Dairy and weight loss hypothesis: an evaluation of the clinical trials

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This review evaluates evidence from clinical trials that assessed the effect of dairy product or calcium intake, with or without concomitant energy restriction, on body weight and adiposity. Of 49 randomized trials assessing the effect of dairy products or calcium supplementation on body weight, 41 showed no effect, two demonstrated weight gain, one showed a lower rate of gain, and five showed weight loss. Four of 24 trials report differential fat loss. Consequently, the majority of the current evidence from clinical trials does not support the hypothesis that calcium or dairy consumption aids in weight or fat loss.

INTRODUCTION

Some researchers have hypothesized that dairy products and calcium may assist in the loss of excess weight and body fat,[1–4] and extensive commercial advertising campaigns have been based on this hypothesis (e.g. http://www.healthyweightwithdairy.com). However, this hypothesis is contradicted by studies showing that dairy products or calcium supplementation may have no effect[5–8] or even an adverse effect on body weight.[9,10]

In some,[11–13] but not all,[14,15] cross-sectional trials, intake of dairy products or calcium has been shown to be inversely associated with body weight or fatness. However, by design, cross-sectional studies are not useful for observing associations with weight loss (which implies a change in weight over time). Longitudinal studies on the other hand, can be used to shed light on the dairy and weight loss hypothesis, but have generally shown no relationship between dairy or calcium intake and weight loss. Rather, associations, when observed, were with a higher or lower *rate of gain* in longitudinal studies.

Ten longitudinal studies (four in adults, six in children or adolescents) investigated an association between calcium or dairy product intake and body weight.[16–25] Of the four longitudinal studies investigating the relationship between calcium or dairy intake and BMI, weight, or change in body weight or BMI in adults, one reported no association,[25] one reported an inverse relationship between dairy intake and weight in some, but not all, subpopulations,[22] one reported an inverse relationship as evidenced by a slower rate of weight gain in those consuming more calicium/kcal/day,[19] and one reported increased weight loss in calorie-restricted adults with type 2 diabetes who consumed more low-fat dairy products.[24] Of the six longitudinal studies of children and adolescents investigating the same relationships, one study demonstrated a direct relationship between higher dairy intake and weight gain,[16] three showed no relationship,[17,21,23] one reported inverse relationships between calcium and dairy intake and measures of obesity in some but not all subpopulations,[18] and one showed a slower rate of weight gain with higher dairy intakes.[20]

Similarly, six longitudinal studies have assessed the effect of calcium and/or dairy intake on body fatness.[17–19,23,26,27] As with body weight, the findings relating body fatness to dairy or calcium consumption have been inconsistent across studies. Of these six studies relating calcium or dairy intake to body fat in adults, adolescents, and children, one observed no relationship,[23] two showed an inverse relationship with some subpopulations or analyses, but no relationship with others,[17,18] and three observed an inverse relationship.[19,25,26]

An association of calcium or dairy products with body weight or fatness, when found, may not be specific

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to these dietary factors alone, but may instead relate to a food pattern that is conducive to achieving and maintaining a healthy weight. Three additional studies investigated the relationship between food patterns including dairy products and body weight and/or adiposity.[28–30] Newby et al.[28] identified five dietary patterns among participants in the Baltimore Longitudinal Study. The "healthy pattern" that was associated with the lowest mean annual gain in BMI was high in fruits, vegetables, reduced-fat dairy products, and whole grains, and low in red and processed meat, fast food, and soda.[28] In this study, high-fat dairy consumption was highest in the "sweets" pattern, which was associated with the largest mean annual increase in waist circumference.[28] Using factor analysis, in a second paper these same authors identified a healthy food pattern (high-fiber foods and low-fat dairy products) that was associated with the smallest mean annual gains in weight and waist circumference.[29] While these two studies taken together might indicate that high-fat dairy intake is associated with higher gains in body fat and low-fat dairy intake is associated with smaller gains in weight and fat, the authors state that "neither specific nutrients nor specific foods can be pinpointed for the differences in gain".[28] In a study of changes in food patterns over time, Drapeau et al.[30] found that individuals who reported eating less fatty or sugary food or more fruit had smaller increases in body weight and body fat than those who consumed more of these foods. When physical activity was controlled for, increases in skimmed milk consumption were not associated with body weight or body fat.[30] Food-pattern studies reinforce the notion that single foods or nutrients are unlikely to by themselves be responsible for weight loss or gain.

Taken together, the observational studies addressing the dairy and weight loss hypothesis are inconclusive, but several suggest an inverse association between dairy or calcium consumption and body weight or body fatness in some groups. When found, the relationship is generally with a decreased rate of weight or fat gain, rather than weight or fat loss. Two of the largest prospective studies, one including 12,829 adolescents, and the other including >19,000 adult men, found the reverse: increased milk intake was associated with increased weight gain.[16,25] The associations observed in longitudinal studies suggesting a benefit of dairy products or calcium may be due to the convergence of higher dairy intakes with healthy diets or lifestyle behaviors.

In light of this inconclusive evidence from longitudinal studies, this review evaluates evidence from clinical trials that addressed the effect, if any, of dairy product intake or calcium supplementation on body weight and body fatness with or without energy restriction (dieting) in children and adults. In 2003, Barr[5] reviewed the available evidence largely from studies with bone density as the primary endpoint as of 2001 and found that, of the nine clinical trials with dairy product treatments, two showed an increase in body weight with dairy supplementation,[9,10] seven showed no difference in body weight or composition.[31–37] In the 16 calcium supplementation trials reviewed by Barr, where the treatment did not affect energy intake, changes in body weight or body fat (where noted) were similar among groups in 15 studies, while one study found greater weight loss in the supplemented group (0.67 vs. 0.32 kg/y).[5,38]

Since then, two other reviews have been published addressing calcium and weight in children[6,7] and numerous additional clinical trials have been conducted specifically addressing the hypothesis that dairy products or calcium-supplements aid in weight loss with or without energy restriction. In 2006, Trowman et al.[8] published a systematic review and meta-analysis of 13 randomized clinical trials addressing whether increased calcium intake through supplements or dairy products is associated with weight loss in adults, but did not address the question of whether the weight-loss effect occurs in the context of energy restriction.[8] To further assess whether calcium or dairy supplementation is a potentially useful method for weight or body fat loss, we undertook a review of studies addressing calcium or dairy supplementation in adults or children with or without energy-restriction (dieting).

A MEDLINE (National Library of Medicine, Bethesda, MD) search was conducted for studies published on the relationship between milk, dairy products, or calcium intake and body weight, body mass index (BMI), or adiposity using the key words *milk*, *dairy*, *calcium* and *weight*, *BMI*, or *body fat*, limiting the search to human studies published in the English language for the period catalogued from 1966 through August 2007. Additional articles were identified from the cited references of these reports and from the National Dairy Council's website (http://www.healthyweightwithdairy.com). Reports available only in abstract form and those that did not address change in body weight, BMI, or body fat were excluded. This search yielded 49 clinical trials directly or indirectly assessing the hypothesis.

Clinical trials were categorized based on whether or not the studies used an energy restriction protocol. They were further categorized by age, and again based on whether the treatment included dairy products, calcium supplementation, or both. In some studies body weight and/or BMI were the key outcomes whereas other studies used other indicators of body fatness (see Figure 1).

Of the 49 clinical trials, 38 observed the effect of dairy products (17),[9,10,31–37,39-46] or calcium (21)[38,47–66] on bone health, weight, BMI and/or body composition in the absence of energy restriction. Eighteen of these trials were

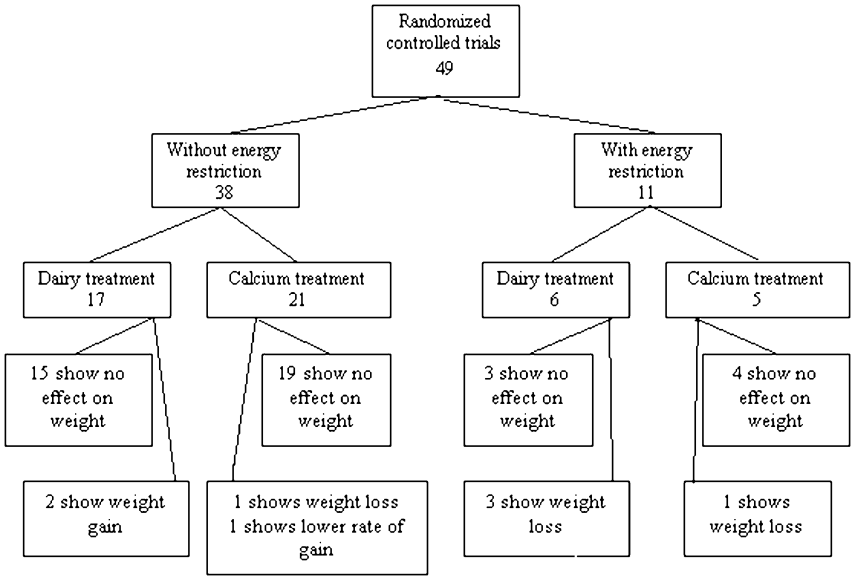

Figure 1 **Randomized controlled trials of calcium and/or dairy supplementation on weight.**

conducted with children and adolescents[32,33,36,37,39–41,45–47] and 20 with adult populations.[9,10,31,34,35,38,42–46,58–66] The remaining 11 studies assessed the effect of calcium or dairy supplementation along with energy restriction on weight.[46,67–75]

Because gradual weight gain is normal during childhood and adolescence, clinical trials of the effect of dairy or calcium on weight gain address the question of whether the addition of dairy products may prevent obesity or excess weight gain. Studies with adults, on the other hand, have addressed either potential weight accrual or weight loss, depending on other variables such as stage of life (e.g. age, pregnancy, lactation, postmenopause) or health status (e.g. baseline body weight, or bone fragility).

WEIGHT LOSS FINDINGS: CALCIUM OR DAIRY SUPPLEMENTATION WITHOUT ENERGY RESTRICTION IN CHILDREN AND ADOLESCENTS

Of eighteen trials conducted in children or adolescents, seven used dairy treatments, while eleven used calcium supplements. None of the seven dairy trials with children[32,33,36,39,40] or adolescents[37,41] demonstrated an effect on weight accrual or, when measured, body fat deposition. These trials varied in length from 3 months to 2 years. Dairy supplementation ranged from one carton (330 mls) to four servings per day, and sample size ranged from 28 to 757 children, including participants from the United Kingdom, the United States, China, Hong Kong, and New Zealand. The two largest trials were conducted with children in China and Hong Kong who had baseline calcium intakes between 400 and 500 mg/day. In one, calcium intake from milk was increased on average by 245 mg Ca/day for 2 years.[39] In the other, the children consumed 40 g (650 mg/Ca) or 80 g (1300 mg/Ca) of milk powder daily for 18 months.[40] Supplemented children in this trial gained slightly, but not significantly, more weight and fat mass than the untreated children. Controls gained a mean of 5.05 kg; those supplemented with 40 g milk powder gained 5.53 kg; and those supplemented with 80 g milk powder gained 5.43 kg. Of the trials in countries where children typically consume cow's milk, the larger studies (80 and 91 girls) with the strongest designs, where calcium intake was approximately doubled and whose duration was 18 months or longer, no significant differences in body weight or weight gain were observed.[32,37]

As with dairy consumption trials, none of the 11 calcium supplementation trials in children[47–54] or adolescents[55–57] demonstrated an effect of calcium on body weight, or, where measured, rate of weight change or body fat. These trials ranged in size from 84 to 162 children, in length from 6 months to 3 years, and in calcium supplementation level from 300 mg to 1200 mg Ca/day. They included participants from Gambia, Switzerland, Australia, the United States, Hong Kong, Denmark, and the United Kingdom. While some of the trials with small increments in calcium consumption might not be expected to have had sufficient power to detect differences in weight or weight change, even those with the largest number of participants,[49] longest observation periods,[50] and largest increment in calcium intake[48] failed to detect differences in body weight, fat, or weight change in trials with children and adolescents.

WEIGHT LOSS FINDINGS: CALCIUM OR DAIRY SUPPLEMENTATION WITHOUT ENERGY RESTRICTION IN ADULTS

Of twenty trials conducted in adults without energy restriction, ten tested the effects of dairy products and ten studied calcium supplements. Of ten trials observing the effects of dairy product consumption on body weight or composition in adults in the absence of energy restriction, two found increases in body weight with increased dairy intake,[9,10] while the remainder found no significant difference in resultant weight or rate of weight loss or gain.[31,34,35,42–46] The two trials demonstrating weight gain were among the four studies with sample sizes greater than 150; both were conducted with older adults. In one of these, 204 healthy American men and women with baseline intakes of <1.5 servings of dairy/day were asked either to continue their usual diets or to increase milk servings by three per day for 12 weeks. The milk-treated group gained significantly more weight (0.6 kg; $p < 0.01$) than the usual diet group.[10] In the other trial, 185 postmenopausal women in Hong Kong either followed their usual diets, or added 50 g/day of high-Ca, low-fat milk powder to their diets. Greater weight gain was observed among the dairy-treated women (0.52 ± 0.27 kg) compared with controls (-0.26 ± 0.28 kg; $p < 0.010$).[45] The remaining eight trials all showed no significant differences in body weight with dairy treatments. These studies ranged in size from 34 to 200 participants, in supplementation levels from 430 mg Ca/day to 1600 mg Ca/day, and in duration from 12 weeks to 3 years.

Of the ten randomized controlled trials that have observed the effect of calcium supplementation on body weight in adults, one demonstrated greater weight loss in the supplemented group,[38] one showed a small reduction in the rate of weight gain,[58] while none of the other eight trials showed a significant difference in body weight or rate of weight gain or loss.[59–66] The largest of these studies was part of the Women's Health Initiative clinical trial in which 36,282 postmenopausal women in the US were treated with 1000 mg Ca/day plus 400 IU cholecalciferol or placebo and were followed for 3–7 years. The risk of small weight gain (1–3 kg) was not significantly different between the groups (OR = 0.95, 95% CI 0.90–1.01). However, the treatment group had a lower risk of moderate weight gain (>3 kg, OR = 0.94, 95% CI 0.90–0.99). The strongest effect was seen in women who had baseline Ca intakes <1200 mg/day.[58] The other trial that observed a differential effect of calcium supplementation on body weight included 197 postmenopausal women in the United States. Those who were treated with 1200 mg Ca carbonate daily for 4.3 years lost more weight than those in the placebo group (-0.67 ± 0.11 vs. -0.33 ± 0.11 kg/year; $p < 0.025$).[38] The remaining eight trials were also all conducted with women. They ranged in duration from 4 months to 6 years and varied in size from 37 to 1471 participants. These studies included post-menopausal women from the United States, Spain, and New Zealand, perimenopausal women from the Netherlands, pregnant women from Gambia, and lactating women from the United States. None of these trials observed a differential effect of calcium on weight loss.[59–66]

In summary, 37 of 38 randomized controlled trials of dairy product or supplemental calcium intake in the absence of energy restriction did not support the suggestion that such products facilitate weight loss. Two trials using dairy treatments showed increased weight gain among participants, as compared to controls.[9,10] One calcium supplementation trial observed a small effect on the rate of weight gain over 3 years[58] and a second calcium supplementation trial observed increased weight loss among postmenopausal women over a period of 4 years.[38]

WEIGHT LOSS FINDINGS: CALCIUM OR DAIRY SUPPLEMENTATION WITH ENERGY RESTRICTION IN ADULTS

Eleven clinical trials with adults have assessed whether dairy products or calcium supplements facilitate weight loss in the context of a reduced-energy diet. Because these trials are designed to directly address the dairy and weight loss hypothesis these are covered in more detail. Of the eleven trials, seven found no effect,[67–69,72–75] while four found a significant positive association between dairy or calcium and weight loss.[46,70 (dairy/Ca),71]

Of these eleven trials, six investigated the possibility that dairy products facilitate weight loss among overweight and obese adults when paired with a reduced-energy diet.[46,67–71] When 50 overweight Australian adults were randomly assigned to an energy-restricted diet that derived 34 percent of calories from protein either largely from dairy products (2400 mg Ca/day) or mixed sources (500 mg Ca/day), there was no significant difference in weight loss between the groups over 12 weeks (dairy, -9.0 ± 0.6 kg; mixed, -9.3 ± 0.7 kg).[67] In a 6-month trial at the University of Vermont, 54 obese adults were randomly assigned to either a high- or low-dairy treatment along with energy restriction (500 kcal/day). There was no significant difference in weight loss between the groups (high-dairy, -10.8 ± 5.9 kg; low-dairy, -9.6 ± 6.5 kg; $p = 0.56$).[68] In a 48-week randomized controlled trial with 72 obese completers in the United States, participants were asked to do moderate exercise four times a week for at least 30 minutes and were assigned to one of three calorie-restricted diets: 1) high-dairy (four servings/day), 2) medium-dairy (two servings/day), or 3) high-dairy (four servings/day) and higher-fiber. Neither of the high-dairy diets resulted in significantly greater weight

loss, compared with the medium-dairy diet (high-dairy, −11.8 ± 6.1 kg; high-dairy and high-fiber, −10.6 ± 6.8 kg; medium dairy, −10.0 ± 6.8 kg; $p = 0.45$).[69]

In contrast with these studies, Zemel et al.,[46,70,71] reported three small trials showing an effect on body weight of increased dairy and/or calcium intake in the context of energy restriction. The first of these was a 24-week trial in 32 obese individuals assigned to three different energy-restricted diets: low-calcium ($n = 10$; 430 ± 94 mg Ca/day), high-dairy ($n = 11$; 1137 ± 164 mg Ca/day), and calcium-supplemented ($n = 11$; 1256 ± 134 mg Ca/day). All participants were instructed to restrict daily energy intake by 500 kcals/day. The high-dairy-product consumers lost, on average, 11.07 ± 1.63 kg over 24 weeks, which was significantly more than the low-calcium (6.6 ± 2.58 kg; $p < 0.01$) and calcium-supplemented (8.58 ± 1.60 kg; $p < 0.01$) groups.[70] In a subsequent 12-week study by Zemel et al.,[71] 34 obese adults were similarly instructed to reduce energy intake by 500 kcal/day and assigned to consume either 1100 mg calcium per day (contributed mostly by yogurt) or a control level of 500 mg calcium/day (no added yogurt). The yogurt group ($n = 18$) lost significantly more weight compared with the control group ($n = 16$); 6.6 kg and 5.0 kg, respectively.[71] In a third study, 29 obese African American adults were instructed to reduce energy intake by 500 kcal per day and were assigned to a low-dairy ($N = 12$, <1 serving/day) or high-dairy ($N = 17$, 3 servings/day) treatment group for 24 weeks. Weight loss reported for the high-dairy group was significantly greater than for the low-dairy group (11.0 and 6.0, respectively; $p < 0.01$).[46] In these three trials, neither baseline energy intake nor change in energy intake was reported, making it impossible to determine whether the observed differences in weight loss were due to the dairy or calcium treatment or differential compliance with the calorie-restriction protocol.[46,70(dairy/Ca),71]

Five trials investigated supplementation with calcium during energy restriction.[70,72–75] One by Zemel was described above.[70] In another, 62 obese women in Denmark who were motivated to lose weight were prescribed a modestly low-calorie diet and assigned to take either a 1 g/day calcium supplement or no treatment in order to observe effects on bone turnover. The weight loss observed in these groups at 1 month (−3.3 kg untreated vs. −3.1 kg calcium-treated) and 3 months (an additional −2.9 kg untreated and −2.3 kg calcium-treated) were not significantly different.[72] In a third trial, 31 postmenopausal American women were placed on a moderate energy-restricted diet with either calcium supplementation (1 g/day) or placebo. After 6 months, the calcium and placebo groups had similar changes in weight (calcium −9.0 vs −8.8 kg) and fat mass (calcium −7.3 vs placebo −7.3 kg).[74] The fourth trial followed 63 overweight or obese Canadian women with <800 mg Ca/day baseline intakes for 15 weeks. All were prescribed an energy-restricted diet (decreased by 700 kcal/day). One group was given 1200 mg Ca/day and 400 IU of vitamin D, while the other group was treated with placebo. Weight loss was similar between the two groups (−4.0 kg for the treatment vs. −3.0 kg for control; $p = 0.32$)[73] The last of these trials studied the effect of calcium supplementation (1 g/day), compared with placebo, on weight and fat loss in 100 women who were enrolled in a weight-loss program for 25 weeks. Calcium supplementation did not significantly affect the amount of weight lost by the participants.[75]

In summary, among the 49 randomized clinical trials (38 conducted without energy restriction and 11 conducted with energy restriction), 42 indicate that neither added dairy products nor calcium supplements facilitate weight loss. In the context of energy restriction, seven of eleven trials showed no significant effect of dairy products or calcium on weight loss. Only four trials (two of which were reported in the same article), all by the same lead investigator, showed a potential effect of dairy products or calcium on weight loss.[46,70,71]

If the trials with sample sizes <50[31,33,41,46,61,70,71,74] and those with increases in calcium intake <400 mg a day[39,43,51] are excluded from the analysis so that only the studies with stronger designs are included, the findings remain unsupportive of a relationship between dairy or calcium and weight loss. Of the 30 trials meeting these criteria and investigating the relationship of dairy or calcium supplementation with body weight or body mass index, one with postmenopausal women showed greater weight loss during calcium supplementation,[38] two demonstrated greater weight gain with dairy supplementation in older adults,[9,10] and one showed a small reduction in weight gain among calcium- and vitamin D-supplemented older adult women.[58] The remaining 26 studies indicated that neither dairy nor calcium supplementation facilitated weight loss in the absence of caloric restriction. All six trials investigating potential relationships between dairy or calcium intake and weight loss in conjunction with an energy restriction protocol failed to demonstrate an effect.[67,68,69,72,73,75]

FAT LOSS FINDINGS

Fifteen of the 16 clinical trials that measured body fat in the absence of energy restriction showed no difference in body fat change between high-dairy or high-calcium treatment and controls in adults[42,9,61,64–66] or children and adolescents.[33,36,37,40,41,49,53,54,57] Only one study, by Zemel et al.,[46] reported greater fat loss in high-level dairy consumers compared to low-level dairy consumers in the absence of weight loss.

Eight of the trials pairing calcium or dairy supplementation with energy restriction also reported on changes in body composition; three of these reported significantly greater fat loss between the high-dairy groups and the low-dairy groups in calorie-restricted overweight or obese adults.[46,70(dairy/Ca),71] The remaining five studies found no significant difference between high- and low-level dairy- or calcium-consuming groups in loss of body fat.[68,69,72–75]

CONCLUSION

Accumulated evidence from randomized clinical trials indicates that neither dairy products nor calcium supplements reliably facilitate weight loss. Of 49 clinical trials, two demonstrated an increase in body weight with a dairy treatment;[9,10] four small trials demonstrated a differential weight loss with calcium supplements and dairy products when paired with a calorie-restricted diet,[46,70,71] and another showed a greater rate of weight loss with supplemental calcium in the absence of caloric restriction.[38] Even in the largest of the trials, the Women's Health Initiative, which followed 36,282 postmenopausal women for 7 years, the women supplemented with calcium and vitamin D did not demonstrate weight loss – only a slower rate of weight gain was observed among the individuals with initial calcium intakes below 1200 mg, which was observed only in the first three of the seven years.[58] The remaining 41 trials showed no significant effect of dairy or calcium on body weight, with or without energy restriction. Of 23 trials studying the effect of calcium on adiposity, three reported greater fat loss with high-versus low-dairy or calcium treatments,[46,70,71] while 20 did not. These trials demonstrate that increasing dairy product intake does not consistently result in weight or fat loss with or without caloric restriction and may have the opposite effect.

Why do some observational studies show reduced weight gain with increased calcium or dairy intake, while most randomized clinical trials show no effect? This divergence may be explained by associations between higher consumption of dairy products and dietary or lifestyle habits, such as exercise, increased fiber or fruit and vegetable intake, decreased soda intake, etc., that aid in achieving and maintaining lower weights and body fat levels. In the CARDIA study, for example, dairy consumption was positively associated with whole grain, fruit, vegetable, and saturated fat intake and inversely associated with sugar-sweetened soft-drink intake.[22] In the Women's Health Study, women with high calcium intakes were less likely to smoke or drink alcohol and were more likely to exercise and use multivitamins. In this study, calcium intake was also positively associated with dietary fiber and inversely associated with dietary fat and cholesterol.[76] In a study by Skinner et al.,[27] the strongest positive predictor of calcium intake was diet variety score, while carbonated beverage and other non-dairy beverage intake were inversely associated. These and other studies of dietary patterns[28–30] suggest that the association between calcium or dairy intake and body weight may be attributable to other factors, such as total energy intake and sweetened beverage intake.

Recently, Trowman et al.[7] completed a meta-analysis of 13 randomized controlled trials in adults that used calcium supplementation (either from dairy products or pills) as a treatment and body weight as an outcome. They concluded that "calcium supplementation has no statistically significant association with a reduction in body weight." Similarly, Huang et al.[6] reviewed both clinical and observational evidence linking dairy intake and obesity in children and adolescents, noting that "collectively, findings across studies fail to demonstrate compellingly a beneficial effect of dairy intake [on body weight or metabolic health] in children and adolescents".[6] In a meta-analysis of 17 studies addressing the effects of calcium supplementation on body weight in children, Winzenberg et al.[8] concluded "there were no statistically significant effects of calcium supplementation on weight . . . or body fat." In extending these findings to include all 49 randomized controlled trials addressing this question in children and adults, we conclude that current evidence does not support the hypothesis that dairy or calcium consumption alone, or in conjunction with caloric restriction, results in weight or fat loss in the short or long term.

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