Online Supplementary Material for “Will reducing sugar-sweetened beverage consumption reduce obesity? Evidence supporting conjecture is strong, but evidence when testing effect is weak.” - Kaiser, Shikany, Keating & Allison, 2013

UPDATED LITERATURE REVIEW, SELECTION, AND DATA EXTRACTION METHODS

Identification of Studies

Since our last review (7), we conducted new searches of PubMed, PsycINFO, the Cochrane Collaborative Website, SCOPUS, and Dissertation Abstracts (PROQUEST) to identify sources, including recent and unpublished sources that may not have been included in other reviews. Databases were searched from January 2010 to October 2012. No sources were excluded on the basis of language, because all were available in English. See (7) for search methods, outcome measures, and inclusion criteria. See Figure 2 in the companion article for a flow chart of the studies screened and selected. Newly published articles meeting our original inclusion criteria (1-6) were combined with the originally meta-analyzed studies (7) in the present analysis. We attempted to get additional data from trials registered in ClinicalTrials.gov, but were unable to secure any from corresponding authors who replied to our queries.

Statistical Analysis

Updated forest plots were generated with Review Manager, version 5.1.6 software (8).

Risk of Bias Assessment

To assess the study-level risk of bias, two authors (KAK and JMS)

independently reviewed the newly included studies by using the guidelines contained in the Cochrane Handbook for Systematic Reviews of Interventions (9). Disagreements in ratings were discussed until consensus was reached. Risk of bias detail and summary figures were generated with Review Manager, version 5.1.6 software (8).

Data Extraction

Two authors (KAK and KDK) examined all publications in the present analysis and independently extracted data on study design, participant characteristics, analysis methods, missing data handling, and results. Extracted data were compared and discrepancies were reviewed until consensus was reached before analysis. All calculations for meta-analysis performed by KDK were verified by KAK. Raw data were requested and analyzed as noted in Table 1 in the companion article.

NEW STUDIES SINCE JANUARY 2010

This section briefly describes each of the newly reported studies since Mattes et al. 2011 (7) that met the original inclusion criteria. We found three new studies of the effects of added sugar-sweetened beverages (SSBs) and three studies that examined the effects of reduced consumption of SSBs on one or more measures of body composition. Here we provide relevant summaries of the methods and results of each study as reported in the published article.

Studies Evaluating Reduction of SSB Intake Among Those Who Drink SSBs

Tate et al., 2012 (5). This 6-month trial assigned 318 obese adults who drank at least two SSBs per day (≥200 kcal/day) at baseline to replace these beverages with either diet soda (n=105) or water (n=108). In addition, an attention control group (n=105) received generalized weight loss advice but were not encouraged to change their beverage intake and were not given beverages. The attention control group received equivalent treatment contact time, monthly weigh-ins, and weekly monitoring in the same manner as given to the water and diet beverage groups. Outcome measures at 3 and 6 months included weight, waist circumference, blood pressure, fasting blood glucose, and hydration status as measured by urine osmolality. Missing data were imputed and a secondary analysis of study completers was performed to examine differences in outcomes.

The outcome of body weight change did not differ significantly between the diet soda and water groups compared with the attention control group (P = 0.2361 and 0.9949, respectively). All groups lost a statistically significant amount of weight from baseline (P = 0.0001 to 0.0027). No significant changes in waist circumference from baseline were observed within or between groups. All groups reduced their beverage energy intakes (mean ranging from 106.7 to 259.8 kcal/day) and food energy intakes (mean ranging from 344.4 to 474.7 kcal/day) from baseline, but only the beverage energy reductions were significantly different among the groups. The mean total energy reduction for the attention control group (beverage and food) was 581.4 kcal/day; the diet beverage group reduced their intake by a mean of 659.1 kcal/day, and the water group reduced their intake by a mean of 531.8 kcal/day. The authors did not discuss the

possibility of a greater reduction in food energy intake as compared with beverage intake having an impact on the various outcome measures. Rather, the water and diet beverage groups were combined in a *post hoc* analysis to compare the odds of achieving at least a 5% weight loss. This secondary analysis indicated an odds ratio for 5% weight loss of 2.07 [95% confidence interval (CI) = 1.02 – 4.22] for the beverage groups compared with the attention control group. Testing this contrast after a null finding of the among-groups 2-df omnibus test is an unusual statistical choice and different than the approach the investigators took with their primary continuous measure. Our analysis using a chi-square, 2 degrees of freedom test found no statistically significant result for proportion of subjects losing at least 5% of baseline weight.

The strengths of this study included a relatively large sample size and a single-blind design. The limitations included that the attention control group was given weight loss advice that was not also given to the two treatment arms. In addition, the planned analysis according to information given in the clinical trial registry was unclear compared with the article's statistical analysis and results sections. This study was funded by Nestlé Waters USA.

de Ruyter et al., 2012 (1, 10). This 18-month, double-blind, randomized controlled trial included 641 children (80.8% normal weight or below) who were 5 to 12 years of age and were recruited from urban elementary schools near Amsterdam. Children were eligible if they commonly drank SSBs, specifically at least one per day for 3 of 5 weekdays. Subjects were provided with one can per day of either a noncaloric,

artificially sweetened, noncarbonated beverage (sugar-free group; n = 319) or a sugar-containing, noncarbonated beverage (sugar group; n = 322). The sugar-free and sugar-containing beverages tasted and looked essentially the same, as did the cans in which they were provided. Children received a box at school each week containing 8 cans: one for each day of the week and one spare in case a can was misplaced. Teachers confirmed that the children consumed their beverage during a morning break and reminded them to take the cans home for consumption on weekends. Frequent incentives were provided, including birthday cards and small gifts. Study staff visited the schools at least once a month to ensure that the study beverages were delivered correctly. The primary outcome was body mass index (BMI) *z*-score change over the 18-month intervention period.

The predefined primary analysis involved the children who consumed the study beverages throughout the 18-month period (siblings were shifted in assignment to be concordant within a household but were not counted as one analysis unit in the primary report; they were analyzed later in supplemental material). In addition, multiple imputation was used to impute outcome values for the 164 children who did not complete the study at 18 months. The primary outcome was the BMI *z*-score, expressed as the number of standard deviations by which the BMI differed from the mean for a child's age and sex in the Netherlands. In the 474 subjects (74%) who consumed the study beverages for the full 18 months, the mean BMI *z*-score increased by 0.02 ± 0.40 (mean ± SD) units in the sugar-free group and by 0.15 ± 0.42 units in the sugar group, with the mean difference of -0.13 units (95% CI: -0.20 to -0.06) being significant (P = 0.001). The results in the full cohort with the use of imputed data were nearly identical.

The strengths of this study included the double-blind design with nearly the same intervention provided to both groups, with the only difference being the sweetener used in the study beverages. A possible shortcoming was the predefined primary analysis, which included only children who completed the study rather than being an intention-to-treat analysis. However, the nearly identical results for both analyses seem to minimize concerns about this limitation.

Ebbeling et al., 2012 (2). In a trial by Ebbeling and colleagues, 224 adolescent boys and girls with a BMI above the 85th percentile for sex and age who reported consuming at least one serving per day of SSBs or 100% fruit juice were randomly assigned to one of two groups. The experimental group (n = 110) included a multi-component intervention designed to reduce the consumption of SSBs in the home, with the emphasis on displacing these beverages with non-caloric beverages. The intervention consisted of home delivery of non-caloric beverages (e.g., bottled water and diet beverages) every 2 weeks, monthly motivational telephone calls by study staff with parents, and three check-in visits with subjects conducted by study staff. Subjects also received written instructions by mail to drink the delivered beverages and to not buy or drink SSBs. There was no attention to other dietary behaviors or to physical activity. Control group subjects (n = 114) received $50 supermarket gift cards by mail at 4 and 8 months as a retention strategy (without instructions on what to purchase with the cards) and no other intervention. This 2-year study included 1-year intervention and 1-year follow-up phases, with the primary outcome being change in BMI at 2 years.

Analyses followed the intention-to-treat principle. At 1 year, the change in consumption of SSBs was significantly different between the groups (P <0.001), declining to almost 0 in the experimental group, with the consumption of unsweetened and diet beverages increasing significantly in the experimental group compared with the control group (P <0.001). A similar pattern was seen at 2 years except that the consumption of diet beverages did not differ significantly between the groups. Whereas the net intervention effect on BMI (the change in the experimental group minus the change in the control group; mean ± SE) at the end of the 1-year intervention phase (secondary endpoint) was significant (-0.57 ± 0.28; P = 0.045), the net intervention effect on BMI at 2 years (primary endpoint) was not significant (-0.30 ± 0.40, P = 0.46). The authors found evidence of effect modification according to ethnic group (secondary analysis), with the change in BMI differing significantly between groups in Hispanic but not in non-Hispanic subjects after year 1 and year 2.

An apparent shortcoming of this study was the lack of an attention placebo in the control group, allowing for potential “Hawthorne effects.” Control group subjects did not receive monthly telephone calls, check-in visits by study staff, or mailings. Thus, it is not clear whether the effects observed were due to reduction in SSB consumption or to other nonspecific factors and intervention components that were allowed to be perfectly confounded with treatment assignment.

Studies Evaluating the Effect of Added SSB Intake

Maersk et al., 2011 (3). This randomized trial was 6 months in duration and

included overweight or obese nondiabetic adults (N = 47). Four treatment groups were instructed to drink 1 liter per day of regular cola, isocaloric semi-skim milk, aspartame-sweetened diet cola, or water. The article stated that the primary outcome was ectopic fat (intra-hepatic and intramyocellular fat), measured with magnetic resonance imaging (MRI). Other endpoints of interest reported in the article were fat mass and fat distribution, as measured by dual-energy X-ray absorptiometry (DXA) and MRI, as well as metabolic risk factors. The stated hypothesis was that consumption of sucrose-sweetened cola for 6 months would cause an increase in ectopic fat, total body fat, and metabolic risk factors compared with consumption of the other three beverages. The metabolic risk factors examined included total and high-density lipoprotein (HDL) cholesterol, triglycerides, fasting glucose, insulin, and insulin sensitivity by use of homeostasis model assessment–insulin resistance (HOMA-IR).

The randomization matched the treatment groups well for age and BMI but the regular cola group included more men. The results were analyzed by using sex and baseline-adjusted relative changes. According to the trial registration information on ClinicalTrials.gov, the primary outcome measures were listed as body weight, MR spectroscopy, MRI, and DXA (specific measures from imaging studies were not listed). The registry entry indicated the secondary outcome measures as circulating metabolic variables and blood pressure.

For the primary outcome of body weight, no significant differences were reported in the published article for body weight, lean body mass, or total fat mass (DEXA) among the four treatment groups. No significant differences in visceral adipose tissue, liver fat, or intramyocellular fat were observed at the 6-month endpoint in the milk, diet

cola, and water groups. The regular cola group had a higher relative amount of visceral adipose tissue than did the other groups (P = 0.03), and the ratio of visceral to subcutaneous adipose tissue was higher in the regular cola group than in the milk group (P< 0.01) after 6 months.

The primary limitations of this study included the small sample sizes with unequal gender distribution between treatment groups, as well as the lack of participant blinding inherent in the choice of comparison groups to include water and milk. The strengths of the study included the longer time period with greater added energy (454 kcal for the milk group and 430 kcal for the cola group) and more comprehensive measures of body composition. Semi-skim milk was donated by the Danish Dairy Company, Arla Foods, which was reported by the authors to have no influence on the design, interpretation, or conclusions of the study.

Njike et al., 2009 (4). This three-condition crossover trial (6 weeks on each treatment with a 4-week washout between) evaluated the effects of a sugar-sweetened cocoa beverage (2x/day, 460 kcal total) versus an artificially sweetened version containing the same cocoa flavanols (2x/day, 90 kcal total) and a sugar-sweetened "placebo" that contained no cocoa flavanols (2x/day, 500 kcal total). The primary outcome of interest was endothelial function as measured by flow-mediated dilation. Body weight and waist circumference were secondary measures for this sample of 44 adults with a BMI ranging from 25 to 35 kg/m^2. Also evaluated were effects on serum cardiometabolic risk variables and blood pressure. Standard 3-day food diaries were completed during each treatment and washout phase.

In the primary results reported for the effects on body weight, the authors found that body weight did not change over the 6 weeks of treatment by use of unadjusted models and when controlled for age, gender, and treatment assignment in the multivariate models. A nonsignificant reduction in waist circumference was observed in the two cocoa (sugar free or sugar sweetened) groups compared with the placebo group. The limitations of this study included a small, predominantly female sample size and a relatively short duration of each phase (6 weeks). Strengths included the double-blind, crossover design. Note that in Nijke et al., 2009, Table 3 reports the weight change data in pounds. It was actually in kilograms (personal communication, November 9, 2012). The Hershey Company provided test products used in this study.

Vaz et al., 2011 (6). The primary purpose of this study was to evaluate the effects of micronutrient supplementation on physical performance in normal to underweight children (greater than -3 to 0 age- and gender-adjusted BMI, or zBMI). An untreated control group was compared for change from baseline to 120 days with an unfortified group (who received the 158-kcal beverage once per day) and a fortified group (who received a micronutrient version of the fortified beverage once per day, also 158 kcal). Effects on body composition were also reported.

The published article did not report the values for weight change, but stated that weight increases were not significantly different among the groups. Mean (SD) changes for the experimental groups ranged from 1.01 kg (0.89) in the treatment group (fortified beverage) to 0.87 (0.86) and 0.98 (0.76) in the unfortified beverage and no treatment groups, respectively (personal communication from Tinku Thomas to first author,

December 12, 2012).

The strengths of this study included a large sample size, longer duration, and double-blind design. It is unclear from the data reported whether the children in the sample had a relatively high level of physical activity compared with other studies we analyzed, possibly making it more difficult to detect weight gain effects from the added 158 kcal per day. This study was sponsored by GlaxoSmithKline Consumer Healthcare Ltd., Gurgaon, India.

Other Studies Not Meeting the Strict Inclusion Criteria

Other reports of randomized trials of beverage intake studies were found that otherwise met the inclusion criteria (11-16), but the beverages provided did not contain added sugars (e.g., 100% fruit juice, low-sodium vegetable juice, and whey or soy protein). Two other studies (17, 18) examined reduction of SSBs as part of one or more other components of an intervention program, e.g., reduced “screen time” or increased physical activity. The effect of SSB reduction could not be separately evaluated for effects on weight in these reports. Other studies examined effects of added alcohol or unsweetened milk on body composition. These interventions were not of the beverage type we prespecified in our inclusion criteria. Other reviews have included a 4-week trial of added SSBs in women (19), but we were unable to determine whether the study was randomized and authors were not able to respond to our requests for more information on randomization and exact weight outcome data prior to the need to finalize this paper (the paper reports no significant weight gain but provides no statistics).

Notes about Our Prior Review and the Present Update

We included one comparison of milk to SSBs in children (20) in our original review (21) as it is informative on the effects of making this substitution, recommended by such bodies as the U.S. Institute of Medicine (22). The sensitivity analysis excluding this study shows the overall standardized effect becomes 0.07, with a 95% CI of -0.01 to 0.14. We did not include the James et al. (2007) three-year follow-up of the James et al. (2004) paper herein, but had we done so, it would have reduced the apparent effect of SSB reduction further as there was no observed effect at the three-year follow-up.

In the present analysis, we combined male and female samples for Tordoff and Alleva (1990) and Addington (1998) so that the largest amount of data is represented for each analysis unit. Slight changes in calculations for standardized effects and associated errors were made for Sichieri (2009) to use the correct N for the completer's analysis and incorporating clusters in the determination of pooled standard deviations. The standard error we originally reported for Munoz (2006) was calculated using incorrect sample sizes, which are now correct in the present analysis. All other differences in the present analysis are due to rounding.

In James et al. (2004), the data were analyzed and reported with cluster as the unit of observation (that is, the numbers reported therein are based on the within-cluster means for 29 clusters). In our present paper, the standardized mean difference was calculated with the estimated within-treatment among-subject standard deviation as the denominator. This makes the effect size estimate comparable to that of the other trials, which were not cluster-randomized, and is the appropriate statistic as discussed by Hedges (23). Note that James et al. (2007) provide slightly different numbers for the

12-month data, but here we use the data in the 2004 paper, which produced a slightly stronger effect size estimate than we reported in our prior paper (Mattes et al., 2011). Note also that Te Morenga et al. (24) published a much larger estimated standardized mean difference (0.39) for the James et al. (2004) result, which we believe was obtained by incorrectly using the estimated among-cluster standard deviation in the denominator.

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Table S1. Unstandardized effect sizes of new studies assessing the effects of adding mandatory SSB consumption to persons' diets

Study	N	Daily Energy (Kcal)	Duration	Effect Size (Δ_{SSB} - $\Delta_{control}$)	SE effect size	Comments[+]
Njike et al., 2011(adults) (4)	116	90, 460 or 500	6 weeks/phase with 4 week washout between phases	0.386 kg	0.345	Unstandardized difference
Vaz et al., 2011(children) (6)	192	158	120 days	0.110 kg	0.117	Unstandardized difference
Maersk et al., 2012 (adults) (3)	22	430	6 months	1.17% (1.14 kg)	1.56	Unstandardized difference

SSB, sugar-sweetened beverage.

[+] All variables are change scores, i.e., changes in the variable from baseline to endpoint.

Table S2. Standardized effect sizes from new studies assessing the effect of attempting to get people to reduce or eliminate SSB consumption on body composition/adiposity indicators

		Standardized Effect Size (*d*)				
Reference	**N**	Effect Size (Standardized mean difference)	SE	Lower Limit of 95% CI	Upper Limit of 95% CI	**Variable[+] for which effect size is calculated**
Tate et al., 2012 (adults) (5)	318	0.128	0.119	-0.11	0.36	Percent weight loss
de Ruyter et al., 2012 (children) (1)	375	0.329	0.104	0.13	0.53	BMI z-score
Ebbeling et al., 2012 (children) (2)	224	0.272	0.134	0.01	0.53	BMI

SSB, sugar-sweetened beverage.

[+] All variables are change scores, i.e., changes in the variable from baseline to endpoint.

Table S3. Standardized effect sizes from new studies assessing the effect of attempting to get people to reduce or eliminate SSB consumption on body mass index only for subjects overweight/obese at baseline or above the top tertile of baseline BMI

		Standardized Effect Size (*d*)				
Reference	**N**	Effect Size (Standardized mean difference)	SE	Lower Limit of 95% CI	Upper Limit of 95% CI	**Variable[+] for which effect size is calculated**
de Ruyter et al., 2012 (1)	91	0.727	0.217	0.30	1.15	BMI z-score
Ebbeling et al., 2012 (2)	224	0.272	0.134	0.01	0.53	BMI
Tate et al., 2012 (5)	318	0.128	0.119	-0.11	0.36	Percent Weight Loss

SSB, sugar-sweetened beverage.

[+] All variables are change scores, i.e., changes in the variable from baseline to endpoint.

Figure S1. Study screening and selection process for new studies added since the original meta-analysis (21).

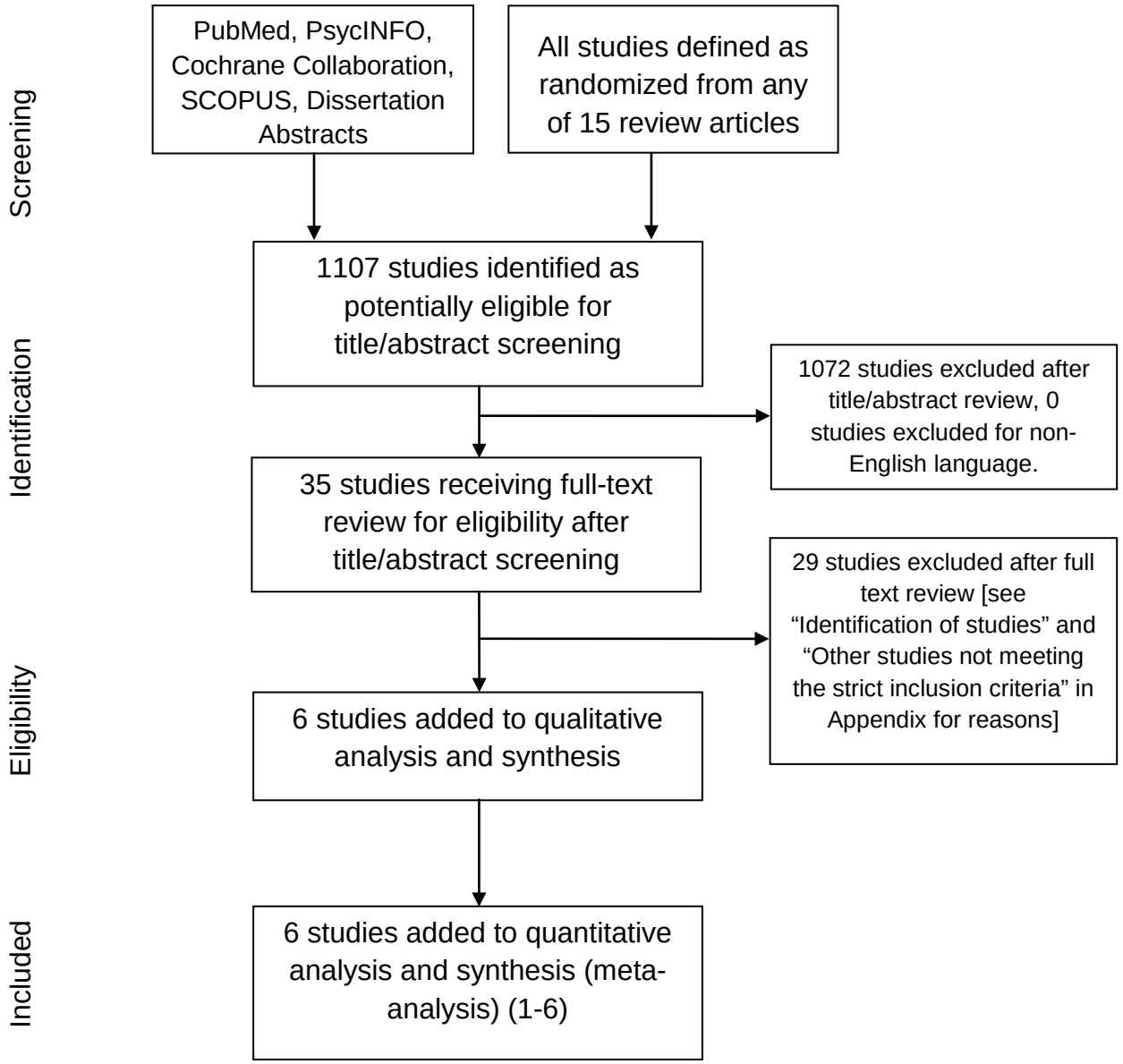
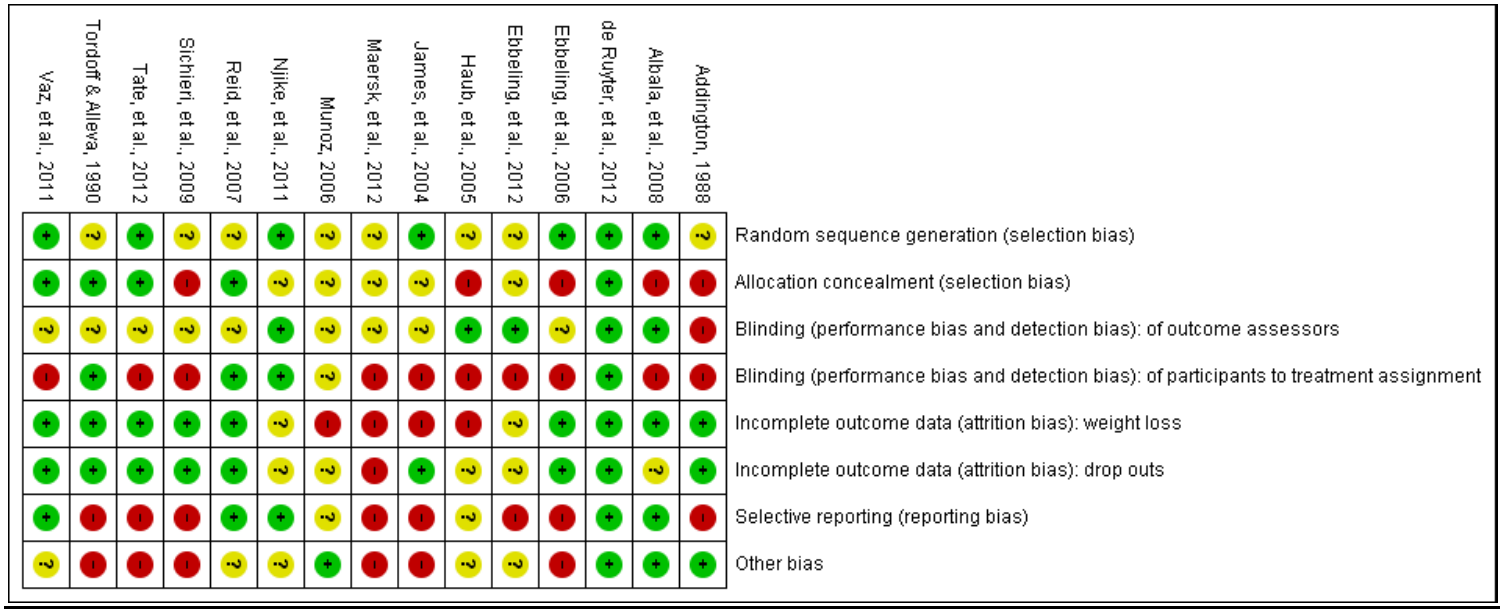


Figure S2. Methodological quality summary: review authors' judgments about each methodological quality item for each included study (1-6, 20, 25-32).



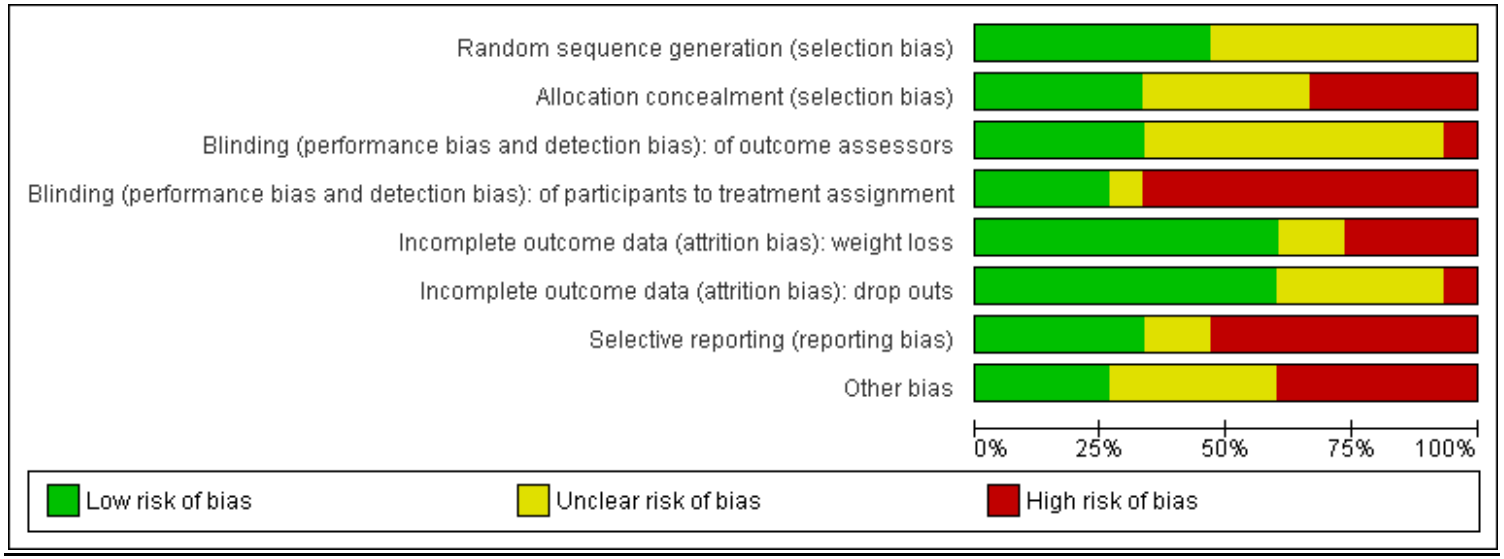


Figure S3. Funnel plot of published studies of added sugar-sweetened beverage (SSB) consumption (3, 4, 6, 27, 30, 32).

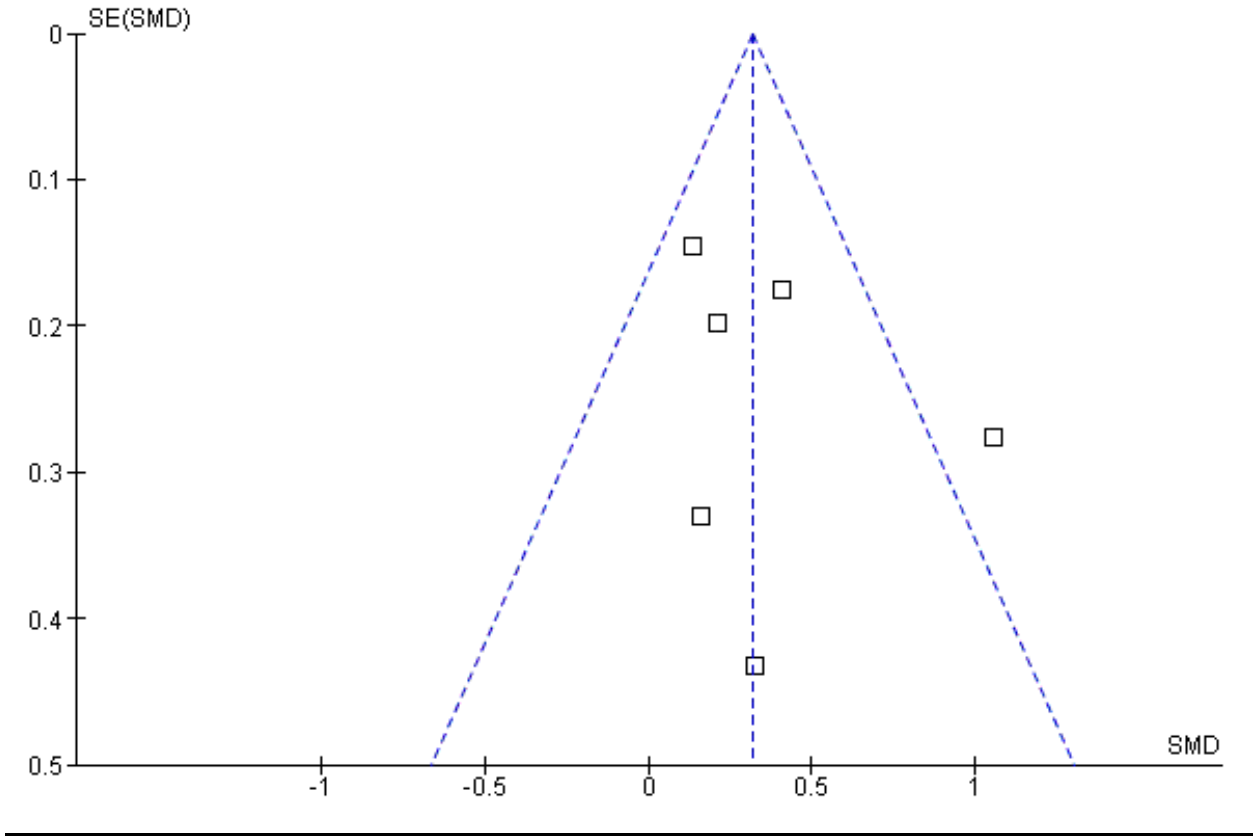


Figure S4. Funnel plot of published studies on reduced sugar-sweetened beverage (SSB) consumption in subjects of all weight categories (1, 2, 5, 20, 26, 28, 31).

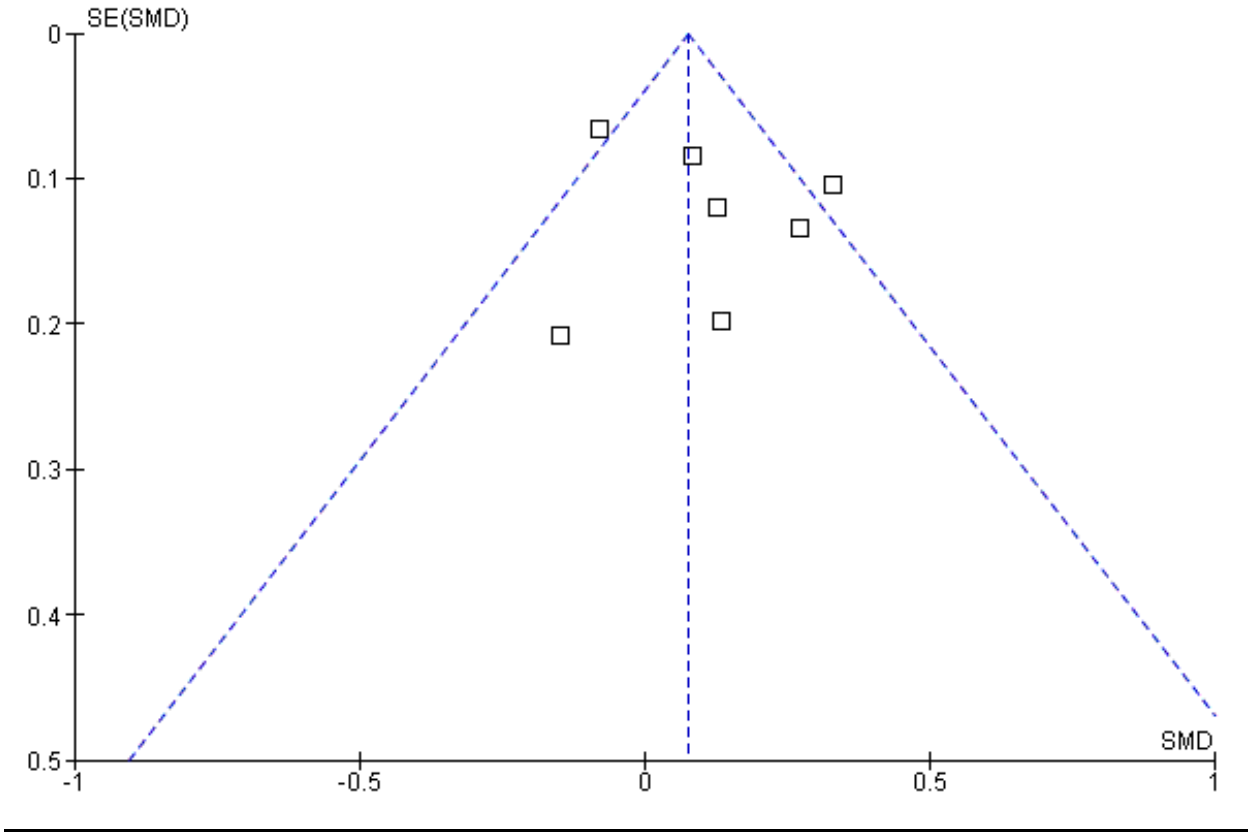


Figure S5. Funnel plot of published studies of reduced sugar-sweetened beverage (SSB) consumption in subjects overweight/obese at baseline (2, 5, 20, 26, 31).