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Effects of vegetable consumption on weight loss: a review of the evidence with implications for design of randomised controlled trials

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Abstract

Vegetable consumption is a key strategy in many weight loss programs but establishing the evidence that vegetable consumption per se assists with weight loss may be difficult. Creating a dietary energy deficit involves the whole diet, so research on the effects of vegetables may need to consider the whole-dietary model. The aims of this review were to examine the evidence on whether a higher vegetable consumption resulted in greater weight loss in overweight adults (compared to lower intakes) in view of a critique study designs with respect to their potential impact on outcomes. Using the PubMed search engine, a systematic review of randomized controlled trials (RCTs) published in the period 1988 to 2011 was conducted. Of the 16 RCTs scrutinized, five reported greater weight loss, nine no difference, one showed weight gain, and one reported a positive association between weight loss and high vegetable consumption. Trials which showed beneficial effects compared a healthy high vegetable diet with a control diet based on usual consumption patterns, and/or included behavioral support and counseling. On face value, the evidence reviewed appeared inconclusive but closer examination of study designs exposed important implications for RCTs that examine effects of foods on weight loss.

Keywords

trials, loss, vegetable, weight, controlled, review, evidence, consumption, implications, effects, design, randomised

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Effects of Vegetable Consumption on Weight Loss: a review of the evidence and implications for design of randomised controlled trials

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Effects of Vegetable Consumption on Weight Loss: a review of the evidence with implications for design of randomised controlled trials

Abstract: Vegetable consumption is a key strategy in many weight loss programs but establishing the evidence that vegetable consumption per se assists with weight loss may be difficult. Creating a dietary energy deficit involves the whole diet, so research on the effects of vegetables may need to consider the whole dietary model. The aims of this review were to examine the evidence on whether a higher vegetable consumption resulted in greater weight loss in overweight adults (compared to lower intakes) in view of a critique study designs with respect to their potential impact on outcomes. Using the PubMed search engine a systematic review of randomised controlled trials (RCTs) published in the period 1988-2011 was conducted. Of the 16 RCTs scrutinised, 5 reported greater weight loss, 9 no difference, one showed weight gain and one reported a positive association between weight loss and high vegetable consumption. Trials which showed beneficial effects compared a healthy high vegetable diet with a control diet based on usual consumption patterns, and/or included behavioural support and counselling. On face value the evidence reviewed appeared inconclusive but closer examination of study designs exposed important implications for RCTs that examine effects of foods on weight loss.

Keywords: vegetables, weight loss, evidence



Introduction

Vegetables retain a key position in cultural cuisines and their consumption is recommended in national dietary guidelines (NHMRC, 2010, U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2010). While evidence for protective effects against cardiovascular disease have been known for some time (Ness and Powles, 1997), the situation with vegetable consumption and obesity is less clear, as it is for all foods. This is because over-consumption of food generally leads to obesity. The full report of the 2010 Dietary Guidelines for American attributed an evidence grade of 'moderate' for a modest association between increased fruit and vegetable intake and lower body weight with a trend towards decreased weight gain over ≥ 5 yrs in middle adulthood. However the evidence on the efficacy of increased fruit and vegetable consumption in weight loss diets was seen as inconclusive (U.S. Department of Agriculture, 2010).

Eating less food is an obvious strategy for weight loss but knowing which foods to consume to support overall health with weight management is a current imperative. Determining the value of each food in the total diet requires a systematic approach to evaluating the evidence and proving effects. Consistent results from randomised controlled trials (RCTs) provide the highest form of evidence for practice (National Health and Medical Research Council, 1999). Heterogeneity in study design, however, can weaken the ability to generalise across studies. Much of the evidence on effects of food consumption comes from observational studies that examine the association between food consumption patterns and health outcomes. RCTs directly examine the effect by comparing outcomes between a control and intervention diet, where the intervention diet contains the dietary variable of interest.

Food based RCTs, however, present with substantial design challenges (Ludwig and Ebbeling, 2010), and even more so with examining weight loss outcomes given that weight is sensitive to the total diet. In addition, it is likely that short term effects on weight loss may be effective from a range of dietary means, but the long term effects have the greater health significance (Sacks et al., 2009). The content of the background diet can confound results because it may interfere with the ability to attribute effects to the dietary variable of interest.

Likewise the strategy for implementing the dietary trial (e.g. providing forms of dietary advice with or without food provisions) will influence what participants actually eat. Poor adherence to study dietary targets may render the study futile in answering the question. The aims of this review were to examine the evidence on whether a higher vegetable consumption resulted in greater weight loss in overweight adults (compared to lower intakes) in view of a critique study designs with respect to their potential impact on outcomes.

Methods

The review was conducted with reference to frameworks for establishing evidence for practice provided by the Australian National Health and Medical Research Council (National Health and Medical Research Council, 2009). Using the PICO format, the Population was defined as overweight adults, the Intervention as vegetable intakes, the Comparator as high vs. low vegetable intake and the Outcome as weight loss. The review addressed the question, 'Does a higher intake of vegetables result in greater weight loss in overweight adults than a lower level of consumption?'

The primary search was conducted in 2009 (Fig 1) and a follow up search was conducted in 2011. Using the PubMed database and limiting outputs to human studies reported in English since 1988 the first review involved a first pass search which produced 16000 articles using the single key word vegetable*. Adding weight* as a second key word reduced this to 1810 papers. Adding further limitations for clinical trials, meta-analysis, randomized controlled trials, and reviews narrowed the database to 758 papers. Limiting studies to those on human adults resulted in 408 articles. These articles were then examined in full using the inclusion and exclusion criteria. Reference lists and citations of included studies were also checked to identify additional papers missed in the search. *Inclusion criteria* were studies involving adult overweight subjects, randomized controlled trials, studies measuring body weight as a primary outcome, and trials that included vegetable consumption in the primary intervention. *Exclusion criteria* were studies lacking an RCT design, studies where vegetable consumption was not noted in the dietary intervention, and trials where vegetables were not treated as a whole food. Applying these criteria reduced the database to 148 studies which were

reviewed to identify 12 RCTs for detailed analysis as befitting the review question. In 2011 a further PubMed search was conducted for the period 2008-2011 using the key word vegetable*. This produced 3481 articles. Adding weight* as a keyword reduced this to 549. Further limiting the search to clinical trials, meta-analysis, RCTs and reviews and studies that only referred to adult subjects reduced this number to 95 articles. Hand searching of these articles produced a further 4 eligible studies (5 articles, with one study reporting the 6 mo intervention and 12 mo follow up data). Combined with the original 12 RCTs this produced a total of 16 RCTs for critical appraisal.

Each trial was analysed in terms of their characteristics: profile of the study population (including study context, sample size, sex and BMI), intervention and control diets, duration of intervention and effects on weight loss. Comparisons were then made between trial designs that showed a positive effect from vegetable consumption with those that did not.

Results

Of the 16 RCTs scrutinised, 5 reported greater weight loss effects from an intervention group targeting higher vegetable intake compared to a control group (Azadbakht et al., 2005, Burke et al., 2007, Ello-Martin et al., 2007, Svendsen et al., 2007, Shenoy et al., 2010), 9 found no difference (Nowson et al., 2004, Saquib et al., 2008, Thomson et al., 2005, Gardner et al., 2005, Rodriguez-Rodriguez et al., 2008, Tanumihardjo et al., 2009, Jenkins et al., 2009, Lapointe et al., 2010b, Whybrow et al., 2006), and 1 showed weight gain (Djuric et al., 2002) (Table 1.0). Another study applied a cohort analysis to the trial and demonstrated an association between increased consumption of vegetables with greater weight loss (Sartorelli et al., 2008). On face value the body of studies appears to present an inconclusive result. Nevertheless, there was substantial heterogeneity in study design, in particular with respect to vegetable dose and background diet.

Description of trials

Study populations: Reports from 16 RCTs conducted in the period 2002-2011 (Lapointe et al., 2010b, Whybrow et al., 2006, Jenkins et al., 2009, Tanumihardjo et al., 2009, Rodriguez-Rodriguez et al., 2008, Gardner et al., 2005, Thomson et al., 2005, Saquib et al., 2008, Nowson et al., 2004, Sartorelli et al., 2008, Shenoy et al., 2010, Azadbakht et al., 2005, Burke et al., 2007, Ello-Martin et al., 2007, Svendsen et al., 2007, Djuric et al., 2002) were examined in detail (Table 1). They represented studies in 8 different countries with sample sizes ranging from 49-100 (n=11), 101-250 (n=4) and >2000 (n=1). Seven of the studies involved only females. BMI values of the study samples ranged from 23 -38 kgm⁻². The median BMI was around 28 kgm⁻² which is in the overweight range (World Health Organization, 2011).

Intervention and control diets: Most of the interventions included a higher proportion of vegetables in the context of a healthy background diet (Azadbakht et al., 2005, Burke et al., 2007, Ello-Martin et al., 2007, Svendsen et al., 2007, Lapointe et al., 2010a, Lapointe et al., 2010b, Shenoy et al., 2010, Nowson et al., 2004, Saquib et al., 2008, Thomson et al., 2005, Gardner et al., 2005, Tanumihardjo et al., 2009, Djuric et al., 2002, Sartorelli et al., 2008). The healthy background diet was defined by various means. For the intervention, 4 studies used the DASH diet framework (including 5 serves vegetables/day) (Nowson et al., 2004, Shenoy et al., 2010, Azadbakht et al., 2005, Burke et al., 2007), others specifically targeted high fruit and vegetable consumption (Sartorelli et al., 2008, Whybrow et al., 2006, Djuric et al., 2002, Jenkins et al., 2009, Tanumihardjo et al., 2009, Ello-Martin et al., 2007, Svendsen et al., 2007, Lapointe et al., 2010a, Lapointe et al., 2010b, Shenoy et al., 2010, Saquib et al., 2008, Thomson et al., 2005, Gardner et al., 2005, Rodriguez-Rodriguez et al., 2008), and one study provided participants with fruit and vegetables to consume in their usual diets (Whybrow et al., 2006). The nature and extent of dietary advice varied, with more specific advice limiting energy intakes. Given that weight loss results from a lowering of energy intake, there would have been a number of ways in which these strategies may have influenced this behaviour (or not).

Duration of intervention: The period of intervention was 4 weeks to 4 years, but just over half the studies were conducted for at least 6 months. Eleven of the studies were conducted over periods of 4wks-6 mo

(Azadbakht et al., 2005, Burke et al., 2007, Lapointe et al., 2010b, Svendsen et al., 2007, Shenoy et al., 2010, Nowson et al., 2004, Gardner et al., 2005, Rodriguez-Rodriguez et al., 2008, Whybrow et al., 2006, Jenkins et al., 2009, Sartorelli et al., 2008), with 2 papers reporting 12 mo data (Ello-Martin et al., 2007, Djuric et al., 2002), 2 reporting 18 mo data (Tanumihardjo et al., 2009, Lapointe et al., 2010a) and 2 reporting a 4 yr follow up (Saqib et al., 2008, Thomson et al., 2005). Thus there was evidence of short and long term effects, although the extent of intervention would vary across these periods.

Comparisons between trials

Study populations: There did not appear to be any particular regional pattern as to whether a study would show an effect or not. A greater weight loss in the intervention groups with higher vegetable consumption was found in different population groups. Positive effects were seen in studies from 4 regions of the globe: Iran (Azadbakht et al., 2005), Australia (Burke et al., 2007), USA (Ello-Martin et al., 2007, Shenoy et al., 2010), and Norway (Svendsen et al., 2007).

Intervention and control diets: A feature of the studies that showed a positive effect was the attention to the whole diet in the intervention model. The DASH diet framework was used in 3 of these studies (Azadbakht et al., 2005, Burke et al., 2007, Shenoy et al., 2010). The DASH diet stipulates the number of serves of staple food groups (vegetables, fruits, wholegrains, lean meats, low fat dairy foods (U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2010)) in a total diet, including 5 serves of vegetables/day. In two of these studies, the control diets were based on 'usual intake' and this was assumed to be 3 serves vegetables per day (based on population surveys) which meant a difference between groups of 2 serves/day (Azadbakht et al., 2005, Burke et al., 2007). Both studies had low drop out rates (0 and 20% respectively) and assessed dietary intakes to confirm the control diet intake of 3 and 2.7 serves vegetables/day respectively. Their intervention intakes were below target, but higher than controls at 4.4 and 3.1 serves per day respectively. The Iranian study included a second intervention diet of 500kJ energy deficit (Azadbakht et al., 2005). While this group consumed less legumes than the DASH diet group, they reported consuming 4.1

serves vegetables per day and lost more weight than the controls ($P<0.05$), but the DASH diet produced a greater weight loss ($P<0.05$). The third study used a calorie deficit DASH diet for both the intervention and control groups, but were given vegetable juice in the intervention diets. This study found those who received the vegetable juice lost more weight than the control ($P<0.05$) and those not consuming the vegetable juice reported a significantly lower vegetable intake ($P=0.002$) (Shenoy et al., 2010).

While the DASH diet was not stipulated in other studies showing a positive effect, the same principles applied. In the 12mo American study (Ello-Martin et al., 2007), participants were given detailed instructions on the types and amounts of all foods to consume in a total diet model. Substantial behavioural support was provided through group and individual sessions, but the intervention group was given more information on alternatives to high fat foods (i.e. fruits and vegetables) compared to the control group. The intervention group in the 3 mo Norwegian trial (Svendsen et al., 2007) received 6-10 group support sessions in addition to the individual dietary advice provided to the control group. Both these trials assessed differences in vegetable intakes at the completion of the study (intervention vs. control = 416g vs. 302g, and 457g vs. 238g respectively) and produced relatively low drop out rates (27% and 7% respectively).

Thus a key finding of this analysis was that studies that were able to show an effect from a higher vegetable intake paid particular attention to the total diet (including energy intakes), and focused on healthy diet models based on defined food groups in the high vegetable diets groups. They also confirmed a higher vegetable consumption in the intervention groups. To confirm this observation, we examined the dietary prescription detail of trials that failed to show an effect. In one study, no attempt was made to change the usual diet in the control and intervention groups, but moderate and high quantities of fruit and vegetables were provided to the intervention participants (Whybrow et al., 2006). A higher fruit and vegetable consumption was found compared to the control group in the two intervention groups (207 g vs. 451g vs. 640g/day respectively), but no other effects, (and the drop out rate was moderate at 34%).

The lack of control on energy intakes might also explain the result from a crossover study with 2 DASH diet periods and 2 control (low vegetable) diet periods. In this study with a low drop out rate (3%), participants reported difficulty in consuming the amount of food (Nowson et al., 2004) and the proportion of dietary carbohydrate reported for the test diet period which was less than in the DASH study itself (Appel et al., 1997). Importantly though, the reported energy intake was higher in the DASH diet period compared to the control (1.4MJ; $P < 0.001$). It should also be noted that the primary outcome for this study was change in blood pressure, not weight (Nowson et al., 2004). In this study, a second intervention group (low sodium, high potassium) that also included 5 serves of vegetables/day did produce a weight loss effect compared to the control (-0.4kg; $P < 0.05$), but that may have reflected a tighter dietary prescription in that arm of the study. Since weight loss effects are dependent on energy deficit, a focus on energy control appears to be necessary

A second group of trials that did not show effects compared high vegetable diets with control diets that were also well controlled for energy intake. In one 4week trial both the intervention and control diets were tightly controlled, food was provided and almost total compliance was achieved, with a low drop out rate (4%) (Gardner et al., 2005). In this trial both diets were designed to provide the same levels of energy, total and saturated fat, protein, carbohydrate and cholesterol, but the intervention diet contained much greater amounts of vegetables (10 vs. 2 serves), wholegrains and legumes. There was no difference between groups in weight loss but the intervention diet produced greater reductions in total and LDL cholesterol levels ($P < 0.05$). Another trial was a 6 week intervention where both diets had a 20% energy deficit and the control emphasised cereals rather than vegetables (Rodriguez-Rodriguez et al., 2008). Differences in vegetable consumption were measured (control 3.48 serves/day; NS from baseline; intervention 4.84s.day vs. 2.94 at baseline $P < 0.01$) and the drop-out rate was mild (17%). There were some noted differences in micronutrient status reflecting the food sources. Likewise a more recent study comparing plant based low carbohydrate diet with a high carbohydrate lacto-ovo vegetarian diet found a similar weight loss effect with study foods providing 60% of calorie requirements (Jenkins et al., 2009). In all of these studies energy intakes were constrained to a similar extent in both the control and high vegetable diets.

Thus where both the control and intervention diets focus on healthy eating patterns and control for energy intakes, a difference in weight loss is not likely to be seen. This is logical as weight loss is contingent on control of energy intake. A high vegetable intake may have a further influence on weight if it causes even greater reduction in energy intake, possibly through increased satiety (an effect possible seen in the Shenoy study (Shenoy et al., 2010)). Higher vegetable intake may also modify the total dietary fat and fibre content and have effects on blood lipids. Vegetables may also deliver phyto-chemical that may have a positive effect on the inflammatory status of the person. These latter effects may not be associated with weight loss but could improve overall health status.

A third group of trials were all longer term behavioural interventions targeting changes in dietary patterns. These studies focus more on general dietary advice strategies rather than specific individualised dietary advice with attention to all food groups. A recent Canadian trial comparing positive messages to promote fruit and vegetables vs. eat less fat found the low fat strategy more effective at 6 mo (Lapointe et al., 2010b) but there was no difference between groups at the 12 mo follow up (Lapointe et al., 2010a). This was similar to a previous US trial that found both the high vegetable and low fat advice strategy effective at 3mo, but better maintained at 12 and 18 mo by the low fat strategy (Tanumihardjo et al., 2009).

The remaining studies were analyses conducted within larger trials, such as the Women's Healthy Eating and Lifestyle (WHEL) (Saquib et al., 2008, Thomson et al., 2005) and Nutrition and Breast Health (Djuric et al., 2002) (NABH) studies and the Brazilian Diabetes prevention trial (Sartorelli et al., 2008), comparing healthy diets (significantly containing vegetables) with usual diet. Two studies assessed outcomes after 4 years in participants recruited from the WHEL cancer prevention trial (Saquib et al., 2008, Thomson et al., 2005). At this stage the behavioural support took the form of telephone counselling and monthly cooking classes (S) or quarterly phone calls (T). In the Saquib et al study (2008), the intervention group had increased its daily vegetable intake by 2.7 serves at 1 yr and 2.3 serves at 4 yrs. A greater weight loss in the intervention group

was observed after 1 yr (-0.05kg; $P < 0.001$) but not after 4 yr. In the Thomson study (2005), compared to virtually no change in the control group, the intervention group demonstrated an initial increase in daily serves of fruits and vegetables consumed after 6 mo which declined with time (4.7 at baseline, 8.4 at 6mo, 7.3 at 12mo, 5.3 at 48mo). This pattern concurred with the intensity of the dietary support. The drop-out rates were also higher (15% S and 32% S) as would be expected for the longer term follow up. Within the NABH trial, the 12 mo dietary study (Djuric et al., 2002) found a low fat dietary advice strategy to be the most effective for weight loss (-11lb, $P < 0.05$), but that advice to increase a food intake (even if it is fruit and vegetables) resulted in weight gain (+4lb, $P < 0.05$). When the negative diet message (low fat) was combined with a positive one (increase F&V) then weight maintenance was seen. Within the Brazilian Diabetes prevention trial, the authors of the dietary study (Sartorelli et al., 2008) applied a different form of analysis to examine the association between increased vegetable consumption and weight loss. In this way they were able to show a positive effect of vegetable consumption on weight loss (CI CI 0.00497; -0.008, -0.002).

Duration of intervention

The studies that showed a difference in effects were designed specifically to test the effects of a high vegetable consumption and were conducted between 3 and 12mo. Shorter term studies tended to have tight controls on energy intake in both the control and intervention groups, and longer term studies tended to be behaviourally focused and opportunistic. In the latter case the analysis was more observational in nature and there were likely to be confounding factors that would be difficult to overcome in specifically exposing the effects of vegetable consumption.

Discussion

On face value, this review confirmed an inconclusive position on the effect of vegetable consumption on weight loss. Trials of various durations were located from across the world, involving essentially overweight populations, but with variations in study design. A key finding was that studies that were able to show a desirable effect paid particular attention to the total diet (including energy intakes), and focused on healthy

diet models based on defined food groups in the high vegetable diets groups. These studies also confirmed a higher vegetable consumption in the intervention groups. Secondly it appeared that dietary strategies that focus on the behavioural choices of low fat eating or eating more vegetables do not necessarily test the effects of high vegetable consumption. These are behavioural strategies rather than ‘whole of diet’ prescriptions that enable a focus on individual food groups. Finally, behavioural interventions can also be found embedded in larger disease focused studies. They provide an opportunity to make observations on effects of vegetable consumption in that context but are not specifically designed to test the effects of a high vegetable consumption on weight loss outcomes.

Notwithstanding weight loss effects, where energy intake is controlled in both the intervention and control diets, improvements in other related health variables (lipids and micronutrient status) can be seen. This suggests that more subtle outcomes might deserve greater attention in food based studies in overweight populations. In our own research, we find that when we provide structured dietary advice to both the control and intervention arms, we do not see a difference in overall energy intakes and subsequent weight loss (Tapsell et al., 2004, Tapsell et al., 2009, Tapsell et al., 2010). We do however see a difference in other risk factor variables that may reflect dietary attributes other than total energy. For example, in our trials (Tapsell et al., 2004, Tapsell et al., 2009) including walnuts in the diet model resulted in a substitution of saturated fat (SFA) with polyunsaturated fat (PUFA) which may have influenced other risk factors associated with the metabolic syndrome. A recent meta-analysis has shown that replacing dietary SFA with PUFA is important in reducing risk of coronary heart disease (Mozaffarian et al., 2010).

Given that weight loss is dependent primarily on total dietary energy there are substantial implications for RCT design. While studies that control for dietary patterns (structured advice vs. usual diet) may produce differences in weight loss, studies that control for individual foods (structured advice with test food vs. structured advice with control food) might elucidate more subtle effects on related disease risk factors. The DASH diet background may have a particular profile that results in more effective weight loss than a simple

energy deficit diet, but as the authors of one of the studies (Azadbakht et al., 2005) noted, one of the limitations of this ‘whole of diet’ research is that it cannot clearly differentiate between individual foods and the sum of the parts in diet.

When food is simply added to usual intakes it is not surprising that weight loss effects are not seen. This was the case in a vegetable supplementation study (Whybrow et al., 2006), where both the control and intervention groups applied a ‘usual diet’ framework. It is important to note that this group had a lower BMI ($23.7 \pm 2.7 \text{ kg m}^{-2}$), compared to the others ($\sim 26\text{-}36 \text{ kg m}^{-2}$). This design may be useful in seeing if supplementation had any behavioural effect on total intake (for example by displacing other foods or increasing satiety). This did not appear to be the case, at least not in a less overweight group. Where we have used supplemental foods and advised participants to replace other foods with the supplements in a ‘usual diet’ framework, we have found that providing supplemental foods increased overall energy intake and introduced a confounder of weight gain (Murphy et al., 2007). This was also the case in another of the studies reviewed here (Djuric et al., 2002), where the arm receiving advice to consume large amounts of fruit and vegetables produced weight gain. In the end it is not vegetable consumption *per se* that effects weight loss, but total dietary energy. This is an important distinction that needs to be drawn in RCTs for foods. Under certain dietary conditions increased vegetable consumption may support weight loss but they also deliver components that may have protective effects on disease risk factors.

In a recent multi centre trial of various dietary prescriptions for weight loss it was found that no difference between diet groups could be found in the long term, however, dietary targets were not reached in many cases (Sacks et al., 2009). In order to answer the question, does a higher intake of vegetables produce a greater weight loss, it is necessary to know that the trials produced a different intake between comparative groups. In the studies we reviewed, these differences were confirmed, although the intakes at the end of the intervention were not always as high as intended. The serve sizes varied between but not within studies, and most studies did not specify the types of vegetables used. Both of these factors may benefit from further research in

exposing greater detail on the effects of vegetable consumption. Where longer term follow up (4yr) was reported, the lack of effects may have been due to the reported decline in vegetable intake (Saquib et al., 2008, Thomson et al., 2005). The reason for the decline in intakes may have to do with the extent of support for behaviour change. In this case we can only say that the advice strategy, not higher vegetable consumption itself, failed to show a long term effect.

In the two long term studies reviewed here (Thomson et al., 2005, Saquib et al., 2008), the reduction in contact and change in nature of behavioural support between the early and later stages of the intervention are likely to explain the difference in intakes and thereby effects seen at 1 yr vs. 4 yrs. The detailed behavioural support for the intervention groups in which positive effects were seen (Ello-Martin et al., 2007, Svendsen et al., 2007) was also likely to assist in those studies being able to produce effects due to high levels of compliance to the study diets. Given the complexity of dietary change and the need for a good understanding of food attributes, behavioural support and dietary counselling is an important element of dietary intervention design. In other major dietary intervention trials, effects seen reflect the intensive dietary counselling and advice provided to participants (Zazpe et al., 2008). In our review of the literature, successful trials were able to demonstrate effects at 3, 4, 6 and 12 mo. In our own trials we have consistently shown significant effects in the first intensive period of intervention (Tapsell et al., 2004, Tapsell et al., 2009, Tapsell et al., 2010), but with a waning after 6 mo when contact is less intense. We suggest that the true effects of diet can be established within a couple of months with strong support, and that any recidivism is likely to be due to changes in food choice. Future studies may need to focus attention on behavioural support in the later stages of longer term studies so that effect of the dietary model is not confused with efficacy of the treatment advice.

On face value, there is some evidence that a healthy diet higher in vegetables may be conducive to weight loss in overweight adults. In the studies reviewed better weight loss was consistently found in higher vegetable (and otherwise healthy) intervention diets compared to 'usual diets'. This effect was seen regardless of the considerable variation in the manner in which weight loss results were reported and analysed. Factors over

and above weight loss are of clear interest in dietary studies, given that in addition to weight loss (Sartorelli et al., 2008, Ello-Martin et al., 2007, Rodriguez-Rodriguez et al., 2008, Saquib et al., 2008, Thomson et al., 2005), the outcomes analysed for the studies reviewed here ranged from multiple features of the metabolic syndrome (Azadbakht et al., 2005, Burke et al., 2007, Svendsen et al., 2007), weight loss and dietary compliance (Djuric et al., 2002, Whybrow et al., 2006), plasma lipids (Gardner et al., 2005), and blood pressure (Nowson et al., 2004). Given that the primary outcome was not always weight loss, the main reported result for our purposes was the weight loss compared to baseline and/or comparative group. We have found that even with isocaloric dietary advice strategies, weight loss results from dietary intervention (Tapsell et al., 2004, Tapsell et al., 2009, Tapsell et al., 2010), so greater confidence would be expected where results are presented with significant time X group effects. This may not always do justice to the research, however. In their study of participants in a Diabetes prevention trial, Sartorelli et al. (Sartorelli et al., 2008) argued for the value of presenting the analysis on the total group data, exposing the relationship between increased vegetable consumption and greater weight loss. This was in consideration of the substantial problems with drop outs and lack of compliance in conducting food based dietary interventions under free living conditions. This is an important issue and has implications for publication bias, given the increasing requirement to register clinical trials (ANZCTR, 2011) and address study attributes as outlined in the CONSORT statement (Schulz et al., 2011). To this end we also acknowledge the limitations of our review in that we did not formally apply critical appraisal methods outlined in the Cochrane or PRISMA approaches (Moher et al., 2009), however, the focus of this review was to highlight issues of study design rather than establish an evidence statement for practice where risk of bias is a critical consideration. Indeed we may have uncovered another form of bias that may require more detailed attention.

Conclusion

This review found evidence that a higher vegetable consumption in a healthy diet may prove beneficial for weight loss in overweight adults from Western populations when the trial compares a healthy high vegetable diet with a control diet based on usual consumption patterns, and where behavioural support and counselling

are provided throughout the period of the study. Changes in dietary intakes need to be confirmed by dietary assessment techniques, and there are challenges for considering how the results might best be analysed and presented. This is because body weight is dependent on total energy intake, but more subtle effects related to the pathology of overweight (such as effects on lipids, blood pressure and other biomarkers) may help to differentiate the benefits of single foods that would otherwise appear to have a real place in a healthy weight loss diet.

CONFIDENTIAL

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Fig 1. Search Strategy Flow Diagram

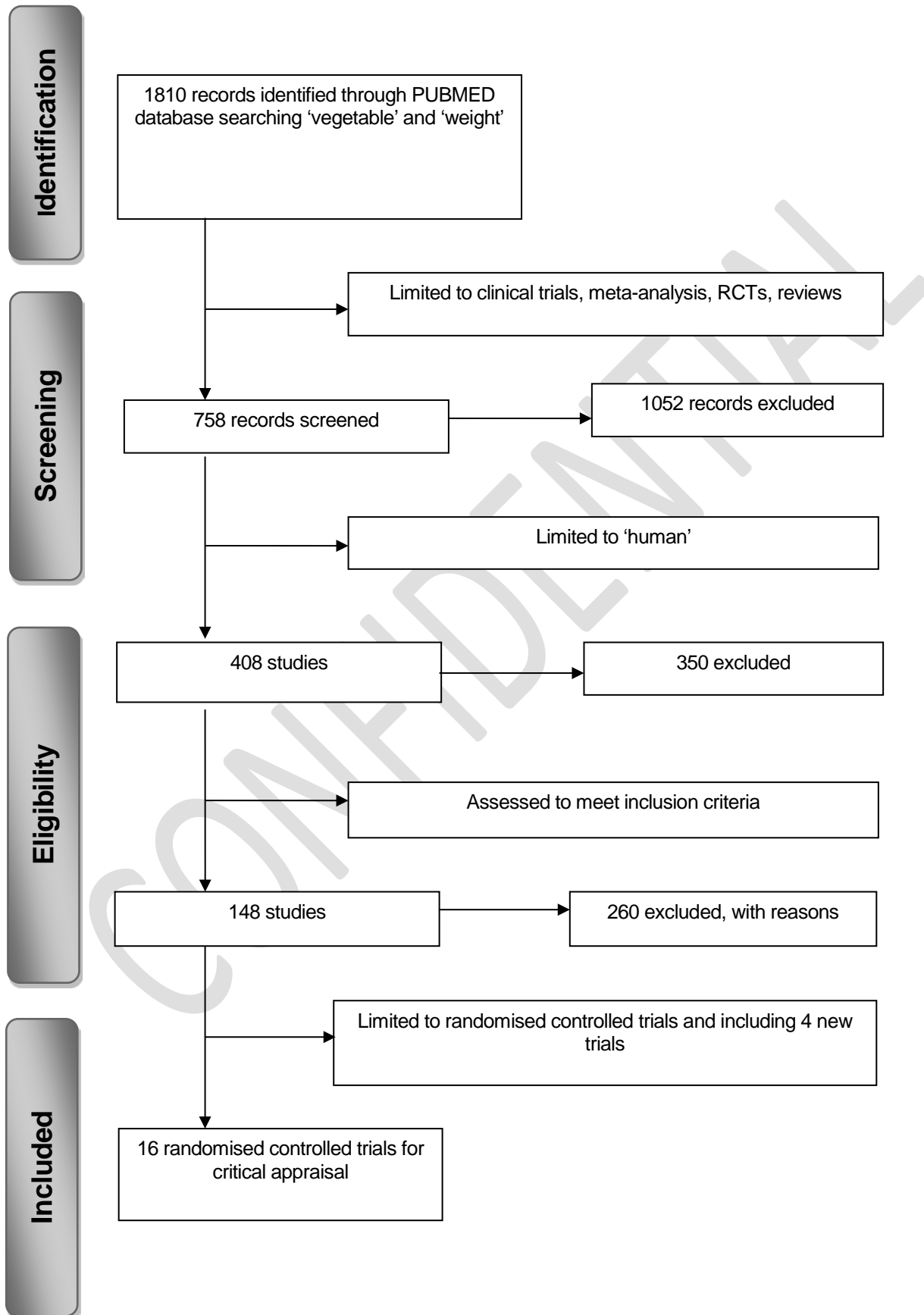


Table 1. Randomised controlled trials on vegetables consumption and weight loss 1998-2010 – Positive effects

Study Population	Intervention Diet(s)	Control Diet	Duration	Results	Reference(s)
Iranian TLGS study participants n = 116 (82 F, 34 M) MetS BMI = 29.7 +/-10kgm ⁻²	DASH Diet (including 5 serves vegetables/day) Energy Deficit Diet (-500kJ)	Usual diet (assumed 3 serves vegetables/day)	6mo	Greater weight loss with DASH diet compared to the control (-16kg for M and -14kg for F; P<0.001) Greater weight loss with energy deficit diet compared to control (-13kg for M and -12kg for F; P<0.05)	Azadbakht et al Diabetes Care 2005;28:2823-31
Australian n = 241 (134 F, 107 M) BMI = 30.0 +/- 2.7kgm ⁻²	DASH Diet (including 5 serves vegetables/day)	Usual diet (approx 3 serves vegetables/day)	4mo	Greater weight loss with DASH diet compared to control (-2.8kg; P<0.001)	Burke et al J Clin Epi 2007;60:133-41
American (USA) n = 71 (F) BMI = 33.3 +/- 0.4kgm ⁻²	Lower fat + FV (approx 400gFV/day)	Lower fat (LF) (approx 300gFV/day)	12mo	Greater weight loss in LF+FV compared to LF group (-1.5kg; P <0.01)	Ello-Martin et al Am J Clin Nutr 2007;85:1465-77
Norwegian n = 138 (35 F, 103 M) BMI = 36.7 +/- 5.8kgm ⁻²	Healthy diet [targeting ≥400g/day vegetables and ≥300g/day fruit)	Usual diet	3mo	Greater weight loss from healthy diet (-2kg; P<0.001)	Svensen et al Eur J Clin Nutr 2007;61:1301-11
USA (ethnically diverse) n = 81 (59 F, 22 M) BMI = 37.8±4.9 kgm ⁻²	8 fluid ozs. of low Na vegetable juice/d + DASH diet 16 fluid ozs. of low Na vegetable juice/d + DASH diet	No vegetable juice/d + DASH diet	12wks	Subjects consuming ≥1 serve of veg juice lost more weight than those who did not	Shenoy et al Nutr J 2010; 9:8-19

Table 2. Randomised controlled trials on vegetables consumption and weight loss 1998-2010 – No effect

Study Population	Intervention Diet(s)	Control Diet	Duration	Results	Reference(s)
Australian n = 94 (38 F, 56 M) BMI = 29.0 +/- 3.8 kgm ⁻²	DASH diet (including 5 serves vegetables/day) Low Na High K (LNHK) (including 5 serves vegetables/day) High Ca (HC) (no specification for vegetables)	Low Ca / Low K (including 3 serves vegetables)	2 x 4wks	No difference in weight between DASH and control. Greater weight loss between LNHK and control (-0.4kg; P<0.05) Greater weight gain between HC and control (+0.9kg; p<0.001)	Nowson et al J Nutr 2004;134:2322-39
USA WHEL study participants n = 2718 (All F) BMI = 27.3+/- 6.3kgm ⁻²	Healthy diet (including ≥5 serves vegetables)	Usual diet	4yr	Greater weight loss with healthy diet after one year (-0.05kg; P<0.0001) No difference after 4 yr.	Saquib et al Nutr Cancer 2008;60:31-8
American (USA) WHEL study participants n = 97(F) BMI = 26.7 +/- 4.5kgm ⁻²	Low fat diet [including 8 serves fruit and vegetables/day)	General dietary advice for cancer prevention	4yr	No difference between groups in body weight change	Thomson et al Eur J Nutr 2005;44:18-25.
American (USA) n = 120 (60 F, 60 M) BMI = 26.5 +/- 3kgm ⁻²	Low fat plus (including 10 serves vegetables/day)	Low fat (including 2 serves vegetables/day)	4 wk	No difference between groups in body weight change	Gardner et al Ann In Med 2005;142:725-33.
Spanish n = 49 (F) BMI = 28.5 +/- 2.8kgm ⁻²	20% energy deficit Vegetable diet (including 4.5 serves vegetables/day)	20% energy deficit Cereal diet (including 3.5 serves vegetables/day)	6 wks	No difference between groups in body weight change	Rodriguez et al IJO 2008;32:1552-58.
Scotland (UK) n = 62 (28 F, 34 M) BMI = 23.7 +/- 2.7kgm ⁻²	300g fruit and vegetables provided 600g fruit and vegetables provided	No food supplements	2mo	No difference between groups in body weight change	Whybrow et al BJN 2006;95:496-503
USA n = 60 (44 F, 16 M) BMI = 33.7±3.8 kgm ⁻² (HiVeg); 33.3±3.5 kgm ⁻² (Reduction)	High vegetable (≥ 8 serves/d) and moderate fruit (2-3 serves/d) consumption (HiVeg)	Energy- and fat- reduction diet (Reduction)	18mo	HiVeg group lost weight after 3mo (p=0.0087), but did not maintain weight loss at 12- and 18-mo. Control group lost weight at 3mo (p<0.0001) and maintained weight loss at 12- and 18-mo.	Tanumihardjo et al Exp Biol Med 2009; 234:542-552

Table 2. Randomised controlled trials on vegetables consumption and weight loss 1998-2010 – No effect cont.

Study Population	Intervention Diet(s)	Control Diet	Duration	Results	Reference(s)
Canadian N = 68 (All F)	Positive messages to promote fruit and vegetable intake (HIFV)	Restrictive messages to decrease fat intake (LOFAT)	6mo	HIFV weight loss: -1.6 ± 2.9 kg (p=0.0004) LOFAT weight loss: -3.5 ± 2.9 kg (p<0.0001) LOFAT group lost more weight than HIFV group from 0 to 6mo (p=0.01)	Lapointe et al Eur J Clin Nutr 2010; 64:194-202
Canadian N = 68 (All F) Weight = 85.8 ± 8.9 kg (LOFAT); 85.0 ± 8.9 kg (HIFV)	Positive messages to promote fruit and vegetable intake (HIFV)	Restrictive messages to decrease fat intake (LOFAT)	6mo intervention 12mo follow-up	No difference between groups in body weight change at 12mo follow up	Lapointe et al Brit J Nutr 2010; 104:1080-1090
Canada/USA (ethnically diverse) n = 47 (26 F, 18 M) BMI = 31.0 ± 2.4 kgm ⁻² (High CHO); 30.6 ± 2.9 kgm ⁻² (Low CHO)	40% energy deficit low CHO plant based diet (low CHO - 26%, high veg protein - 31% & veg oil - 43%)	40% energy deficit high CHO lacto-ovo vegetarian diet (58% CHO, 16% protein & 25% fat)	4wks	No difference between groups in body weight change	Jenkins et al Arch Intern Med 2009; 169:1046-4054

Table 3. Randomised controlled trials on vegetables consumption and weight loss 1998-2010 – Other effect

Study Population	Intervention Diet(s)	Control Diet	Duration	Results	Reference(s)
American (USA) NABH study participants n=97 (F) BMI: not specified Weight = 150±30 lbs	Low fat (LF) High fruit & vegetable (HFV) Low fat-high FV (including 9 serves vegetables & fruit/day)	Usual diet (approx 2 serves FV/day)	12mo	Weight loss with LF: -11lb (p<0.05) Weight gain with HFV: +4lb (p<0.05) No change with LFHFV No change Control Diet	Djuric et al Nutr & Cancer 2002; 43:141-51
Brazilian Diabetes prevention trial participants n = 80 (61 F, 19 M) BMI = 28.7+/- 2.5kgm ⁻²	Healthy diet (including 5 serves vegetables/day)	Usual diet	6mo	Increased consumption of vegetables associated with greater weight loss [CI- 0.00497; -0.008, -0.002]	Sartorelli et al Nutr Res 2008;28:233-8

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