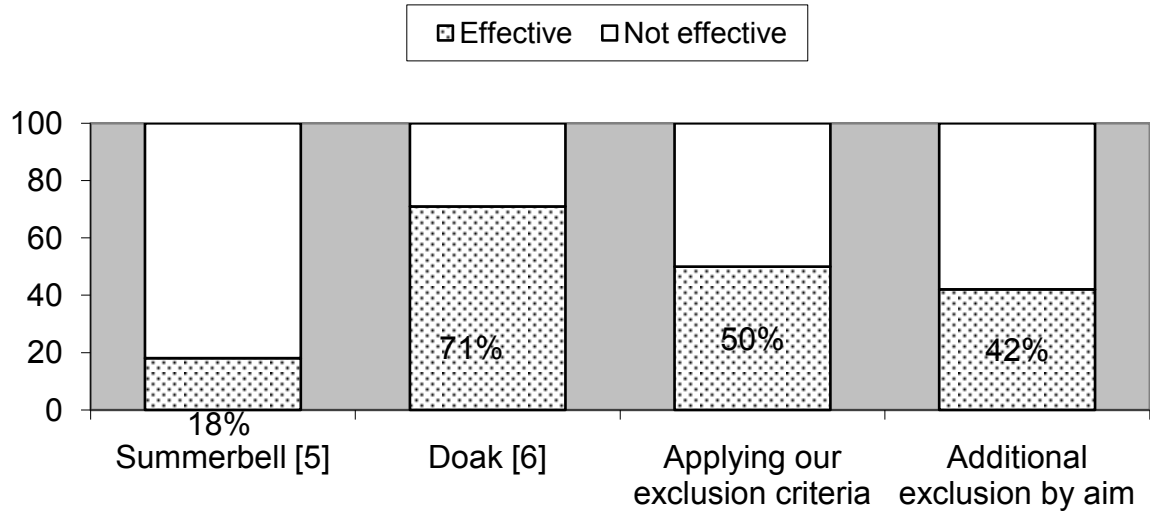
8.Outcome by anthropometric measures not reported within the article. Information from some articles did not include results for anthropometric outcomes such as BMI, height/weight measures, or skinfolds in the published results. It is well known that non-significant findings are more likely to be excluded from published results. Thus, following recommendations to track down unpublished results to minimize publication bias, Summerbell *et al.* (5) contacted authors of articles reporting data collection on anthropometric outcomes. Thus the Summerbell *et al.* (5) review includes results not published in the original article. Because unpublished data were not subject to the peer review process such results are not included in the Doak *et al*. (6) review. **Authors' decision:** Where outcome data are not included in the publication, they cannot be considered peer reviewed and must be excluded.

9. Definition of effectiveness. In addition to differences in the above inclusion/exclusion criteria, the results of the reviews also differed according to which outcomes were used to assess interventions as effective. Where discordant outcomes were reported, Summerbell *et al*. (5) decided on effectiveness using mean change in BMI. The Doak *et al*. (6) accepted any

statistically significant, beneficial change in anthropometric outcomes as evidence of an “effective” intervention, even where there were discordant results. Discordant assessment of outcomes explains differences in the classification of three articles as effective (by Doak *et al*. (6)) versus not effective (5). These differences relate to results that were not effective by the Summerbell *et al*. (5) review because they were not effective by mean BMI change, but were effective by other measures, such as prevalence change (8), effect on slope of BMI in a multivariate model for girls (9) or an effective result for skinfolds (10). Due to these differences in assessing outcomes, the two reviews provide different conclusions even for the 10 interventions that fit the inclusion criteria of both reviews. The manner of assessing outcomes results in 3 out of the 10 (30%) by Summerbell *et al*. (5) compared to 6 out of the same 10 (60%) interventions assessed as effective by Doak *et al*. (6). **Authors’ decision:** The authors concluded that any obesity outcome may be acceptable, in either gender. Ideally an intervention will be effective both through change in mean BMI and change in prevalence of obesity. Due to the focus on prevention of obesity development- and not on weight loss –prevalence change brought about through weight loss in the overweight and obese groups not be considered prevention. Likewise, a reduction in mean BMI that is not related to improved incidence of overweight/obesity is also not effective prevention. Thus where intervention effects on the prevalence and mean BMI differ, it is important to evaluate results with caution.

Final Results: Figure 1 shows that the Summerbell *et al*. (5) review had 18% positive results as compared to 71% positive studies from the Doak *et al*. (6) review. Combining both reviews together results a total of 36 studies. Applying our agreed criteria excludes six studies from the combined total (see Appendix Table 1) leaving 30 studies. Figure 1 shows that after applying our exclusion criteria to the combined total, 50% (15/30) of the remaining studies are positive. The exclusion by aim of the study was left open, but the impact of the exclusion is shown in Figure 1. Applying the criteria that studies must have an aim specific to preventing weight gain excludes an additional six studies (Appendix Table 2). If these studies are also excluded, the proportion of effective interventions is reduced to 42% (10/24) as shown in Figure 1. Details of the remaining 24 studies are described in Table 3 (Appendix).

Figure 1. Combining both reviews and applying new exclusion criteria



Discussion/Conclusions:

This comparison of two systematic reviews with similar aims illustrates a number of underlying biases that are inherent to this type of research. While decisions were made based on criteria fitting scientific objectives, the differences in decisions made by two independent researches highlights the subjective element even in carefully designed systematic reviews. In this case, the first authors of two reviews have chosen different sets of inclusion/exclusion criteria and outcome assessments. While not made explicit in the reviews, there were clear differences in the handling of unpublished data and how outcomes were evaluated. These differences resulted also in opposite conclusions about "effectiveness" as measured by the two reviews. The results clearly show that interventions assessed by height/weight outcome measures resulted in more conservative estimates of effect. Other outcome measures of obesity resulted in more optimistic conclusions. After assessment of the key differences in inclusion/exclusion criteria, the majority opinion of this viewpoint is that the quality of reviews will be improved if future reviewers exclude non-peer review articles; establish a six month lower limit for duration of study; include interventions from before 1990, include pre-school age groups; include pilot studies and include interventions in high risk communities.

There was no consensus on two points, first whether or not studies with aims not specific to preventing weight gain should be included and the second, the manner of assessment of anthropometric measures. Both issues require further exploration. However, these results clearly illustrate the limitations to evaluating interventions only as "effective" or "not effective" as many interventions show significant results only in one group or by a single outcome. In conclusion, the totality of the evidence can look very different depending on how the systematic

review is designed. The question remains, which are the appropriate criteria to apply? We look forward to a lively debate on this topic.

Appendix

Table 1: Excluded interventions based on universal criteria

Author	Year	Outcome	Reason for exclusion
Rodgers (11)	2001	**Effective** skinfolds, not by height weight	non-peer review article
Harrell (12)	1996	**Effective** skinfolds, Not by height/weight	<12 weeks duration Aim other than to prevent obesity
McMurray (13)	2002	**Effective** skinfolds, Not by height/weight	<12 weeks duration
Dennison (14, 15)	2004	Not effective skinfolds Not effective height/weight	Outcome by anthropometric measures not reported within the article.
Pangrazi (16)	2003	Not effective height/weight	“
Stolley (17)	1997	Not effective height/weight	“

Table 2: Six studies excluded for aims not specific to preventing weight gain

Author	Year	Outcome	Reservation
Alexandrov (18)	1992	**Effective** height/weight	Effective at 52 weeks but not at 156 weeks
Manios (19)	1998	**Effective** height/weight and skinfolds	
Sallis (20)	2003	**Effective** height weight	
Tamir (21)	1990	**Effective** height/weight	
Vandongen (22)	1995	**Effective** height/weight and skinfolds	
Leupker (23)	1996	Not effective height/weight	

Table 3: Remaining 24 studies

Author	Year	Outcome	Reservation
Effective (10)			
Dwyer (24)	1983	**Effective** skinfolds, not effective height/weight	
Flores (25)	1995	**Effective** height/weight and skinfolds	
Gortmaker (26)	1999	**Effective** height/weight and skinfolds	
James (8)	2004	Not effective mean BMI, **effective** prevalence obesity	No difference using mean BMI change
Kain (9)	2004	**Effective** height/weight, not effective by skinfolds	No difference using mean BMI change
Killen (27)	1988	**Effective** height/weight and skinfolds	
Mo-Suwan (28)	1998	**Effective BMI,** not effective skinfolds	
Müller (10)	2001	**Effective** skinfolds, not height/weight	No difference using mean BMI change
Robinson (29)	1999	**Effective** height weight and skinfolds	
Simoneti D'Arca (30)	1986	**Effective** height/weight	
Not effective (14)			
Baranowski (31)	2003	Not effective height/weight	Pilot study
Beech (32)	2003	Not effective height/weight	Pilot study
Bush (33)	1989	Not effective height/weight or skinfolds	
Caballero (34)	2003	Not effective height/weight or skinfolds	

Donnelly (35)	1996	Not effective height/weight	
Epstein (36)	2001	Not effective height/weight	Is it primary prevention?
Harvey-Berino (37)	2003	Not effective height/weight	
NeumarkSztainzer (38)	2003	Not effective height/weight	Is it primary prevention?
Robinson (39)	2003	Not effective height/weight	Pilot study
Sahota (40, 41)	2001	Not effective height/weight	
Sallis (42)	1993	Not effective height/weight	
Story (43-45)	2003 a	Not effective height/weight	Pilot study
Walter (46)	1988	Not effective height/weight	
Warren (47)	2003	Not effective height/weight	Pilot study

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