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Approaches to Weight Maintenance in Adults: A Comparative Effectiveness Review

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Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Prepared by:

Investigators:

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public and private sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting comparative effectiveness reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see http://www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input from are essential to the Effective Health Care Program. Please visit the Web site (http://www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e mail to epc@ahrq.hhs.gov.

Carolyn M. Clancy, M.D.
Director,
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Stephanie Chang M.D., M.P.H.
Director, EPC Program
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Christine Chang, M.D., M.P.H.
Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

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Key Informants

Technical Expert Panel

Comparative Effectiveness of Approaches for Weight Maintenance in Adults

Structured Abstract

Objectives

One of the Healthy People 2020 objectives is to reduce the prevalence of obesity among adults to less than 30 percent and to increase the prevalence of healthy weight adults to 34 percent. Adults tend to gain weight progressively through middle age. Although the average weight gain is 0.5 to 1 kg per year, this modest accumulation of weight over time can lead to obesity. We aimed to compare the effectiveness, safety, and impact on quality of life of approaches to prevent weight gain in adults. Studies targeting a combination of weight loss with weight maintenance or weight loss exclusively were considered to be outside of the scope of this review.

Data sources

We searched MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, CINAHL, and PsycINFO through May 2011 for published articles that were potentially eligible for this review..

Review methods

Two reviewers independently reviewed titles, abstracts and articles, and included English language articles that reported on maintenance of weight or prevention of weight gain in adults. Trials and observational studies with at least one year of followup were included. Data was abstracted on measures of weight, adherence, obesity related outcomes, safety, and quality of life. The timepoints of interest for data abstraction of weight outcomes were at: 1 year, 2 years, 5 years, and the last reported timepoint after 5 years. For the other outcomes, we abstracted data only from the last reported timepoint on or after 1 year. We selected a clinically meaningful threshold in addition to a statistically significant threshold ($p<0.05$) for reporting on the outcomes. A clinically meaningful difference was defined as 0.8 units of BMI (based on a 3 percent change in baseline for an individual with a BMI of 27), 2.5 kg of weight or 2 cm of waist circumference less than the comparison group. For example, if an intervention group's average weight at the end of the study was closer to their baseline average weight than the control group, and the intervention group's weight change was at least 2.5kg less than the weight change in the control, we considered the finding clinically significant. We qualitatively synthesized the studies by population, intervention, and outcome.

Results

We included 50 publications (describing 44 studies) involving 555,659 patients. Two approaches were effective at preventing weight gain compared with no intervention with moderate strength of evidence: a college class about nutrition, and exercise performed at home among patients with cancer. Effective approaches with low strength of evidence included watching less television, eating meals prepared at home, avoiding potato chips and French fries, initiating and maintaining an exercise program and a multimodal approach based on goal-setting. When reported, adherence tended to be below 80 percent. There were no adverse events. Study quality tended to be poor due to knowledge of the intervention by the study personnel who measured the weight of the participants. The lack of blinding of the outcome assessor combined with studies that were not designed to prevent weight gain resulted in lower strength of evidence for the majority of comparisons

Conclusions

The evidence provides some, although limited, support for interventions to prevent weight gain. More studies are needed to evaluate the comparative effectiveness of these interventions.

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Executive Summary

Background

Condition

One of the Healthy People 2020 national objectives is to reduce the prevalence of obesity among adults to less than 30 percent and to increase the prevalence of a healthy weight among adults to 34 percent.[1] From 2005 to 2008, only 31 percent of adults were at a healthy weight.[2] Obesity was estimated to cost $79 billion dollars in the U.S. during 1995. By 2008, it was thought to have risen to $147 billion dollars. The U.S. Government pays about one half of the cost of obesity care through Medicaid and Medicare spending.[3]

Body mass index (BMI) – expressed as weight in kilograms divided by height in meters squared (kg/m^2) – is commonly used to classify underweight (BMI <18.5 kg/m^2), healthy or normal weight (BMI 18.5–24.9 kg/m^2), overweight (BMI 25.0–29.9 kg/m^2), obesity (BMI ≥30.0 kg/m^2), and extreme obesity (BMI ≥40.0 kg/m^2).

Adults tend to gain weight progressively through middle age. Although the average weight gained per year is 0.5 to 1 kg, the modest accumulation of weight over time can lead to obesity.[4] The estimated age adjusted prevalence of overweight and obesity (BMI ≥25.0 kg/m^2) was 68 percent in the US from 2007 to 2008. Despite the doubling in the prevalence of obesity between 1976 and 1980 and 2007 to 2008 (13 to 34 percent), the prevalence of overweight has remained stable between the same time periods (32 to 34 percent).

Obesity is a risk factor for chronic conditions including cardiovascular disease, type 2 diabetes, arthritis, certain types of cancer, and cancer recurrence.[5 12] Obesity can also be caused by medications used to treat chronic disease as is the case for many patients with mental illness.[13] Higher grades of obesity are associated with excess mortality, primarily from cardiovascular disease, type 2 diabetes, and certain types of cancer.[14]

We aimed to review studies of strategies for weight maintenance in adults. The strategies of interest were self management techniques, diet, physical activity, use of the dietary fat absorption inhibitor, orlistat; or combinations of these approaches applied at the individual or community/environment level. These strategies could have been implemented in any setting, including clinical care sites, community settings, higher education institutions, and workplaces. Approaches could have targeted individuals at high risk of gaining weight because of a family history of obesity or diabetes mellitus, or because of use of medication associated with weight gain,[15] or have more inclusive enrollment criteria.[16 17]

Scope and Key Questions

We aimed to compare the effectiveness, safety, and impact on quality of life of independent and combined approaches to preventing weight gain in adults. Studies targeting a combination of weight loss with weight maintenance or weight loss exclusively were considered to be outside of the scope of this review.

The specific Key Questions (KQ) are:

KQ 1: What is the comparative effectiveness of self management approaches for the prevention of weight gain in adults?

KQ 2: What is the comparative effectiveness of dietary approaches for the prevention of weight gain in adults?

KQ 3: What is the comparative effectiveness of physical activity approaches for the prevention of weight gain in adults?

KQ 4: What is the comparative effectiveness of orlistat for the prevention of weight gain in adults?

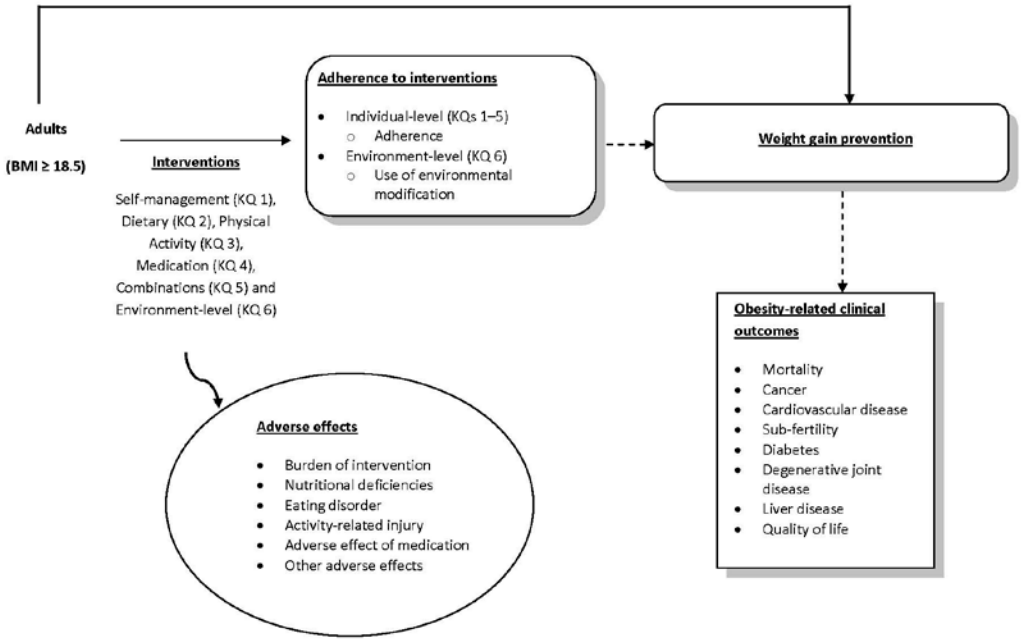
KQ 5: What is the comparative effectiveness of a combination of self management, dietary, physical activity, and orlistat approaches for the prevention of weight gain in adults?

KQ 6: What is the comparative effectiveness of environment level approaches for the prevention of weight gain in adults?

We aimed to answer these questions by reviewing studies of adults, including subgroups of individuals at high risk of weight gain, which compared diet, physical activity, use of orlistat, or a combination of these interventions over at least one year on the individual or environment level. The outcomes of interest were BMI, weight, waist circumference, obesity related clinical outcomes, health related quality of life and adverse effects (Figure 1).

Adverse effects included burden of the intervention (which may impact adherence), nutritional deficiencies (for dietary interventions), eating disorders (from an increased focus on weight among non obese individuals), activity related injury (for physical activity interventions), and adverse effects of orlistat. Clinical outcomes of interest included conditions associated with obesity.

Figure 1. Analytic framework for comparative effectiveness of approaches to weight maintenance in adults



Abbreviations: BMI = body mass index; KQ = key question.

Methods

Literature Search Strategy

We searched the following databases for primary studies: MEDLINE® through May 2011, Embase through May 2011, the Cochrane Central Register of Controlled Trials, CINAHL and PsycINFO through May 2011. We developed a search strategy for MEDLINE, accessed via PubMed and developed comparable searches using the other databases. We also reviewed the reference lists of each included article and relevant review articles.

We performed title, abstract and full article reviews performed by two independent reviews to identify relevant publications. Only one reviewer had to identify the publication as relevant to be included at title review. At abstract review, both reviewers had to agree that the study did not include any exclusion criteria (Table 1). At full article review, both reviewers had to agree that the article met the inclusion criteria. Conflicts were resolved by consensus adjudication.

Relevant data were extracted from eligible articles with a focus on items related to the population, approaches and interventions, comparisons, outcomes, timing and setting. Each article was serially abstracted first by a first reviewer then by a more senior reviewer. Serial data abstraction involved a senior reviewer (project investigator) abstracting data from articles while having access to the first reviewer's data. Differences in opinion were resolved through consensus adjudication and in difficult cases, during team meetings. The timepoints of interest for data abstraction of weight outcomes were at: 1 year, 2 years, 5 years and the last reported timepoint after five years of followup. For the intermediate outcomes, safety and quality of life outcomes, we only abstracted data for the last reported timepoint on or after one year.

Quality Assessment of Individual Studies

The quality and risk of bias were assessed using the Downs and Black methodologic quality assessment checklist.[18] This checklist was developed to assess the quality of reporting, internal validity and external validity for individual randomized and non randomized studies. Two reviewers independently completed the checklist for each article and came to consensus for each individual item on the checklist.

Data Synthesis

When there were three or more studies with comparable interventions and comparable outcome measures, we considered quantitative pooling of the results. We examined the studies' designs and planned meta analyses if the studies were qualitatively similar. Because we found that no groups of studies were amenable to pooling with meta analyses, we calculated and displayed the individual mean differences, risk differences or relative risks with 95 percent confidence intervals (CI) for the individual studies grouped by study population or comparable interventions.

We selected a clinically meaningful threshold in addition to a statistically significant threshold ($p<0.05$) for reporting on the outcomes. A clinically meaningful difference was defined as 0.8 units of BMI (based on a 3 percent change in baseline for an individual with a BMI of 27), 2.5 kg of weight or 2 cm of waist circumference less than the comparison group.

Table 1. Study inclusion and exclusion criteria

Population and condition of interest	Human participants Adult participants for KQ1 5. If a study includes some participants under age 18 years and results are not reported separately for adults, the study will be included as long as 90percent of the total population is 18 years and older. Studies of obese patients were included if the study did not describe the goal of the intervention to be weight loss or maintenance of weight after weight loss. All ages are included for KQ6; approaches are implemented at the community level. *Excluded* studies if they included only pregnant women. *Excluded* studies that included only patients at risk of weight loss (*e.g.,* wasting disease, eating disorders), or with a BMI <18.5
Interventions and approaches	Studies must have evaluated an approach of interest as defined by KQ1 5. Included studies of orlistat Included studies of caloric substitutes, such as olestra or artificial sweeteners. Included studies of lifestyle interventions for KQ5. Included studies implemented at a community level for KQ6. *Excluded* studies if the goal of the study was weight loss, a combination of weight loss and weight gain prevention (without a separate reporting of results), or weight maintenance after weight loss. *Excluded* studies of biological determinants (such as genes) as the exposure. *Excluded* studies of herbal supplements, vitamins, and minerals. *Excluded* studies that included a smoking cessation intervention or approach.
Comparisons of interest	No intervention, usual care, or comparison to other self management, dietary, physical activity, device, pharmaceutical or combination of approaches will be included. Included studies comparing different intensities of the same approach (*e.g.,* low fat versus high fat diet) *Excluded* studies if a study compares an approach of interest to an approach not of interest *Excluded* studies if there was no comparison
Outcomes and Timing	One year of observation of weight during adulthood was required. Weight change must have been reported relative to an approach of interest. Measures of weight change included weight, BMI or waist circumference. Obesity related clinical outcomes, intermediate outcomes, adverse effects and quality of life were abstracted only if the study also reported a qualifying measure of weight.
Type of study	Accepted studies with any sample size from any year that met all other criteria. Included all studies designs including prospective (randomized and non randomized), retrospective, crossover, and case control studies. Serial cross sectional studies of the same population were also eligible for KQ6. Observational studies had to account for confounding and losses to followup in the design or analysis to be eligible. Crossover studies must have reported at least 1 year of weight change in each phase of the crossover to be included. For KQ1 5 inclusion, the participants measured at the first time point must have been the same participants measured at the later time points. For KQ6 inclusion, the participants measured at the first time point were not required to be the same participants as those measured at the later time points. *Excluded* studies with no original data (reviews, editorials, comments, letters, modeling only studies). *Excluded* studies published only as abstracts. *Excluded* qualitative studies that did not provide quantitative information on an approach of interest and weight, such as focus groups or directed interviews.

KQ=key question, RCT = randomized controlled trial

Rating the Body of Evidence

At the completion of our review, we graded the quantity, quality and consistency of the evidence addressing Key Questions 1 through 6 by adapting an evidence grading scheme recommended by the Guide for Conducting Comparative Effectiveness Reviews.[19] We created evidence grades for each comparison and outcome. We used four domains to yield a final evidence grade: Risk of Bias, Consistency, Directness and Precision.

We classified evidence pertaining to Key Questions 1 through 6 into four categories: (1) "high" grade (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of the effect); (2) "moderate" grade (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of the effect and may change the estimate); (3) "low" grade (indicating low confidence that the evidence reflects the true effect and further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate); and (4) "insufficient" grade (no evidence identified). A comparison outcome pair with high strength of evidence was one with low risk of bias, consistency (or not applicable if only one study contributed), directness and precision. Moderate strength of evidence indicated that one domain did not receive an optimal score (one of the following was observed: moderate risk of bias, inconsistency, indirectness or imprecision). Low strength of evidence indicated a low risk of bias or two or three of the following were observed: inconsistency, indirectness and imprecision. Details on how the risk of bias, consistency, directness and precision were identified are provided in the body of the report.

The team discussed the process they used to grade evidence throughout the report writing process. When a team member felt the evidence grade was questionable, this comparison outcome evidence grade was discussed at a team meeting.

Applicability

We describe the applicability of studies in terms of the degree to which the study population, approaches or interventions, outcomes, and settings were relevant to individuals at risk of weight gain and features that may affect the effectiveness of the intervention.[20]

The populations included in the studies affect the generalizability of the results. For this reason, we report the results ordered by the studied population. The most inclusive population (adults from the general population not selected based on underlying comorbidity or setting) is reported first, followed by interventions that were tested in individuals in a specific setting (workplace based and college based) and finally by groups of individuals with a disease or at risk of a disease (cardiovascular disease, cancer and mental health). For consistency with the reporting of the results, we graded the strength of evidence using the above process for each population and setting.

Results

Results of Literature Searches

From the 22,861unique articles identified from electronic resources, 50 publications were included describing 44 studies. Thirty three interventional studies included 134,673 participants

at baseline. The majority of interventional studies were randomized trials that were not designed to prevent weight gain. Twelve observational studies included 420,986 participants at baseline. Most of the observational studies were sub analyses of existing cohorts or randomized trials. Only one of the observational studies came from a cohort that was explicitly designed to measure weight change over time. [21]

Results by Population or Setting of the Intervention or Approach

Very few interventions or approaches led to a clinically meaningful maintenance of weight as measured by changes in BMI, weight or waist circumference. When adherence was reported, it tended to be poor (less than 80 percent adherence). Poor adherence may have been one reason for the lack of effectiveness observed across interventions and populations.

Very few studies reported on obesity related clinical outcomes or adverse effects. All evidence for these outcomes was graded as low strength of evidence. No comparative study of orlistat for indications other than weight loss or weight maintenance after weight loss was identified. For this reason, Key Question 4 has no studies upon which we can report.

The interventions that did prevent weight gain are described by population below; if no intervention prevented weight gain in a population, we describe the interventions that were identified. The strength of evidence for the body of evidence is provided in Table 2.

Evidence Among Adults From a General Population

Eleven randomized trials (52,832 participants) and 11 prospective cohorts (418,520 participants) were identified. The strength of evidence is low but supports that watching less television, eating fewer meals prepared outside of the home, avoiding potato chips and French fries, monitoring heart rate during exercise and increasing the duration of exercise over time contribute to weight maintenance.

Evidence for Workplace Based Approaches

Four randomized trials (73,012 participants) were identified. The strength of evidence is low that workplace based approaches do not prevent weight gain.

Evidence for College Based Approaches

Two randomized trials (155 participants) were identified. The strength of evidence is moderate thatcoursework about nutrition and weight, taken for credit, prevents weight gain in the subsequent year.

Evidence Among Adults at Risk for or With Cardiovascular Disease or Diabetes Mellitus

Ten randomized trials and one non randomized trial (3,693 participants) were identified. The strength of evidence is low but supports that goal setting and strategies involving a multimodal approach prevent weight gain.

Evidence for Adults With Cancer

Three randomized trials (2,671 participants) and one prospective cohort based on a cancer registry (1,966 participants) were identified. The strength of evidence is moderate that aerobic and resistance exercise performed at home prevent weight gain among women with cancer. The

strength of evidence is low that dietary interventions aimed at decreasing the percentage of calories from fat prevent weight gain among women with cancer.

Evidence for Adults With Mental Illness

Two trials were identified (163 participants). A randomized trial provided fruits and vegetables to group homes of people schizophrenia. A non randomized trial combined a behavioral intervention with education on diet and exercise among patients initiating anti psychotic medications. Neither intervention prevented weight gain.

Table 2. Summary of the Strength of Evidence*

	BMI	Weight change	Waist circumference	Progression to overweight or obese	Adherence	Quality of Life	Mortality	Adverse events
General population								
Self management	Insufficient	**Low Less TV viewing favored**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	**Low No difference**	**Low Dietary change favored**	**Low Dietary change favored**	**Low Dietary change favored**	Insufficient	Insufficient	**Low No difference**	Insufficient
Physical activity	**Low Physical activity favored**	**Low No difference**	**Low No difference**	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	**Low No difference**
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low No difference**	**Low No difference**	**Low No difference**	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient
Environment level	**Low No difference**	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
College based								
Self management	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Physical activity	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Moderate No difference**	**Moderate No difference**	**Low No difference**	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient
Environment level	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Workplace based								
Self management	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Physical activity	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low No difference**	**Low No difference**	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient
With or at risk for cardiovascular								

disease or diabetes mellitus								
Self management	**Low Goal setting favored**	**Low No difference**	**Low Goal setting favored**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	**Low No difference**	**Low No difference**	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Physical activity	**Low No difference**	**Low No difference**	**Low Endurance exercise favored**	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low Diet and exercise favored**	**Low Diet and exercise favored**	**Low No difference**	Insufficient	**Low No difference**	Insufficient	Insufficient
Cancer								
Self management	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	**Low Decreasing fat favored**	**Low No difference**	Insufficient	Insufficient	**Low Adherence was good**	Insufficient	Insufficient	Insufficient
Physical activity	Insufficient	**Moderate Home exercise favored**	Insufficient	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low No difference**	Insufficient	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	**Low No adverse events**

Table 2. Summary of the Strength of Evidence*(continued)

	BMI	Weight change	Waist circumference	Progression to overweight or obese	Adherence	Quality of Life	Mortality	Adverse events
Psychiatric disorders								
Self management	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	**Low**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Physical activity	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	Insufficient	**Low**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient

* No studies were identified that assessed the impact of orlistat on weight maintenance (Key Question 4).

Discussion

Key Findings and Strength of Evidence

We did not find strong evidence to support any approach for preventing weight gain. This conclusion is similar to a previous systematic review on prevention of weight gain.[22]

Approaches that were effective include watching less television, eating meals prepared at home, avoiding potato chips and French fries, initiating and maintaining an exercise program, and taking a for credit college course prevent weight gain. However, only two of these approaches had moderate strength of evidence: taking a for credit college course and home based exercise among women with cancer.

No comparison was graded as high strength of evidence. Three comparisons were graded as moderate strength of evidence. All others were low or insufficient evidence. The strength of evidence was low for many comparisons because the studies were not designed to measure weight maintenance and the study staff that measured weight in the intervention studies may have been aware of the participants' exposure groups.

Despite the attention on primary prevention of obesity,[23 29] there is little evidence to recommend specific interventions that will achieve this goal. Existing recommendations are frequently based on intermediate measures of changes in diet or physical activity. For example, the recommendations by the Centers for Disease Control and Prevention for community interventions to prevent obesity acknowledge that the evidence to support the recommendations were not based on studies of at least one year duration that measured weight as an outcome, but on short term changes in food choices or use of environmental modifications to facilitate physical activity.[23]

The World Health Organization European Ministerial Conference on Counteracting Obesity recommended that primary care providers play a more active role in preventing obesity.[26] Although the American Medical Association recommends the prevention of inappropriate weight gain[30] reimbursement for the time required to provide weight maintenance counseling for the non obese is not supported by Medicare.[31,32]

The lack of reimbursement may at least partly explain the low adherence with these recommendations by providers. An analysis of the Behavioral Risk Factor Surveillance Survey data in 2003 indicated that only 2.6 percent of individuals with a BMI between 18 and 25 received advice to maintain their current weight by a healthcare provider.[33]

Although evidence is limited to support factors associated with weight gain prevention, the theoretical rationale to prevent weight gain is sound given the robust evidence that obesity is associated with poor health outcomes,[5 12] is costly,[3] and is difficult to reverse.[34]

Three of the interventions targeted populations experiencing life changes such as attending college[35] or beginning to cohabitate with a partner.[36] During these periods of change, individuals may be more amenable to accept a lifestyle modification or more likely to be adherent to the changes. Although these interventions did not uniformly result in weight maintenance compared to control or result in higher levels of adherence, designing interventions to be implemented during these and other life changes (*e.g.*, post partum, retirement, relocating to a new region) may be considered in future research.

Identifying an individual's interest level in an intervention prior to recommending a weight maintenance strategy may also be of interest. Many studies randomized participants to an intervention followed by multiple in person visits, phone calls and mailings. One trial opted to

provide patients with up to three phone invitations to participate in a walking program compared to an information session. Only 33 percent of those invited to walk, took part in walk.[37] Allowing the option of participating in an intervention (rather than required visits, phone calls, etc) demonstrates that individuals who consent to participate in a weight related study may not have the motivation to participate in the particular intervention of interest. Combining a time when a person is already in a period of change with an intervention that an individual is motivated to participate in may be an area for future research.

Applicability

Because adherence was poor in many interventions, the results may have been more useful if they had been reported by adherence status. For example, if participants who adhered to an intervention were more likely to maintain weight than the non adherent participants, we may have been able to make more recommendations based on the evidence. Adherence may explain why we observed effective strategies resulting from observational studies rather than intervention studies in the general population.

Behavior change is difficult for individuals whose goal is weight maintenance, just as behavior change is difficult for those attempting to lose weight. Avoiding potato chips and French fries is a simple, low cost intervention that prevented weight gain. College coursework on healthy diets and physical activity also prevented weight gain. The more intensive interventions, such as increasing exercise intensity over time to prevent weight gain, reported few adverse events. Although these intensive interventions did not result in strong evidence to promote their adoption, there is no evidence that *not* adopting a weight maintenance strategy is preferable.

Limitations

The strength of evidence was low or insufficient for almost all comparison outcome relationships. There are several reasons for these low grades based on how we assessed each study's quality and graded the strength of evidence. First, intervention trials were frequently downgraded for lack of blinding, for not reporting the blinding of outcome assessors, or for not accounting for losses to followup. We feel that these are required in these trials to reduce the risk of bias. We included in this review only observational studies that accounted well for confounding and for losses to followup to ensure that we included only the highest quality observational studies. This narrowed the body of evidence but we could not have confidence in outcomes from studies that did otherwise. Second, very few interventions had a stated goal of weight maintenance or weight gain prevention. We excluded studies that explicitly mentioned that at least some of the patients had a goal of weight loss. The best known weight gain prevention trial was excluded for this reason (Pound of Prevention).[38] Only one observational study was nested within a cohort whose original design had a weight related outcome of interest.[21] Third, very few studies reported standard errors or confidence intervals for the between group differences in change in a weight related outcome over time. When the majority of studies did not report a measure of variability, we graded the body of evidence as imprecise. In some instances, the studies did not report a mean difference or point estimate stating *there was no significant difference in weight change between the groups*.

There were also several limitations of the literature base. First, many studies did not report a weight related goal and yet were included because they did report weight outcomes. We may have inadvertently included some trials that had a goal of weight loss but that did not say so

explicitly in the published paper. Studies reported as weight maintenance among overweight and obese individuals may not have been solely targeting weight maintenance, but implicitly implied weight loss. We excluded studies that included specific aims of "weight change" associated with power calculations for an expected decrease in weight among the intervention group. However, some studies did not report power calculations or an expected direction of weight change. These studies were included. Second, controls had better weight maintenance than expected. In many studies, the weight maintenance was better in the control groups than is expected in a general population. Many control groups had no increase in weight over time. In the general United States population, adults gain about 0.5 kg per year.[4] It is possible that the knowledge that one will be evaluated on weight regularly may help people to maintain weight without an intensive intervention. This may support the use of weight surveillance interventions in a workplace or primary care setting. Third, very few studies reported on obesity related clinical outcomes or adverse events. Only one study in the general population reported on mortality. The few trials that did report on adverse events stated that none were associated with the intervention. Although, none of these studies stated what adverse events they collected or how they were measured.

Research Gaps

We suggest that most comparisons and outcomes that have low or insufficient evidence are potential future research needs. In particular, we recommend future research examine interventions to prevent weight gain among normal weight individuals and, separately, overweight and obese individuals. Interventions for individuals taking anti psychotic medications are also a high priority given that participants of a trial gained 10 kg in the first year of medication use. Different degrees of the intensiveness of the interventions should be compared. Less intensive interventions may be possible given that control groups responded nearly as well as intervention groups in most of the studies that we included.

There are design and reporting considerations that should be considered for future studies. Observational cohorts should make measuring weight a stated goal in their protocols. Intervention trials should be of sufficient duration to assess the efficacy of interventions for preventing weight gain. We suggest that one year should be a minimum duration of follow up for these interventions. Longer follow up will make it easier to identify true effectiveness as most individuals only gain 0.5 kg per year.

In conclusion, the evidence provides some, although limited, support for interventions to prevent weight gain. Effective interventions included ones that involve minor behavior change (*e.g.*, decreasing television viewing and eating fewer potatoes) or more major changes (*e.g.*, endurance exercise training in a gym at least three times per week). More studies are needed to evaluate the comparative effectiveness of these interventions.

Conclusions

The evidence provides some, although limited, support for interventions to prevent weight gain. Effective interventions included ones that involve minor behavior change (decreasing television viewing and eating fewer potatoes) or more major changes (endurance exercise training in a gym at least three times per week). More studies are needed to evaluate the comparative effectiveness of these interventions.

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Introduction

Background

Condition

One of the Healthy People 2020 national objectives is to reduce the prevalence of obesity among adults to less than 30 percent and to increase the prevalence of a healthy weight among adults to 34 percent.[129 #77] From 2005 to 2008, only 31 percent of adults were at a healthy weight.[2]

Body mass index (BMI) (see Appendix A[a] for a list of acronyms) – expressed as weight in kilograms divided by height in meters squared (kg/m^2) – is commonly used to classify underweight (BMI <18.5 kg/m^2), healthy or normal weight (BMI 18.5–24.9 kg/m^2), overweight (BMI 25.0–29.9 kg/m^2), obesity (BMI ≥30.0 kg/m^2), and extreme obesity (BMI ≥40.0 kg/m^2).

The estimated age adjusted prevalence of overweight and obesity (BMI ≥25.0 kg/m^2) was 68 percent in the United States (U.S.) from 2007 to 2008. Despite the doubling in the prevalence of obesity between 1976 and 1980 and 2007 to 2008 (13 to 34 percent), the prevalence of overweight has remained stable between the same time periods (32 to 34 percent). The largest increase in obesity during these times was among Americans who live 200 percent or more below the poverty line.[3] Those people living below the poverty line are more likely to live in areas without grocery stores and have fewer places to exercise than individuals who live in more affluent neighborhoods.[4]

Progression to Obesity From Normal Weight can Occur Gradually Over Time

Adults tend to gain weight progressively through middle age. Although the average weight gained per year is 0.5 to 1 kg, the modest accumulation of weight over time can lead to obesity.[5] During 2009 to 2010, 33 percent of men and 32 percent of women age 20 to 39 were obese, compared to 37 and 36 percent at age 40 to 59 and 37 and 42 percent at ages 60 and older.[6]

Obesity Differs By Sex And Ethnicity

The sex specific prevalence of obesity was 32 percent of men and 36 percent of women during 2007 to 2008 in the U.S. The prevalence of obesity is greater among non Hispanic Blacks and Mexican Americans than non Hispanic whites.[7] Access to healthy food and places to exercise, as well as cultural differences, may contribute to the differences in obesity prevalence.[4 8]

Obesity Substantially Increases Morbidity And Mortality

Obesity is a risk factor for chronic conditions including cardiovascular disease, type 2 diabetes, arthritis, certain types of cancer, and cancer recurrence.[9 16] Obesity can also be caused

[a] Appendices are available electronically at: http://www.arhq.gov

by medications used to treat chronic disease as is the case for many patients with mental illness.[17] Higher grades of obesity are associated with excess mortality, primarily from cardiovascular disease, type 2 diabetes, and certain types of cancer.[18]

Obesity Economically Impacts the U.S. Health Care Systems

Obesity was estimated to cost $79 billion dollars in the U.S. during 1995. By 2008, it was thought to have risen to $147 billion dollars. The U.S. Government pays about one half of the cost of obesity and its associated conditions through Medicaid and Medicare spending.[19]

Strategies To Prevent Progression To Obesity Among Adults Are Needed

Several studies have shown that overweight individuals (BMI 25.0 –29.9 kg/m^2) may have morbidity and mortality outcomes equal to or sometimes better than normal weight individuals (BMI 18.5–24.9 kg/m^2).[18 20 21]

Because the health outcomes for overweight individuals may be more like those of normal weight individuals than those with obesity, factors associated with the maintenance of overweight are also of interest to serve as intervention points to prevent obesity. Maintenance of non obese weight is considered to be an adult weight between a BMI of 18.5 and 29.9 kg/m^2 with long term stability within this range.

Strategies To Prevent Progression of Further Obesity Among Adults are Needed

Adults who have the greatest degree of obesity have higher morbidity and mortality than those whose weight is closer to overweight.[18] For example, adults with a BMI 40 kg/m^2 or greater have more co morbidities than those with a BMI of 30 to 39 kg/m^2,[129 #77] and adults with a BMI greater than 35 kg/m^2 have more mortality than those with a BMI of 30 to 34 kg/m^2.[2] Maintaining an obese weight closer to overweight may be advisable compared with maintaining an obese weight that is progressing to more extreme obesity.

Approaches to Maintaining Weight

Multiple approaches have been investigated to identify strategies to effectively maintain weight in adults. These approaches include self management techniques, diet, physical activity, medications, or combinations of these approaches at the individual or community level.

These approaches have been implemented in multiple settings, including clinical care settings, community settings, higher education settings, and workplaces.

Some approaches have targeted individuals at high risk of gaining weight because of a family history of obesity or diabetes mellitus, a diagnosis of these chronic conditions, or because of use of a medication that contributes to weight gain,[22] while others have more inclusive enrollment criteria or are directed at an entire population.[23 24]

Self Management Approaches To Maintaining Weight

Participants recruited to weight maintenance studies may have less motivation to change their behavior than those recruited to weight loss studies because of the absence of obesity and obesity

related disease.[25] As a result, the robust literature on self management strategies to lose weight cannot be applied directly to weight maintenance.[25]

Self management approaches may include goal setting, self monitoring, problem solving, relapse prevention, and stimulus control.[26] Other approaches may include regulating the time spent watching television or sleeping, enhancing self care, or acquiring social support. Studies suggest that frequent contact with interventionists and self monitoring of weight may be particularly valuable.[25]

To date, the most effective elements of behavioral approaches for weight maintenance are not known. From a public health perspective, less intensive interventions[25] and approaches targeting patients at high risk of complications from weight gain (e.g., those with prediabetes) are of great interest.

Dietary and Physical Activity Approaches to Maintaining Weight

Individuals who are successfully maintaining their weight are successfully balancing energy (kilocalories) intake and energy expenditure. These individuals maintain energy balance by having a consistent intake of adequate, rather than excess, kilocalories.[27] Some use specific dietary patterns (e.g., low fat or low carbohydrate).[28] Adequate energy expenditure may come from integration of physical activity into everyday activities or from making time for exercise in the daily routine.[28]

To date, the types of diet and physical activity approaches used for weight maintenance have not been systematically evaluated. Specific dietary approaches of interest include eating patterns, macronutrients (such as fiber) in supplement form and from food sources, micronutrients from food sources, and any physical activity interventions such as walking, biking, or a training program. Physical activity has cardiovascular and psychological health benefits, making it a suitable intervention for individuals with existing chronic diseases or mental health concerns.[29 30]

Medications for Maintaining Weight

In the U.S., there are several medications approved for weight control in individuals with a BMI of 27 kg/m^2 or higher.

The dietary fat absorption inhibitor, orlistat, has been shown to help maintain weight loss and improve cardiovascular risk factors with continued, long term use.[31] Because the sympathomimetic amines (i.e., phentermine or diethylpropion) are only approved by the U.S. Food and Drug Administration for short term use under the indication of weight loss, they are not appropriate for this review.[32]

Because orlistat may be used for weight maintenance independent of weight loss in overweight and obese populations, and because orlistat is approved for long term use, the only medication of interest is orlistat.

Environment level Approaches for Promoting Weight Maintenance

A built environment encompasses all of the buildings, spaces, and products created or modified by people.[33] Built environment approaches are applied at the community level and affect the environment that a community interacts within.

A limited number of environment level approaches have been evaluated to address energy imbalance at the community level (including both obese and non obese individuals). These interventions have been implemented in multiple settings such as fast food outlets and corner

food stores by requiring the posting of calories or increasing the availability of fresh food and at the neighborhood level by increasing sidewalks and walkability. Many approaches have been directed toward individuals at high obesity risk such as low income minority populations.

A previous systematic review that aimed to identify policy studies about weight maintenance, including environment level approaches, did not report identifying any such studies.[34] However, the review did not include serial cross sectional or time series studies. A national policy research group, PolicyLink, recently published a report on the impact of access to grocery stores on health related outcomes.[35] The authors identified several peer reviewed reports that reported weight as a health related outcome of interest, although it is unclear if weight change was reported.

Current Controversies in Weight Maintenance

Previous systematic reviews have concentrated on weight loss or maintenance of weight after weight loss.[36 37] Approaches that are effective for maintaining weight over time may be different than the approaches that are useful for weight loss or for maintenance of weight after weight loss.

Systematic reviews on the prevention of weight gain or weight maintenance are lacking. Previous systematic reviews on weight gain prevention have allowed the inclusion of studies targeting weight loss in the non obese[34] and included studies that were as short as 6 months. [25]

Synthesis of the predictors of longer term weight maintenance is needed. Accounting for adherence to weight maintenance interventions is also needed. Because an intervention can only be effective among those who adhere to it, adherence is an intermediary between the intervention and its effect on long term weight maintenance.

Treatment Guidelines and Meta analyses on Weight Maintenance

We identified no treatment guidelines for maintenance of weight, although several guidelines and systematic reviews address the maintenance of weight after weight loss.[6 36 40] Only one previous review with a meta analysis evaluated obesity prevention. The review was conducted as background for a study on the impact of cancer prevention interventions on obesity prevention.[34] The primary outcome of interest for the meta analysis was the difference in change in BMI or body weight between the intervention and control groups among studies published from 1996 to 2006.

A 2010 Cochrane review examined workplace based diet and physical activity interventions and change in BMI from baseline among non obese and obese employees.[41] The investigators found that the interventions decreased weight by 1.3 kg, on average, at 6 to 12 months of followup and that BMI decreased by 0.5 kg/m^2. The findings are reported as recommendations to implement workplace interventions for controlling overweight and obesity in the Task Force on Community Preventive Services.[6]

Scope and Key Questions

Scope of the Review

The goal was to compare the effectiveness, safety, and impact on quality of life of independent and combined approaches to preventing weight gain in adults. Studies that evaluated interventions targeting a combination of weight loss with weight maintenance, or weight loss exclusively, were excluded.

The specific Key Questions (KQ) are:

KQ 1: What is the comparative effectiveness of self management approaches for the prevention of weight gain in adults?

KQ 2: What is the comparative effectiveness of dietary approaches for the prevention of weight gain in adults?

KQ 3: What is the comparative effectiveness of physical activity approaches for the prevention of weight gain in adults?

KQ 4: What is the comparative effectiveness of medications for the prevention of weight gain in adults?

KQ 5: What is the comparative effectiveness of a combination of self management, dietary, physical activity, and medication approaches for the prevention of weight gain in adults?

KQ 6: What is the comparative effectiveness of environment level approaches for the prevention of weight gain in adults?

We planned to include studies of adults, including various subgroups of individuals at high risk of weight gain, which compared diet, physical activity, use of orlistat, or a combination of these interventions over at least one year. We compared the outcomes of weight, BMI, waist circumference, obesity related clinical outcomes, health related quality of life and adverse effects (Table 1 and Figure 1).

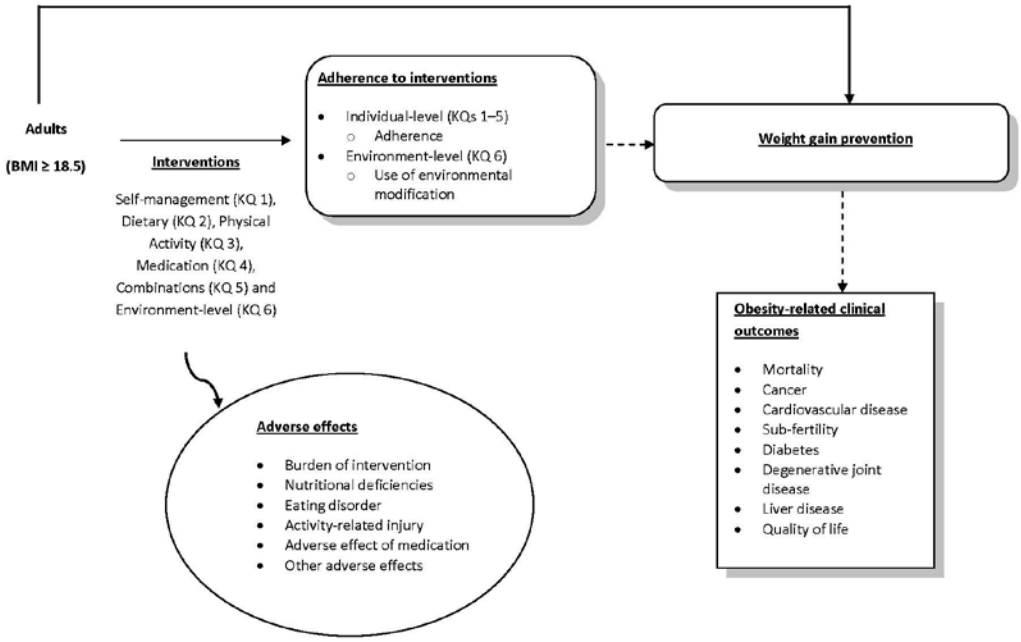
Table 1. Characteristics of the target studies according to the PICOTS framework

Population	• Adults (18 years and older) • Sub groups at greatest risk for weight gain including by: baseline weight (normal/overweight); age groups; life events (college, menopause, retirement); race, ethnicity or cultural group; gender; income, socioeconomic status, or educational attainment; family history of obesity; people with mental illness; cancer survivors not at risk of weight loss; and people with diabetes or cardiovascular disease or those at high risk of these conditions.
Interventions	• For KQ1 6: Self management, dietary, physical activity, medication, or a combination of these approaches. • Approaches that *educate* the participants about an intervention will be reported in the section about that intervention. • Behavior change about an intervention is reported with the intervention and not with the self management interventions.
Comparisons	• For KQ1 6: No approach, usual care, or comparison to other self management, dietary, physical activity, medication, or combination of approaches. • The potential comparisons of interest are self management, diet, physical activity, medications, combination interventions, built environment. Any comparison between these interventions and a control or another intervention.

Outcomes	• Intermediate outcomes of interest include: Adherence to the intervention at the individual level for key Questions 1 through 5, and use of environmental modification for Key Question 6.;
	• Prevention of obesity related clinical outcomes including mortality, cancer, cardiovascular disease, sub fertility, diabetes, degenerative joint disease, liver disease, and quality of life
	• Adverse effects of approaches including burden of intervention, nutritional deficiencies, eating disorders, activity related injuries including fracture, and adverse events of medications (*e.g.,* diarrhea or leakage).
	• Weight gain prevention outcomes include:
	  • Percent or mean change from baseline weight.
	  • Maintenance of weight within same BMI category as the baseline measure. The Centers for Disease Control (CDC) recommended categories of BMI by race/ethnicity will be used. If change in weight by BMI category is not reported, we will report the percent or mean change from baseline BMI. Clinically meaningful weight maintenance as measured by BMI will be defined as within ±3 percent of the baseline measure.[42]
	  • Among those with BMI from 18.5 to 30.0 at the first measure, maintenance of weight as non obese.
	  • Alternative measures of weight other than weight in pounds or kilograms or BMI (*e.g.,* waist to hip circumference, and percent body fat).

Timing	• The approach of interest must occur after age 18. • The study must report the change in weight over at least 1 year during adulthood. • Followup duration will be considered in the analysis. In addition to 1 year, specific timepoints of interest include 2, 5, and 10 years of followup when available. • For intermediate outcomes, adverse effects, and quality of life, additional time points of interest include 3 and 6 months after the commencement of the intervention.
Setting	• Any setting • Studies conducted in educational settings or workplaces will be reported with other studies conducted in the same setting regardless of the approach.

Figure 1. Analytic framework for comparative effectiveness of approaches to weight maintenance in adults



Abbreviations: BMI = body mass index; KQ = key question.

Methods

The methods for this comparative effectiveness review (CER) follow the methods suggested in the AHRQ Methods Guide for Effectiveness and Comparative effectiveness Reviews (available at: http://www.effectivehealthcare.ahrq.gov/methods guide.cfm) The main sections of this chapter reflect the elements of the protocol established for the CER; certain methods map to the PRISMA checklist.[43]

Our Evidence based Practice Center (EPC) established a team and a work plan to develop this evidence report. The project involved recruiting key informants and technical experts, formulating and refining the questions, performing a comprehensive literature search, summarizing the state of the literature, constructing evidence tables, synthesizing the evidence, and submitting the report for peer review and public comment.

Topic Refinement and Review Protocol

The topic for this report was nominated in a public process. At the beginning of the project, we recruited a panel of key informants to give input on key steps including the selection and refinement of the questions to be examined. The panel included experts with expertise in adult obesity and weight maintenance and external informants with complementary expertise, including expertise in environmental interventions and those with unique patient perspectives.

In preparation for this report, we reviewed existing systematic reviews on this topic as well as guidelines prepared by key professional societies about this topic. With input from the key informants, staff of AHRQ, and the Scientific Resources Center, we developed the key questions. Our draft key questions were posted on AHRQ's website for public comment in November 2011. We then refined the key questions based on the feedback received.

The final key questions focus on the comparisons of interventions that prevent weight gain in adults. The key questions focus on the effectiveness of these interventions as well as harms. We drafted a protocol to address these key questions and then recruited a panel of technical experts, including experts on weight maintenance. With input from the technical expert panel and representatives from AHRQ, we finalized the protocol.

Amendments to the protocol were submitted to AHRQ and posted publicly on the Effective Healthcare website in November 2011 and March 2012. These amendments were added to focus the project's scope to weight and clinical outcomes, and to include high quality observational studies in addition to interventional studies.

Search Strategy

We searched the following databases for primary studies: MEDLINE®, Embase through May 2011, and the Cochrane Central Register of Controlled Trials through May 2011. We developed a search strategy for MEDLINE, accessed via PubMed, based on an analysis of the medical subject headings (MeSH), terms, and text words of key articles identified *a priori* (Appendix B[2]) We also reviewed the reference lists of each included article and relevant review articles.

[2] Appendices are available electronically at: http://www.arhq.gov

The results of the searches were downloaded and imported into ProCite® version 5 (ISI Research Soft, Carlsbad, CA). We scanned for exact article duplicates; author/title duplicates, and title duplicates using the duplication check feature in ProCite. From ProCite, the articles were uploaded to DistillerSR (Evidence Partners, Ottawa, Ontario, Canada), a Web based software package developed for systematic review and data management. This database was used to track the search results at the levels of title review, abstract review, article inclusion/exclusion, and data abstraction.

Study Selection

Due to the large volume of studies, we first screened titles for eligibility. This phase of screening was designed to be liberal. All titles were screened by two screeners. Only one screener needed to identify a title as potentially eligible for the associated publication to move to the next screening level (Appendix C.). However, two screeners were required to agree that a title was not eligible for the publication to be removed from the potential pool of articles.

The abstract review phase was designed to identify trials or observational studies that addressed weight maintenance in adults (Appendix C), and potentially applied to the inclusion criteria (Table 2). Abstracts were reviewed independently by two investigators and were excluded if both investigators agreed that the article met one or more of the exclusion criteria (see Table 1). Differences between investigators regarding abstract inclusion or exclusion were resolved through consensus adjudication. We included only articles published in English due to volume of literature and lack of resources to translate all the languages encountered.

Abstracts that were promoted to the next level, article screening, underwent another independent parallel review to determine if they should be included for data abstraction (Appendix C), and potentially applied to the inclusion criteria (Table 2). Differences regarding article inclusion were resolved through consensus adjudication. A third reviewer audited a random sample of abstract and article reviews to ensure consistency in the reviewing process.

Inclusion of Observational Studies

Observational studies that have a high risk of bias add little value to a systematic review of effectiveness. Therefore, only high quality observational studies were included. We used the Downs and Black tool to assess study quality with particular attention to control of confounding and losses to followup.[44] For inclusion, we required that studies adjusted for the following confounders in their analysis: age, sex, race or socioeconomic status, and diet (for physical activity studies) or physical activity (for dietary studies). Included observational studies were required to account for losses to follow up in the analysis, state that the losses to followup were less than 20 percent or state that the individuals included in the analysis were similar to those lost to followup. If the study met both the confounding and losses to follow up criteria and most or all of the other Downs and Black internal validity criteria, the study was considered eligible for the review.

Data Abstraction

Relevant data were extracted from eligible articles with a focus on items related to the population, approaches and interventions, comparisons, outcomes, timing and setting. Each article was serially abstracted first by a junior reviewer then by a senior reviewer. Serial data abstraction involved a senior reviewer (project investigator) abstracting data from articles while

having access to the first reviewer's data. Data abstraction was randomly checked for quality by a third party senior investigator to assure that data were being abstracted accurately and thoroughly. Data were abstracted from the text or tables in the article. When necessary, relevant data were also abstracted from figures. Differences in opinion were resolved through consensus adjudication and in difficult cases, during team meetings.

The timepoints of interest for data abstraction of weight outcomes were: 1 year, 2 years, 5 years and the last reported timepoint after 5 years. For the intermediate outcomes, safety and quality of life outcomes, we only abstracted data for the last reported timepoint at or after 1 year.

For each Key Question, we created a set of detailed evidence tables containing all information abstracted from eligible studies (Appendix C. Data Abstraction Forms). Summary tables were created based on the information in the evidence tables.

When there were three or more studies with comparable interventions and comparable outcome measures, we considered quantitative pooling of the results. We examined the studies designs' and had planned to perform meta analyses if the studies were qualitatively similar. No meta analyses were performed. Because the studies were not amenable to pooling with meta analyses, we calculated and displayed the individual mean differences, risk differences or relative risks with 95 percent confidence intervals (CI) for the individual studies grouped by study population or comparable interventions.

We aimed to compare interventions and approaches for weight maintenance using a clinically meaningful threshold in addition to a statistically significant threshold ($p<0.05$). A clinically meaningful difference was defined as 0.8 units of BMI (based on a 3 percent change in baseline for an individual with a BMI of 27), 2.5 kg of weight or 2 cm of waist circumference less than the comparison group. We reported on the effectiveness of interventions on populations with the different risks of weight gain. These subgroups included baseline weight (normal/overweight); age; life events (college, menopause, retirement); race, ethnicity or cultural group; gender; income, socioeconomic status or educational attainment; family history of obesity; persons with mental illness; cancer survivors not at risk of weight loss; and persons with diabetes or cardiovascular disease or those at high risk of these conditions.

Quality Assessment

Two reviewers independently assessed the risk of bias of each article and came to consensus regarding the bias rating. The risk of bias was assessed using the Downs and Black methodologic quality assessment checklist.[44] This checklist was developed to assess the quality of reporting, internal validity and external validity for individual randomized and non randomized studies.

Data Entry and Quality Control

Each data element was reviewed by at least two reviewers. The second reviewers were generally more experienced members of the research team. In addition, at least one additional investigators audited a random sample of the reviews to identify any problems with data abstraction. If problems were recognized in a reviewer's data abstraction, the problems were discussed at a meeting with the reviewers.. Throughout the review process we held weekly meetings to describe each phase of the review process, discuss identified discrepancies, and discuss any questions which arose about our process. The goal of this part of the weekly meetings was to ensure consistency of article inclusion and data abstraction.

Rating the Body of Evidence

At the completion of our review, we graded the quantity, quality and consistency of the evidence addressing Key Questions 1 through 6 by adapting an evidence grading scheme recommended by the Methods Guide for Conducting Comparative Effectiveness Reviews.[45] We created evidence grades for each comparison and outcome. We used four domains to come up with a final evidence grade: Risk of Bias, Consistency, Directness and Precision.

Risk of bias in each individual study was assessed using the Downs and Black criteria focusing on reporting bias and internal validity.[44] Randomized controlled trials were initially assigned a low risk of bias and could be downgraded for not blinding the outcome assessor to the intervention. If the entire set of randomized controlled trials for a given intervention and outcome were blinded, the set could be downgraded from low risk of bias to moderate risk of bias if there were internal validity concerns or poor reporting. If a set of trials was mostly not blinded, the risk of bias was downgraded to moderate. This set of trials could then be further downgraded to high risk of bias if there were internal validity concerns or poor reporting. Non randomized studies were initially assigned a moderate risk of bias and could be downgraded to a high risk of bias if there were internal validity concerns or poor reporting.

Consistency was assessed based on the direction of the effect estimates. If all studies found no difference between the comparison groups, the body of evidence was graded as consistent. If the direction of effect was largely similar across studies, this was considered to be consistent evidence. Directness was assessed using the following criteria: if most of the studies for a given comparison and outcome pair were not designed to measure weight maintenance, the evidence was considered indirect. If the studies were designed to measure weight maintenance yet the external validity criteria of Downs and Black were not met or poorly reported, the evidence was considered to be indirect.[44]

Precision could only be measured if the variability for the measure of association was reported, which was infrequent. If there was no variability reported for most articles in the set, we graded the evidence imprecise. Otherwise, precision was determined by statistical significance ($p<0.05$ or confidence intervals [CI] excluding 0 for mean differences). When grading precision for the outcome of adherence, if the total number of participant in all studies for a given comparison and outcome was fewer than 400, the set was considered to be imprecise. If only one study was identified for a body of evidence, consistency was not graded and all other domains were graded as described above.

We classified evidence pertaining to Key Questions 1 through 6 into four categories: (1) “high” grade (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of the effect); (2) “moderate” grade (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of the effect and may change the estimate); (3) “low” grade (indicating low confidence that the evidence reflects the true effect and further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate); and (4) “insufficient” grade (no evidence identified). A comparison outcome pair with high strength of evidence was one with low risk of bias, consistency (or not applicable if only one study contributed), directness and precision. Moderate strength of evidence indicated one domain did not receive an optimal score (one of the following was observed: moderate risk of bias, inconsistency, indirectness or imprecision). Low strength of evidence indicated a low risk of bias or two or three of the following were observed: inconsistency, indirectness and

imprecision. Strength of evidence was graded by the core team and conflicts were resolved by discussion and consensus.

Applicability

We describe the applicability of studies in terms of the degree to which the study population, approaches or interventions, outcomes, and settings were relevant to individuals at risk of weight gain and features that may affect the effectiveness of the intervention. The population that received the intervention was the greatest driver of applicability. To clarify the population to whom the intervention was applicable, we describe interventions administered to select populations in separate sections of the report.

Peer Review and Public Commentary

Experts in behavior, policy, medications, nutrition, physical activity and individuals representing stakeholder and user communities were invited to provide external peer review of this CER; AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ website for 4 weeks to elicit public comment. We addressed all reviewer comments, revising the text as appropriate, and documented everything in a ―disposition of comments report-that will be made available 3 months after the Agency posts the final CER on the AHRQ website.

Table 2. Study inclusion and exclusion criteria

Population and condition of interest	Human participants Adult participants for KQ1 5. If a study includes some participants under age 18 years and results are not reported separately for adults, the study will be included as long as 90percent of the total population is 18 years and older. Studies of obese patients were included if the study did not describe the goal of the intervention to be weight loss or maintenance of weight after weight loss. All ages are included for KQ6; approaches are implemented at the community level. *Excluded* studies if they included only pregnant women. *Excluded* studies that included only patients at risk of weight loss (*e.g.,* wasting disease, eating disorders), or with a BMI <18.5
Interventions and approaches	Studies must have evaluated an approach of interest as defined by KQ1 5. Included studies of orlistat Included studies of caloric substitutes, such as olestra or artificial sweeteners. Included studies of lifestyle interventions for KQ5. Included studies implemented at a community level for KQ6. *Excluded* studies if the goal of the study was weight loss, a combination of weight loss and weight gain prevention (without a separate reporting of results), or weight maintenance after weight loss. *Excluded* studies of biological determinants (such as genes) as the exposure. *Excluded* studies of herbal supplements, vitamins, and minerals. *Excluded* studies that included a smoking cessation intervention or approach.
Comparisons of interest	No intervention, usual care, or comparison to other self management, dietary, physical activity, device, pharmaceutical or combination of approaches will be included. Included studies comparing different intensities of the same approach (*e.g.,* low fat versus high fat diet) *Excluded* studies if a study compares an approach of interest to an approach not of interest *Excluded* studies if there was no comparison
Outcomes and Timing	One year of observation of weight during adulthood was required. Weight change must have been reported relative to an approach of interest. Measures of weight change included weight, BMI or waist circumference. Obesity related clinical outcomes, intermediate outcomes, adverse effects and quality of life were abstracted only if the study also reported a qualifying measure of weight.
Type of study	Accepted studies with any sample size from any year that met all other criteria. Included all studies designs including prospective (randomized and non randomized), retrospective, crossover, and case control studies. Serial cross sectional studies of the same population were also eligible for KQ6. Observational studies had to account for confounding and losses to followup in the design or analysis to be eligible. Crossover studies must have reported at least 1 year of weight change in each phase of the crossover to be included. For KQ1 5 inclusion, the participants measured at the first time point must have been the same participants measured at the later time points. For KQ6 inclusion, the participants measured at the first time point were not required to be the same participants as those measured at the later time points. *Excluded* studies with no original data (reviews, editorials, comments, letters, modeling only studies). *Excluded* studies published only as abstracts. *Excluded* qualitative studies that did not provide quantitative information on an approach of interest and weight, such as focus groups or directed interviews.

KQ=key question, RCT = randomized controlled trial

Results

Results of the Literature Search

The literature search identified 22,861 unique citations. During the title screening, we excluded 14,448 citations. During the abstract screening, we excluded 7,083 citations that met at least one of the exclusion criteria (see Chapter 2 for details). During article screening, we excluded an additional 1,298 articles that did not meet one or more of the inclusion criteria (see Appendix D[3]). Twenty six articles were excluded because they were not in English, but may have been relevant based on the English language title or abstract. Fifty articles describing data from 44 studies were included in the review (Figure 2).

Description of Types of Studies Retrieved

Five studies addressed Key Question 1 (self management interventions), 14 studies addresses Key Question 2 (dietary interventions), 13 studies addressed Key Question 3 (physical activity interventions), no studies addressed Key Question 4 (medication interventions), 15 studies addressed Key Question 5 (combination interventions), and 2 studies addressed Key Question 6 (built environment interventions).

Twenty two articles looked at adults in the general population: 11 interventional studies and 11 observational studies. Two articles looked at built environment interventions (Key Question 6), 1 interventional and 1 observational. Four studies addressed in 5 interventional articles took place in the workplace, and 2 studies addressed in 3 interventional articles took place in a college setting. Ten interventional articles addressed adult weight maintenance in populations at risk for or with cardiovascular disease or diabetes mellitus. Three interventional and one observational article looked at adult weight maintenance in adults with cancer. Two interventional studies looked at weight maintenance in adults with psychiatric disorders. Nine of the 11 interventional studies included a comparison to a one-time session, information booklet or no intervention. Three studies compared interventions head-to-head.

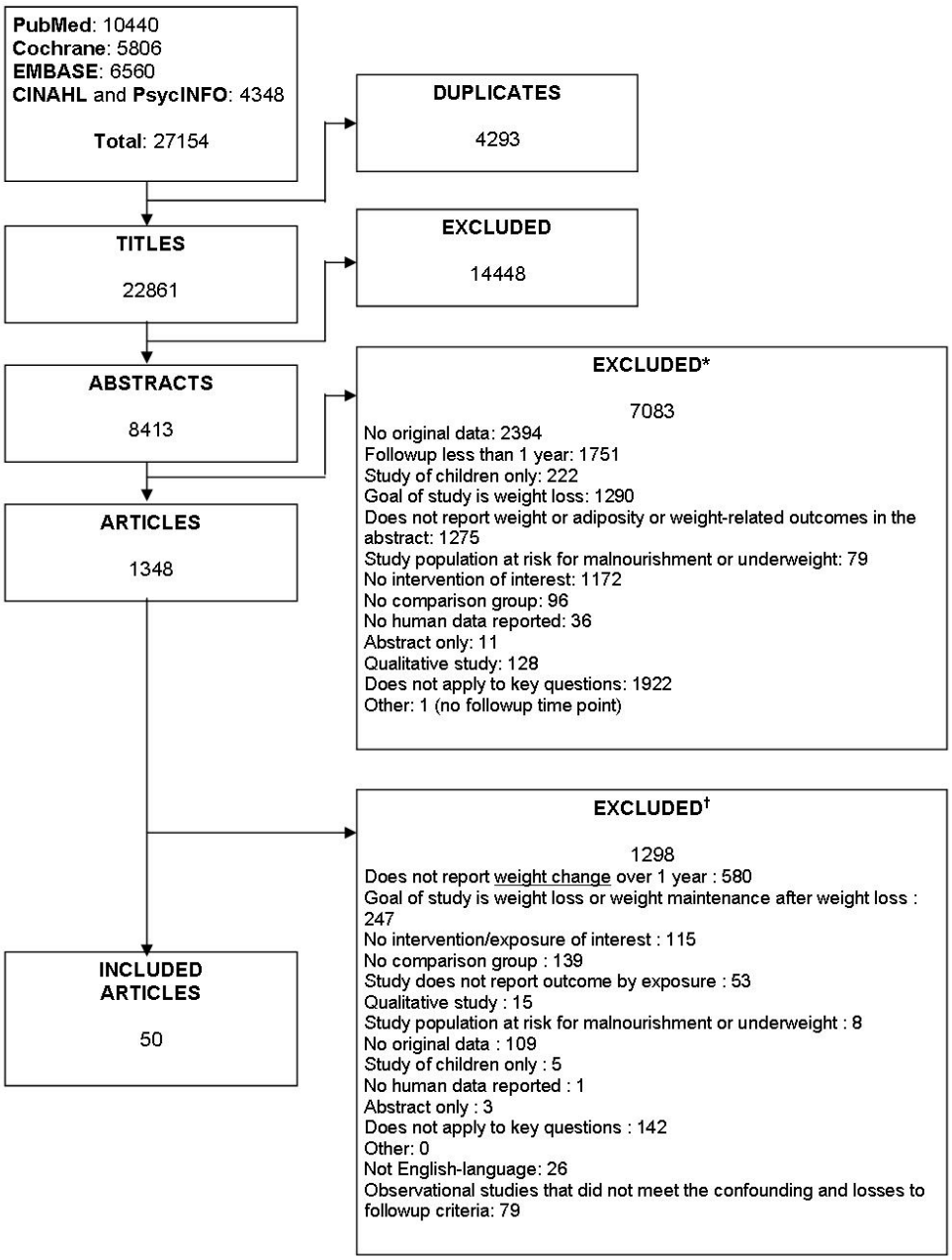
We did not identify any study that included exclusively individuals with normal weight at baseline. We did not identify any studies addressing prevention of weight gain among overweight or obese individuals or socioeconomically disadvantaged individuals that met our inclusion criteria.

Order of the Results

The populations included in the studies affect the generalizability of the results. For this reason, we report the results by population. The most inclusive population (adults without underlying comorbidity) is reported first, followed by interventions that occur in a specific setting (work based and college based) and finally specific groups with a disease or at risk of a disease (cardiovascular disease, cancer and mental health).

[3] Appendices are available electronically at: http://www.arhq.gov

Figure 2. Results of the literature search



* Sum of excluded abstracts exceeds 7083 because reviewers were not required to agree on reasons for exclusion
† Sum of excluded articles exceeds 1298 because reviewers were not required to agree on reasons for exclusion

Weight Maintenance in Adults in the General Population

Study Characteristics

Eleven interventional studies (54,983 baseline participants)[46 55] and 11 observational studies (421,694 baseline participants)[56 66] were included. The duration of the interventional studies ranged from one 30 minute session[52] with followup mailings and phone calls to 144 months of structured visits (Appendix E, Evidence Table 1).[48]

Most of the interventional studies did not follow participants after the cessation of the intervention.[46 48 51 53 67] In the three studies that did follow participants after the intervention, the followup after the intervention ranged from 10 to 12 months.[52 54 55]

The observational studies were sub analyses of participants with available information on weight and diet or physical activity measures from existing cohorts. The maximum duration of followup in the observational studies ranged from 48 to 276 months.[58 63 64]

Study Characteristics of the Interventional Studies

Ten of the interventional studies were randomized trials of individual participants. One trial compared a media campaign among three communities.[47] The stated goal of the intervention was to prevent weight gain in three trials,[53 54 67] prevent increase in percent body and abdominal fat in one trial,[49] change diet or physical activity patterns in five trials,[46 48 50 52 55] improve a cognition score among elderly patients in one trial,[51] and reduce the risk of cardiovascular disease in the community wide trial.[47]

Five trials took place in the United States,[46 47 49 53 54] one in Canada,[50] two in Europe,[51 52] and two in Australia.[55 67] In seven trials, participants were recruited from the local community[46 49 53 55] and from primary care physician clinics in two trials.[50 52] The recruitment source for one trial was the school where the woman had a child enrolled in school.[67] The recruitment source was not reported in one trial.[51]

The calendar years of recruitment were reported in six trials. The earliest recruitment year was 1972[47] and the last recruitment year was 2006.[67]

Interventions were administered at one location in four trials,[51 54] multiple sites in five trials,[46 48 50 67] by mail in one trial, [55] and by a local media campaign combined with mailings in one trial (Appendix E, Evidence Table 1).[47]

Study Characteristics of the Observational Studies

The 11 observational studies were reported in 11 publications. [56 61 63 66 68] One publication reported on three studies,[56] one study reported different approaches in two publications,[59 60] and two sub cohorts were reported on in separate publications.[63 64]

The observational studies included sub analyses from a randomized trial,[66] eight prospective cohorts,[56 58 60 62 65] and two studies followed up of participants who had participated in a previous cross sectional survey.[57 61]

Only one prospective study specifically stated that obesity was a goal of the original study design.[62] Six studies took place in the United States,[56 59 60 65 66] one occurred in Canada,[57] three occurred in Europe,[61 64] and one took place in the Philippines.[58]

The earliest recruitment year was 1976[56] and the most recent recruitment year was 2002 (Appendix E, Evidence Table 1).[57]

Population Characteristics

Interventional Studies

Sixty nine percent (37,685) of the randomized participants were included in the analyses relevant to change in Body Mass Index (BMI), weight, or waist circumference. Inclusion of participants based on household structure, sex, age, or life stage as well as race or ethnicity group were common (Appendix E, Evidence Table 2).

One trial included only heterosexual couples who began cohabitating within two years of recruitment[55] and another trial included households with at least two adults.[53] Five trials included only females.[46 48 49 54 67] Among the trials that included both sexes, the percent of females ranged from 46 to 57 percent. Age restrictions were present in seven trials.[46 48 52 54] The observed ages at recruitment ranged from 25 to 79. The two trials that required patients over 65 years old did not report the age of the oldest participants included. The mean ages at recruitment were 70 and 74 years in these two trials.[50 51] Two trials included post menopausal women exclusively.[46 48] One trial included only women with a child aged 5 to 12 years.[67] No trial included only participants of a particular race or ethnicity background, but three trials specifically targeted recruitment to include an ethnically diverse population.[46 48 49] No trial that occurred outside of the United States reported on race or ethnicity. All of the trials from the United States reported on race. The range of patients of each race or ethnicity group included 50 to 87 percent White, 11 to 28 percent Black, 4 to 16 percent Hispanic, and 0.4 to 12 percent Asian, Native American or Pacific Islander. Educational status was not a requirement for inclusion in any trial, but was reported in eight of the trials.[46 48 51 53 54 67] The percent of participants with a college degree ranged from 28 to 84 percent (Appendix E, Evidence Table 2).

Trials frequently included participants based on weight. Four trials restricted patients based on weight or BMI,[46 49 51 54] of which three trials included only females (Appendix E, Evidence Table 2). [46 49 54]

The trials restricted to females included one study each of females who were no more than 165 percent of ideal body weight,[46] females with a BMI between 21 and 30,[54] females with a BMI between 25 and 35,[49] and all females that were not underweight.[67] Another trial included male and female participants older than 65 with a BMI between 18 and 32.[51] No trial was restricted to participants with a normal BMI (19 to 24). In the trial that randomized couples, females had a mean baseline BMI in the normal range, but the mean BMI of males was overweight.[55] One trial that included participants greater than 65 years of age did not report a baseline value of weight or BMI.[51]All other trials reported a mean or median baseline BMI in the overweight (BMI 25 29) range.[46 48 50 52 54] Two trials explicitly excluded participants who had recently used a weight loss program.[49 54] Another trial required patients to have had a stable body weight over the past year (<10 percent change in weight) (Appendix E, Evidence Table 2).[49]

Other common inclusion criteria included activity pattern, [49 50 52 54] dietary pattern,[46 48]health,[46 48 55] and the likelihood of being adherent to the intervention.[46 48 49 53 55] One trial excluded patients who smoked (Appendix E, Evidence Table 2).[49]

Observational Studies

Forty nine percent (n=205,488) of the baseline participants were included in the weight related analyses. Studies were included only if they accounted for losses to followup in analysis, if they had less than 20 percent attrition from baseline or if the study stated that the analyzed participants were similar to those people recruited at baseline. The majority of studies excluded

participants at baseline or for the weight analyses if they had cardiovascular disease, cancer, or other chronic diseases. Four studies required participants to work in healthcare,[56 66] one study recruited from graduates of a university,[62] one recruited women while they were pregnant,[58] and four studies were generally inclusive of the source population.[61 63 65] Four studies included only women,[56 58 60 66] one study included only men,[56] and five studies included both men and women.[59 65] One study excluded patients weighing more than 300 pounds.[65] No other study reported weight based exclusions (Appendix E, Evidence Table 2).

Interventions

No self management or orlistat interventions were included, while two dietary, four physical activity, and four combination, and one environment level interventions were included. Ten of the 11 studies included a comparison to a one time session, information booklet or no intervention. Three studies compared interventions head to head. The specifics of each intervention are described prior to the results of the appropriate Key Question (Appendix E, Evidence Table 3 and 4).

Approaches

Observational studies did not implement interventions, instead they focused on lifestyle behaviors performed by individuals as part of their normal routines. To differentiate the behaviors examined in observational studies from those performed among the randomized interventions, we refer to the factors examined in observational studies as approaches.

Five observational studies reported on more than one approach. The results of these five studies are reported in the relevant Key Questions (1 through 3) as the studies did not pool the effects of combined self management, diet, or physical activity behaviors with weight outcomes. Three studies reported on a self management approach, nine studies reported on a dietary approach, and six studies reported on a physical activity approach. No observational study reported on the effect of orlistat and a weight outcome. One study reported on an environment level approach (Appendix E, Evidence Table 3 and 4).

Descriptions of the self management, dietary, and physical activities that were associated with a weight related outcome from observational studies are reported in Table 3.

Outcomes

Key Points

- **BMI**
  - No self management studies were identified (insufficient strength of evidence).
  - Clinically meaningful differences in BMI were shown among Whites, Chinese, and Hispanics with very healthy eating patterns in the home compared with those persons with less healthy eating patterns(low strength of evidence).
  - Participants who were taught by their primary care provider to monitor their heart rate during exercise had a greater decrease in BMI than the controls (low strength of evidence).
  - No clinically meaningful differences between the intervention groups and the controls were shown for the combination interventions (low strength of evidence).
  - Neighborhood walkability did not affect BMI change over 6 years (low strength of evidence).

- **Weight**
  - Television viewing of 5 or more hours per day was associated with weight gain (low strength of evidence).
  - A healthy eating pattern and eating more fruits and vegetables were associated with less weight gain (low strength of evidence).
  - Food prepared outside of the home was associated with greater weight gain compared with home cooked meals (low strength of evidence).
  - Greater consumption of potato chips and french fried potatoes were associated with weight gain (low strength of evidence).
  - Increasing physical activity over time was associated with less weight gain (low strength of evidence).
  - No clinically meaningful difference was noted between the combination intervention groups and the controls (low strength of evidence).
  - A community level media campaign combined with mailed cookbooks and educational pamphlets did not prevent weight gain compared to no community intervention (low strength of evidence).
- **Waist circumference**
  - No self management studies were identified (insufficient strength of evidence).
  - Healthy eating scores that were 2 z scores above the mean were associated with 2 to 3 cm smaller waistlines among Whites and Hispanics (low strength of evidence).
  - There was no difference between the gym based exercise group and the control group on weight maintenance in the elderly (low strength of evidence).
  - There was no clinically meaningful difference between the combination intervention groups and the controls (low strength of evidence).
- **Progression to overweight or obesity**
  - No self management or physical activity studies were identified (insufficient, strength of evidence).
  - Eating food outside the home one or more times per week was associated with a 20 to 30 percent increased risk of progressing to overweight or obesity (low strength of evidence).
  - No clinically meaningful differences between the intervention groups and the controls were identified (low strength of evidence).
- **Adherence**
  - Adherence was poor (less than 80 percent) in all intervention trials that reported on an adherence outcome (low strength of evidence).
- **Obesity related clinical outcomes**
  - No study reported (insufficient strength of evidence).
- **Adverse effects**
  - The intervention group had 0.1 percent less mortality than the controls in a dietary trial (low strength of evidence).
  - A physical activity trial reported no difference in adverse events (low strength of evidence).
  - The strength of evidence was insufficient for all other comparisons and adverse effect outcomes.

Key Question 1: What is the comparative effectiveness of self management approaches for the prevention of weight gain in adults?

No trial reported on a self management intervention. Three trials included a self management approach as part of a combination intervention as reported with Key Question 5.[53 55]

Three observational studies (289,916 baseline; 120,877 analyzed) reported on daily hours of sleep and television watching in a single publication.[56] The results were pooled in the publication's analysis so a meta analysis was not performed. Weight change was the only outcome of interest reported. The study adjusted for age, baseline BMI, diet, physical activity, alcohol consumption, and cigarette smoking.

BMI Change

No study reported on self management approaches and BMI change.

Weight Change

The mean weight gain was 7.6 kg over 20 years of followup. Sleeping more than 6 hours per night was associated with less weight gain compared with sleeping less than 6 hours per night, but no sleep duration met the threshold for a clinically significant difference in weight gain.[56] Each hour of television watching was associated with a 0.1 kg increase in weight per 4 year interval of followup. Television viewing met the clinically significant threshold for weight gain over the 20 year period. Five hours of television viewing per day were required for a 2.5 kg increase in weight over 20 years (Appendix E, Evidence Table 5).[56]

Waist circumference Change

No study reported on self management approaches and weight change.

Progression to Overweight or Obesity

No study reported on self management approaches and progression to overweight or obesity.

Other Outcomes

No adherence, clinical, health related quality of life or adverse effect outcomes were reported in studies with self management interventions.

Subgroups

The duration of sleep and television viewing findings were similar when the results were examined separately by age and baseline BMI (Appendix E, Evidence Table 5).[56] No other subgroups were reported.

Applicability

These results are applicable to the general population at risk of weight gain. The Nurses' Health Studies and Health Professionals Follow up Study are generally criticized for including individuals that are employed in the healthcare industry and as a result may be healthier than the general population. In the case that unmeasured confounders of sleep duration and television viewing and weight were unaccounted for, the reported findings are likely minimum estimates of the relationships with weight gain. The studies did not report on other important outcomes of interest such as adherence, obesity related clinical outcomes, health related quality of life, and/or adverse events in the weight change publication. None of the studies were designed to identify predictors of weight gain.[56]

Interpretation

Television viewing of at least 4 hours per day is associated with weight gain. Americans watch about 5 hours of television per day.[69] The strength of evidence was low.

Key Question 2: What is the comparative effectiveness of dietary approaches for the prevention of weight gain in adults?

Two trials (51,043 randomized; 42,279 analyzed) reported on dietary interventions,[46 48] and eight observational studies (371,830 participants at baseline; 165,893 analyzed) [56 58 61 63 65 68] reported on dietary approaches for preventing weight gain in adults. Three trials included a dietary component as part of a combination intervention as reported with Key Question 5.[53 55] The two dietary trials included women exclusively (Table 4). [46 48] Both interventions used group sessions to change consumption of fats, fruits, vegetables, and grains. Neither study's primary goal was weight maintenance. Because fewer than three trials were identified, meta analyses were not conducted.

The observational studies reported on individual foods, energy intake, and eating patterns. No dietary approach was included in a meta analysis because studies did not report on similar dietary exposures. Only one observational study stated that a weight related outcome was a primary goal of the original cohort.[62]

BMI Change

One dietary trial (48,835 randomized; 41,173 analyzed) reported on BMI change.[48] BMI remained within 0.1 units of the baseline in the intervention and control groups at an average of 7.5 years of followup. The BMI increased by 0.3 fewer units (95 percent CI, 0.5 to 0.1) in the intervention compared with the control group after adjustment for age, race/ethnicity, baseline BMI, and changes in dietary and physical activity patterns over time. This finding did not meet the threshold for clinical significance, despite being statistically significant.

Two observational studies (25,308 baseline; 14,698 analyzed) reported on BMI change.[62 65] BMI remained within 2 units of the baseline in both studies. Because ethnicity modified the effect of diet on BMI change and an overall effect was not reported, these results are included in the subgroup analyses.[65] Eating food prepared outside of the home two or more times per week was associated with a clinically insignificant 0.5 increase in BMI over 7 years of followup (Appendix E, Evidence Table 5).[62]

Weight Change

Two dietary interventions (51,043 randomized; 42,279 analyzed) reported on weight change (Figure 3).[46 48] Weight decreased in the intervention and control groups in both trials. Neither intervention met the threshold for clinical significance, although the change in weight between the intervention and control groups in one trial approached the threshold at one year (2.2 kg).[48] However, the difference was not maintained beyond one year. After a mean of 7.5 years of intervention, the intervention group lost 0.7 more kg (95 percent CI0.5 to 0.9) than the control group after adjustment for age, race/ethnicity, baseline BMI, and changes in dietary and physical activity patterns over time.[48]

Eight observational studies (371,830 baseline; 168,921 analyzed) reported on weight change over 4 to 23 years of followup.[56 58 64] Weight increased by around 0.5 kg per year in most studies. The longest study reported a 10 kg increase over 23 years of followup.[58] A variety of dietary approaches were reported on including number of meals eaten outside the home,[62] fast food eaten outside the home,[60] percent of total calories from fat,[59] percent of calories from protein,[58] percent of intake consumed at breakfast,[64] high fiber/low fat dietary pattern,[63] healthy eating pattern based on specific foods consumed[56] and fruit and vegetable intake.[61]

One publication that pooled the results of the three largest studies reporting a clinically meaningful finding for absolute weight gain.[56] The least healthy eaters (those in the bottom quintile) gained 1.8 more kilograms per 4 year period (95 percent CI, 1.3 to 2.3 kg) than the healthiest eaters (those in the top quintile) after accounting for confounders. [56] The second through fourth quintiles also showed significantly more weight gain than the healthiest eaters. The gain in weight met the criteria for clinical significance after 8 years in the least healthy eaters and 12 to 15 years in the other groups. All dietary factors examined, except whole fat dairy foods and low fat or skim milk, were associated with weight change after adjustment for age, baseline BMI, and sleep. [56]The foods that were associated with a clinically meaningful increase in weight included potato chips and French fried potatoes. No other study reported a clinically meaningful dietary approach that affected weight gain.

Two observational studies (20,293 baseline; 9,388 analyzed) reported weight gain according to a threshold. [61 62] Eating meals outside the home was associated with a 10 to 40 percent increased odds of gaining 2 kg or more per year after adjustment for confounders.[62] Eating more than 698g/day of fruits and vegetables compared with eating less than 362/g day was associated with 74 percent decreased odds of gaining 3.4 kg or more over a 10 year period (OR 0.26, 95 percent CI, 0.07 to 0.97).[61] Greater vegetable consumption had a stronger association (OR 0.18, 95 percent CI, 0.05 to 0.3; highest compared with the lowest quintile of vegetable consumption) than fruit consumption (OR 0.62, 95 percent CI, 0.18 to 2.10; highest compared with the lowest quintile of fruit consumption) (Appendix E, Evidence Table 5).

Waist Circumference Change

Two dietary interventions (51,043 randomized; 16,597 analyzed) reported on waist circumference change (Figure 4).[46 48] Neither intervention met the threshold for clinical significance.

One observational study (6,814 baseline; 5,515 analyzed) reported on waist circumference change.[65] Waist circumference remained within 1cm of the baseline measure after four years of followup with many participants having a decrease in waist circumference over time. Because

ethnicity modified the effect of diet on waist circumference change and an overall effect was not reported, these results are included in the subgroup analyses (Appendix E, Evidence Table 5).

Progression to Overweight or Obesity

No dietary interventions and two observational studies (25,308 baseline; 12,089 analyzed) were reported.[62 65] The percent of the population with a normal weight (BMI 19 to 24) at baseline was not reported in one study and was 72 percent of those analyzed in another. The study that did not report the percent of people with normal weight at baseline only reported progression to overweight or obesity by ethnicity and is included in the subgroup section below. The study of university graduates reported that eating one meal a week outside the home was associated with a 22 percent increased risk of overweight or obesity compared with eating 3 or fewer meals per month outside the home (Hazard Ratio [HR] 1.22, 95 percent CI, 1.02 to 1.45) after adjustment for age, sex, baseline BMI, education, physical activity, snacking, fiber, alcohol, total energy intake, specialty diets, and smoking.[62] The risk increased to 33 percent when two or more meals were consumed outside the home per week (HR 1.33, 95 percent CI, 1.13 to 1.57) (Appendix E, Evidence Table 5).

Other Outcomes

One dietary intervention (48,835 randomized; 46,856 analyzed) reported on mortality.[48] There was no meaningful difference in mortality between the intervention and control groups (4.5percent compared with 4.4 percent). No other intermediate, clinical, health related quality of life or adverse effect outcomes were reported (Appendix E, Evidence Table 5).

Subgroups Reported in Interventional Studies

One dietary trial reported on subgroups of interest.[46 48] Weight change by intervention at 1 year approached or met a clinically meaningful threshold when stratified by age (50 to 59, 60 to 69, and 70 to 79 years) and baseline BMI (<25, 25 to 29.9, and ≥30).[48] These changes were not observed at later timepoints.[48] Similar patterns to the main weight change results were observed when women were stratified by malignancy and diabetes at baseline (Appendix E, Evidence Table 5).[48]

Sex subgroups in Observational Studies

Six observational studies (366,704 baseline; 165,687 analyzed) [56 59 62 64] reported on the relationship between diet and weight measures by sex. No clinically meaningful differences were reported (Appendix E, Evidence Table 5).

Age Subgroups in Observational Studies

Five observational studies (320,791 baseline; 148,863 analyzed)[56 58 63] reported on the relationship between diet and weight measures by age. No clinically meaningful differences were reported (Appendix E, Evidence Table 5).

Ethnicity Subgroups in Observational Studies

One observational study (6,814 baseline; 5,515 analyzed) reported on BMI and waist circumference change and risk of overweight or obesity by ethnicity.[65] For each one unit increase in a healthy eating z score (higher scores related to healthier eating according to the 1992 United

States Food Pyramid), a statistically significant BMI decrease occurred among White, Chinese, and Hispanic participants after adjustment for sociodemographic variables, total caloric intake, physical activity, smoking, and alcohol use. There was a decrease in BMI for African Americans, although it did not achieve statistical significance. A clinically meaningful change in BMI was reported for Whites, Chinese, and Hispanics with very healthy eating profiles. Individuals who were 2 z scores above the mean had a 0.8 to 1.1 decrease in BMI over the 4 years of followup.

Waist circumference decreased to a clinically meaningful degree of 2.4 to 3.1 cm in Whites and Hispanics for those 2 z scores above the mean, though the finding was only statistically significant in Whites. Healthy eating z score was associated with a less than 5 percent change in the odds of overweight or obesity (Odds Ratio [OR} 0.97 to 1.01) (Appendix E, Evidence Table 5).

Baseline Weight Subgroups In Observational Studies

Five observational studies (348,210 baseline; 156,505 analyzed) reported on the effects of dietary approaches on change in weight by baseline weight.[56 59 63 64] No clinically meaningful differences were reported, although two studies noted that the association between diet and weight gain was most pronounced among those who were overweight at baseline (Appendix E, Evidence Table 5).

Socioeconomic Status Subgroups in Observational Studies

One observational study (25,631 baseline; 6,764 analyzed) reported on the percent of daily energy intake consumed at breakfast by social class.[64] No differences were reported.

Chronic Disease Subgroups in Observational Studies

One observational study (18,494 baseline; 9,182 analyzed)[62] reported on the relationship between diet and weight measures by chronic disease. No differences were observed (Appendix E, Evidence Table 5).

Applicability

The results from the two dietary intervention studies apply only to women. The interventions were fairly intensive as they consisted of regular in person group sessions to change the eating pattern including consumption of fats, fruits, vegetables, and grains.

Both interventions were compared with a control consisting of a one time distribution of printed dietary guidelines. Individuals who are required to report to a study center to have their weight measured on a regular basis may be more motivated to maintain their weight even without a dietary intervention.

The observational studies were inclusive of many populations and likely have broad applicability. Although the studies reported on weight outcomes, they did not report on other important outcomes of interest such as adherence, obesity related clinical outcomes (other than mortality), health related quality of life, and adverse events. Only one study was specifically designed to examine long term weight outcomes.

Interpretation

There were no differences in weight maintenance between the intervention and control groups. Both the control and intervention groups maintained or lost weight as measured by BMI, waist circumference, and weight in kg. Eating a healthy diet, including fruits and vegetables and the avoidance potato chips and French fries was associated with less weight gain in observational studies. However, these eating behaviors were not consistently measured across studies. The strength of evidence for all outcomes was low.

Key Question 3: What is the comparative effectiveness of physical activity approaches for the prevention of weight gain in adults?

Four studies (828 randomized; 730 analyzed) reported on physical activity interventions[49 52] and six observational studies (338,234 baseline; 161,890 analyzed) reported on physical activity approaches to prevent weight gain in adults.[56 58 59 66] Three trials included a physical activity component as part of a combination intervention as reported with Key Question 5.[53 55]

Two physical activity interventions randomized patients to a community gym supervised exercise program compared with educational materials (Table 5).[49 51] The other two studies took place within primary care practices.[50 52] One study trained physicians to educate their patients about an ideal heart rate and evaluated that heart rate at followup visits compared with no heart rate assessment.[50] The other primary care based study randomized patients to a health walking program compared with a single educational session.[52] Three of the four studies specifically excluded patients who regularly participated in an exercise program.[49 50 52]

Observational study approaches included the change in duration of a treadmill test at baseline and 7 years of followup,[59] categories of physical activity in MET hours per week[56 66] and occupational physical activity.[58]

No study's primary goal was weight maintenance. Because fewer than three studies were identified with a common intervention, meta analyses were not conducted.

BMI Change

Four physical activity interventions (828 randomized; 687 analyzed) reported on BMI change (Figure 5).[49 52] Most participants lost or maintained weight over the 1 to 2 years of followup. Three trials showed there were no differences in BMI change in the gym based or health walks group compared with the control.[49 51 52] The heart rate training program lost 1.5 units of BMI more than the physician advice only group, although both groups lost weight during the 1 year study period (Appendix E, Evidence Table 5).[50]

Weight Change

One physical activity intervention (164 randomized; 138 analyzed) reported on weight change.[49] There was no difference at year 1 or year 2 between the strength training and brochure groups.

Six observational studies (338,234 baseline; 161,890 analyzed) reported on physical activity approaches and weight change.[56 58 59 66] In the followup study of a trial, participants maintained weight within 3 kg over 13 years.[66] In the other observational studies, about 0.5 kg per year was gained over the course of followup. Physical activity was associated with a decrease in weight gain in four of the six studies.[56 59] Participants who were not able to perform a treadmill test for

the same duration as baseline had a 2 kg increase in weight for each minute of decrease in exercise test duration.[59] In the publication reporting on three studies, people who increased their physical activity over time (increased activity 23.2 MET hours/week over 4 years) had less weight gain (0.8 fewer kilograms gained, 95 percent CI, 0.6 to less than 1 kg) than those who decreased their activity over time (decrease of 16.3 MET hours/week).[56] One of the studies that did not report a clinically meaningful finding in absolute weight change characterized the physical activity pattern of the women who successfully maintained normal weight.[66] Women who had a normal BMI at baseline and gained fewer than 2.3 kg at any time point increased their MET hours per week from 17.6 at baseline to 26.1 MET hours per week at 12 years (Appendix E, Evidence Table 5).[66]

Waist Circumference Change

One physical activity intervention (120 randomized; 120 analyzed) reported on waist circumference change.[51] Three times weekly endurance exercise training among the elderly produced no significant changes in waist circumference compared with the control (Appendix E, Evidence Table 5).[51]

Progression to Overweight Or Obesity

No study reported on progression to overweight or obesity and physical activity interventions.

Other Outcomes

Four physical activity interventions (828 randomized; 687 analyzed) reported on at least one other outcome. One trial reported that no serious adverse events were reported during the trial, although they do not mention what events would have been considered serious.[50] Adherence or compliance with the intervention was reported in all four trials. Adherence with the interventions ranged from 33 percent (participated in at least one heart walk)[52] to 71 percent (three or more exercise sessions per week with heart monitoring) (Appendix E, Evidence Table 5).[50]

Subgroups

No subgroups were reported in the interventional studies. Five of the six observational studies (334,907 baseline; 158,862 analyzed) reported on subgroups (Appendix E, Evidence Table 5).

Sex subgroups in Observational Studies

No differences by sex were reported in three studies (Appendix E, Evidence Table 5).[56]

Age subgroups in Observational Studies

In one study, pre menopausal women and those under age 65 had greater absolute weight gain with decreased physical activity compared with menopausal and older women.[66] The publication reporting three studies reported no difference in the physical activity weight gain relationship when stratified by age (Appendix E, Evidence Table 5).[56]

Ethnicity subgroups in Observational Studies

In three studies, no differences by ethnicity were reported (Appendix E, Evidence Table 5).[56]

Baseline Weight Subgroups in Observational Studies

In four studies, participants who were overweight at baseline had a greater increase in weight with decreased fitness than people who were normal weight at baseline.[56 59] Another study found that normal weight individuals had greater weight gain with decreased physical activity than the overweight and obese women (Appendix E, Evidence Table 5).[66]

Smoking Subgroups in Observational Studies

One study reported no physical activity by smoking interaction (Appendix E, Evidence Table 5).[66]

Applicability

The intervention studies targeted selected populations (low income women and the elderly) or took place in a primary care setting. The interventions included specific exercises (gym activities, walking, and running) that may not be accessible to all populations. Because all of the intervention study participants (including the controls) maintained their weight, participation in a study or the knowledge that weight will be measured regularly over time may decrease weight gain.

In the observational studies, the approaches encompassed activities in addition to intentional exercise, including walking at a normal pace and stair climbing. The observational studies were inclusive and likely apply to a broad population.

Interpretation

All participants in physical activity interventions maintained or lost weight despite low adherence to the programs. A primary care provider program to train patients how to measure their heart rate and achieve a target heart rate during regular exercise sessions was associated with a decrease in BMI.

The observational studies that measured change in physical activity over time reported clinically meaningful findings. Five of the six studies reported findings that suggest that weight maintenance requires increasing energy expenditure over time. The strength of evidence for all outcomes was low.

Key Question 4: What is the comparative effectiveness of orlistat for the prevention of weight gain in adults?

No study reported on the use of orlistat and weight maintenance in adults.

Key Question 5: What is the comparative effectiveness of a combination of self management, dietary, physical activity, and medication approaches for the prevention of weight gain in adults?

Four trials (988 randomized; 750 analyzed) reported on a combination of self management, dietary, and physical activity interventions.[53 55 67] One observational study reported that there was no diet by physical activity interaction on weight gain.[56]

The four randomized combination interventions differed in their target populations and interventions (Table 6). One study randomized normal and overweight women of childbearing age aimed to prevent weight gain. Another study randomized normal, overweight and obese

women with a young children to prevent weight gain.[67]In another trial, the intervention groups received self monitoring, dietary, and physical activity strategies over the phone and in group sessions or through the mail and were compared with a control group that received an informational booklet.[54] Another study randomized couples who had lived together for two years of less to in person and mail, mail only, or no intervention to promote healthy diet and physical activity behaviors.[54] A third study randomized households that included at least two adults and a child to a control group or group sessions, phone calls, and a newsletter to change individual and household self monitoring (daily weighing and television viewing), dietary and physical activity behaviors. Information on children is not included in the results below.[53] Two studies' goals included the prevention of weight gain.[53 54] The differences in study populations prevented meta analyses.

BMI Change

Three combination interventions (738 randomized; 535 analyzed) reported on BMI change.[53 55] There was no clinically meaningful difference between the groups on BMI change (Figure 6; Appendix E, Evidence Table 5).

Weight Change

Two combination interventions (534 randomized; 420 analyzed) reported on weight change.[54] There was no difference between groups(Appendix E, Evidence Table 5).

Waist Circumference Change

One combination intervention (274 randomized; 156 analyzed) reported on waist circumference change.[55] There was no difference between groups (Appendix E, Evidence Table 5).

Progression to Overweight Or Obesity

Two combination interventions (558 randomized; 361 analyzed) reported on progression to overweight or obesity.[55] Compared with the prevalence of overweight or obesity at baseline (61 percent of men and 28 percent of women), the respective percent increases in overweight and obesity at 16 months were 8 percent and 3 percent in the controls, 7 percent and 2 percent in the group that received mailings, and 2 percent and 2 percent in those who received mailings and participated in contact sessions.[55] In the female only trial, 40 percent of women remained within 2 kg of their baseline body weight, while 60 percent gained 2 kg or more during the 3 year study period. There was no difference by intervention group (Appendix E, Evidence Table 5).[54]

Adherence

Two combination interventions (464 randomized; 379 analyzed) reported on adherence. The study of women reported 50 percent attendance across 15 sessions over 24 months.[54] In the household study, 73 percent of households attended at least four of five group sessions and completed at least half of the home based activities over 1 year. Twenty percent attended all group sessions and completed 100 percent of the household activities (Appendix E, Evidence Table 5).[53]

Other Outcomes

No clinical, health related quality of life or adverse effect outcomes were reported.

Subgroups

The study of couples reported no differences in the effect of the intervention by sex.[55] The study of women reported no differences in weight gain by intervention when they stratified by women who were normal versus overweight at baseline.[54] The study of women with young children reported that women under 40 with a BMI of 18-24 at baseline who received the intervention lost 0.7 kg compared to a weight gain of 1.7 kg in the control group. This 2.4 kg difference is at the threshold of clinical significance (Appendix E, Evidence Table 5).

Applicability

Younger adults were targeted in these trials. The mean age at baseline was between 27 and 41 years. In two of the trials, the participants were required to cohabitate with another adult and in a third trial 58 to 68 percent were married.

These interventions may not apply to older age groups or single individuals. The interventions were very intensive and required substantial lifestyle changes. Individuals may not be willing or able to make drastic changes to their behaviors. The relatively low adherence rates may reflect how difficult it is for individuals to change their patterns .

Interpretation

Despite the intensive interventions, there were no differences in prevention of weight gain between groups. The low levels of adherence may also have contributed to the lack of difference between the intervention and control groups. Like the other intervention trials, the control participants in these trials tended to maintain weight better than is thought to occur in the general population. The strength of evidence for all outcomes was low.

KQ6. What is the comparative effectiveness of environment level approaches for the prevention of weight gain in adults?

One interventional study (41,958 individuals in the community; 2,151 recruited at baseline; 1,294 analyzed)[47] and one observational study (3,174 at baseline; 500 analyzed) were included (Appendix E, Evidence Table 5). The interventional study included three demographically similar communities in Northern California. A multi stage random sample of the communities were recruited in 1972 and followed through 1975. Two communities received interventions and another community did not.[47]

The two intervention communities had billboard, newspaper, radio, and television advertising with information on cardiovascular disease risk factors and how to reduce them (Table 7).[47] The individuals recruited for outcome assessment also received pamphlets, cookbooks and other information through the mail (Table 7; Appendix E, Evidence Table 7). The comparison community did not receive a mass media campaign. The goal of the study was to reduce the risk of cardiovascular disease (Appendix E, Evidence Table 5).[47]

The observational study was a six year longitudinal assessment of neighborhood walkability in Canada (Appendix E, Evidence Table 5).[57] Neighborhood walkability was measured using Geographic Information Systems (GIS) data from the 2001 and 2006 censuses.[57] This index

incorporated assessments of the density of dwellings, land use mix, and intersections. The index was categorized as lowest, low, mid, high, and highest walkability. Traffic was measured by survey responses from a question assessing whether traffic decreased walkability (Appendix E, Evidence Table 5).

BMI Change

The interventional study did not report on BMI change.

There were no clinically meaningful difference in BMI change by neighborhood walkability or traffic perception (Appendix E, Evidence Table 8).[57]

Weight Change

The community based study calculated "relative weight," defined as actual weight/ideal weight, and evaluated percent change in relative weight as their outcome.[47] The control community demonstrated a slight increase in relative weight (0.3 percent) versus no change in relative weight among both intervention communities. This difference was not clinically meaningful.

The observational study did not report on weight change (Appendix E, Evidence Table 8).

Waist Circumference Change

No study reported on environmental level approaches and their impact on waist circumference change.

Progression to Overweight Or Obesity

No study reported on environmental level approaches and their impact on the progression to overweight or obesity.

Other Outcomes

No adherence, clinical, health related quality of life or adverse effect outcomes were reported.

Subgroups

The community based study examined subgroups of patients at high risk for cardiovascular disease.[47] This subgroup analysis contained four groups: community 1 received no intervention (arm 1; n=95), community 2 received the mass media campaign (arm 2; n=94), community 3 received the mass media campaign (arm 3; n=40), and community 4 received the mass media campaign and individual level counseling (arm 4; n=77). Communities 1 to 3 had a 1 percent decrease in relative weight at 2 years, while Community 4 had a 1.5 percent decrease. There was no clinically or statistically significant difference between groups (Appendix E, Evidence Table 8). No other subgroups were reported.

Table 3. Description of observational exposures studies reporting on the relationship between approaches of interest and weight change.

Author year **Study name*** **Mean duration of followup**	**Primary aim of original cohort**	**Self management measures**	**Dietary measures**	**Physical activity measures**
Studies reporting on more than 1 approach				
Mozaffarian 2011[56] Nurses' Health study Nurses' Health Study II Health Professionals' Follow up Study Duration not reported	Prospective study of cancer and cardiovascular disease risk factors in married female nurses Prospective study of modifiable risk factors for health problems affecting younger women in female nurses Prospective study of nutritional factors and serious illnesses including cancer and cardiovascular disease in male health professionals	Daily hours of sleep, Television watching in hours per day	Fruits, Vegetables, Nuts, Whole fat dairy foods, Low fat dairy foods, Potato chips, Potatoes, Whole grains, Refined grains, 100percent fruit juice, Sugar sweetened beverages, Diet soda, Sweets and desserts, Processed meats, Unprocessed red meats, Trans fat, Fried foods, Quintiles of eating pattern	Metabolic equivalent of task (MET) hours per week, Quintiles of physical activity
Adair 2011[58] Cebu Longitudinal Health and Nutrition Survey Duration not reported	Prospective study of infant feeding patterns among Filipino women	None reported	Energy intake in kilojoules per day, Protein intake as a percent of energy	Occupational physical activity
Lewis 1997[59] Pereira 2005[60] Coronary Artery Risk Development in Young Adults Duration not reported	Prospective study of cardiovascular risk factors in young adults	None reported	Percent calories from fat[59], Fast food consumption per week[60]	Exercise duration in seconds from a treadmill test[59]

Table 3. Description of observational exposures studies reporting on the relationship between approaches of interest and weight change (continued)

Author year **Study name*** **Mean duration of followup**	**Primary aim of original cohort**	**Self management measures**	**Dietary measures**	**Physical activity measures**
Studies reporting on a dietary approach				
Vioque 2008[61] Duration not reported	Followup study of responders to a cross sectional health and nutrition survey in Valencia and Alicante, Spain	None reported	Fruits, Vegetables	None reported
Bes Rastrollo 2009[62] Seguimiento Universidad de Navarra Duration 4.4 years	Prospective study of diet and chronic diseases, including obesity among graduates of a Spanish university	None reported	Eating away from home meals	None reported
Schulz 2005[63] European Prospective Investigation into Cancer and Nutrition Duration 4.4 years	Prospective study of nutrition and cancer in 10 European countries, Potsdam cohort	None reported	Quintiles of high fiber/ low fat food pattern score	None reported
Purslow 2008[64] European Prospective Investigation into Cancer and Nutrition Duration 3.7 years	Prospective study of nutrition and cancer in 10 European countries, Norfolk cohort	None reported	Percent of daily energy intake consumed during breakfast	None reported

Table 3. Description of observational exposures studies reporting on the relationship between approaches of interest and weight change (continued)

Author year **Study name*** **Mean duration of followup**	**Primary aim of original cohort**	**Self management measures**	**Dietary measures**	**Physical activity measures**
Study reporting on a physical activity approach				
Gao 2008[65] Multi Ethnic Study of Atherosclerosis Duratrion not reported	Prospective study of risk factors for cardiovascular disease	None reported	Healthy eating index z score	None reported
Lee 2010[66] Women's Health Study Duration 13.1 years	Trial of low dose aspirin and vitamin E to prevent cardiovascular disease and cancer in female health professionals	None reported	None reported	Metabolic equivalent of task (MET) hours per week

* Study name listed only if applicable

Table 4. Description of dietary interventions in studies among adults in the general population

Author, year **Study name** **Duration of intervention***	**Primary Aim**	**Group 1**	**Group 2**
Bhargava 2002[46] Women's Health Trial Feasibility Study in Minority Populations (WHTFSMP) Duration 1 year	Reduce energy intake from fat, especially saturated fat, to 20 percent of caloric intake. Increase consumption of fruits, vegetables and grains.	Maintained usual diet. Received information on nutrition guidelines.	18 group sessions with a dietician over 1 year. During the sessions, the participants performed role playing activities, provided support and reinforcement and solved problems.
Howard 2006[48] Women's Health Initiative (WHI) Duration 8 – 12 years	Study the effect of a low fat, high fruit, vegetable and grain diet on breast cancer, colorectal cancer and heart disease.	Received information on nutrition guidelines.	18 group sessions with a dietician during the first year. Four group sessions per year for remaining years. Sessions promoted dietary and behavioral changes to reduce total dietary fat to 20 percent of caloric intake, increase fruit and vegetable intake to 5 or more servings per day, increase grains, preferably whole grains, to 6 or more servings daily. Encouraged to maintain usual energy intake by replacing calories from fat with other sources, like carbohydrates.

*Neither study included additional followup after the intervention period.

Table 5. Description of physical activity interventions in studies among adults in the general population

Author, year **Study name*** **Duration of intervention**	**Primary Aim**	**Group 1**	**Group 2**
Schmitz 2007 [49] Strong, Health and Empowered (SHE) Duration 2 years[†]	Assess efficacy of twice weekly strength training to prevent increases in body fat percentage and intra abdominal fat.	Maintained usual diet. Received information on physical activity guidelines, with a focus on starting a walking program.	Maintained usual diet. Received a 2 year membership to a fitness center. Twice weekly 1 hour group sessions with a fitness professional for the first 4 months. Group sessions every 3 months for the remaining 20 months. During sessions, participants taught how to stretch, warm up, cool down, abdominal and low back strengthening exercises and strength training using machines and free weights. Fitness trainers made reminder calls if participants missed a week of sessions. Fitness trainers were available by phone, email or at the gym. Other components included social gatherings, a study website, a monthly newsletter and free childcare for 2 hours per session.
Petrella 2003 [50] Step Test Exercise Prescription (STEP) Project Duration1 year	Compare the effect of an exercise prescription intervention on fitness.	Physician provided exercise counseling at baseline 3, 6 and 12 months including examples and benefits of exercises.	Physician provided exercise counseling at baseline 3, 6 and 12 months including examples and benefits of exercises. Physician administered a stepping test and recorded stepping time and heart rate at the visits. Patients received a target exercise heart rate based on the results of the step test.
Muscari 2010 [51] Pianoro Study Duration 1 year	Study physical activity and cardiovascular risk.	Educational materials to improve lifestyle including physical activity	Three hourly group sessions per week of endurance exercise training supervised by Exercise and Sports Sciences researchers.

Table 5. Description of physical activity interventions in studies among adults in the general population (continued)

Author, year **Study name*** **Duration of intervention**	**Primary Aim**	**Group 1**	**Group 2**
Lamb 2002 [52] Duration 1 year	Study walking program on physical activity levels, physiological and behavioral consequences.	Single 30 minute group session with physiotherapist. The session included benefits of exercise, recommended levels of exercise for adults based on published guidelines, tips to start and maintain an exercise program. Participants were encouraged to take at least 120 minutes of moderate intensity activity per week using an activity enjoyable and convenient to them.	Same 30 minute session as Group 1. Participants were also provided with oral and written information on local walking programs. A local walking coordinator also called each person after the session to further explain the program and invite them to join. Group and individual walking programs were offered over the phone and in the mail. Up to three phone calls were made during year to encourage people to join the program. Family and friends were encouraged to participate in the walks.

* Study name listed only if applicable
† Duration of followup after the intervention = 1 year

Table 6. Description of combination interventions in studies among adults in the general population

Author year **Study name*** **Duration of intervention**	**Unit of intervention**	**Primary Aim**	**Group 1**	**Group 2**	**Group 3**
French 2011 [53] Take Action Duration 1 year	Household	Prevent weight gain over 1 year.	None	Household and individual interventions to decrease television viewing, increase physical activity to at least 30 minutes daily, decrease high calorie snacks and meals, limit sweetened beverages, increase availability of fruits and vegetables, serve smaller portions, limit fast food, and make healthy choices when eating out. Intervention was delivered by trained staff during a home visit, 6 group sessions, home activities and monthly newsletters. The group sessions included behavioral strategies (goal setting, self monitoring, positive reinforcement), interactive activities 20 30 minutes of physical activity and a healthy snack. A scale for home weighing, a tv limiting device and telephone support calls were also used. Gift cards to a grocery store were provided for attending group sessions or completing home activities.	

Table 6. Description of combination interventions in studies among adults in the general population (continued)

Author year **Study name*** **Duration of intervention**	**Unit of intervention**	**Primary Aim**	**Group 1**	**Group 2**	**Group 3**
Lombard 2010 [67]	School attended by participant's child	Prevent weight gain over 1 year.	Thirty minute information session and brochure on diet and physical activity guidelines for Australia.	Four one hour group sessions over 1 month on goal setting, self monitoring, social support, problem solving, training to prevent weight relapse, diet and physical activity. Pedometers distributed with goal of 10,000 steps per day. Individuals set their own goals. Text messages were sent by mobile phone once a month during months 2 through 11.	

Table 6. Description of combination interventions in studies among adults in the general population (continued)

Author year **Study name*** **Duration of intervention**	**Unit of intervention**	**Primary Aim**	**Group 1**	**Group 2**	**Group 3**
Levine 2007 [54] Duration 2 years[†]	Individual	Efficacy of a clinic based treatment and correspondence course to prevent weight gain.	Information session to describe control, clinic based and correspondence interventions. Received a booklet with information about benefits of weight maintenance, low fat eating and regular physical activity.	Information session to describe control, clinic based and correspondence interventions. 15 group sessions with a nutritionist or behavioral interventionist over 2 years. Sessions focused on making dietary and activity changes and monitoring those changes. Lessons during sessions provided on cognitive change strategies, stimulus control techniques, problem solving, goal setting, stress, time management and relapse preventions. Directed to set activity and intake goals to decrease sedentary behavior and increase activity. Written materials on nutrition and physical activity were provided. Homework assignment to practice weight control strategies assigned at each sessions and due at next session. If weight gain of more than 2 pounds occurred over 2 consecutive weeks, given activity and calorie goals to help them return to their baseline weight.	Information session to describe control, clinic based and correspondence interventions. Same information and homework assignments as group 2 except delivered by mail instead of group sessions.

Table 6. Description of combination interventions in studies among adults in the general population (continued)

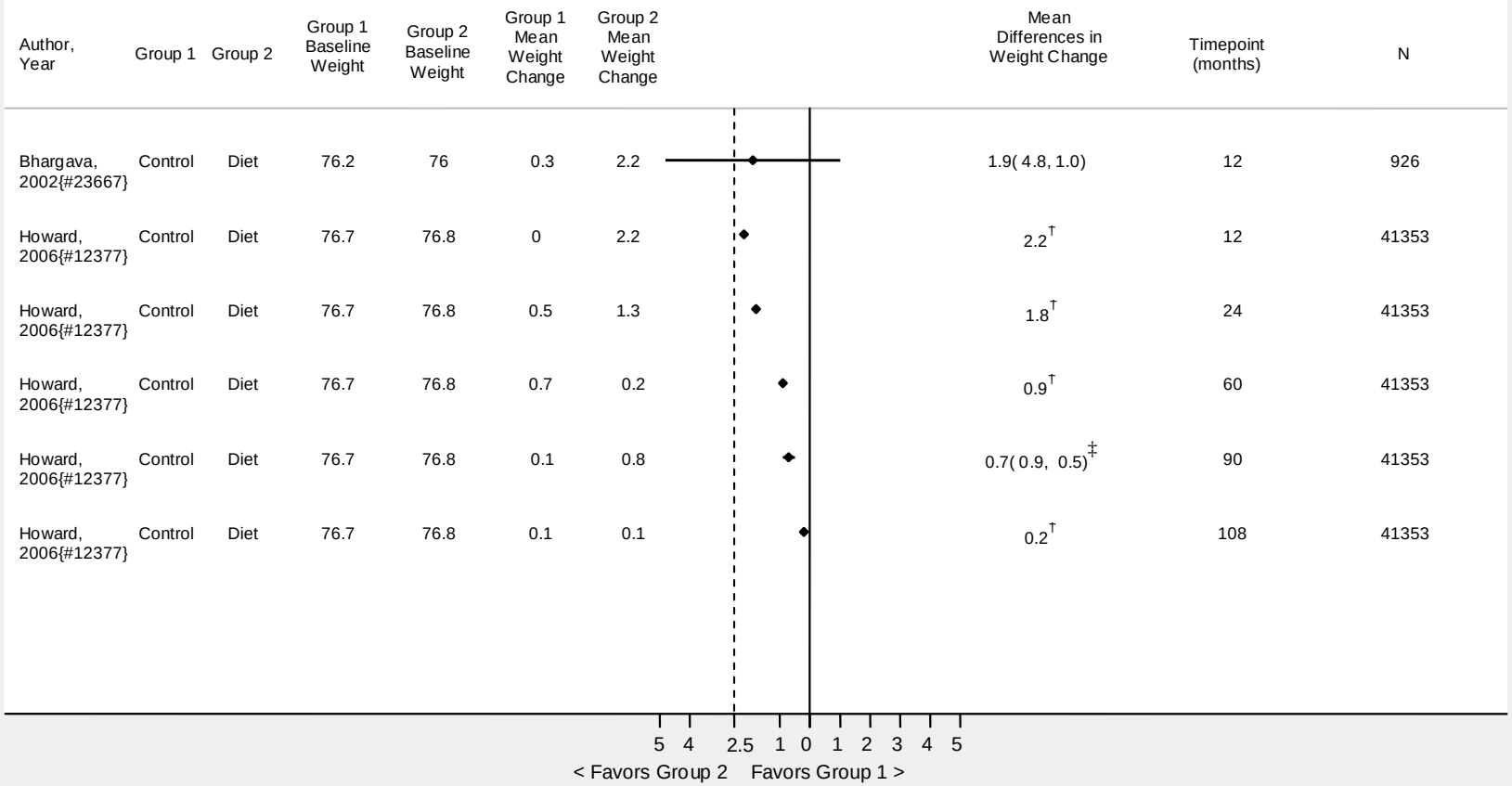
Author year **Study name*** **Duration of intervention**	**Unit of intervention**	**Primary Aim**	**Group 1**	**Group 2**	**Group 3**
Burke 2003 [55] Duration 4 months[‡]	Couples	Encourage adoption or maintenance of physical activity and a healthy diet.	None	One group sessions and five mailed modules aimed to increase moderate physical activity to at least 30 minutes most days, increase incidental activities (*i.e.,* taking stairs instead of elevator, walking instead of driving), eat low fat (no more than 10percent of energy as saturated fat), high fiber (30g daily from grains, fruits and vegetables), low sat foods and increase fruit and vegetable intake. Modules included information on benefits of exercise and nutrition, how to start an exercise program, injury prevention, types and sources of dietary fat, budgeting for healthy foods, choosing meals when eating out, overcoming barriers to change, costs and benefits of a healthy lifestyle, goat setting, time management, stress management, and exercise and diet information relevant to pregnancy. Alcohol consumpition and cigarette smoking were mentioned but not focus of intervention.	Three group sessions and three mailed modules aimed to increase moderate physical activity to at least 30 minutes most days, increase incidental activities (*i.e.,* taking stairs instead of elevator, walking instead of driving), eat low fat (no more than 10percent of energy as saturated fat), high fiber (30g daily from grains, fruits and vegetables), low sat foods and increase fruit and vegetable intake.

* Study name listed only if applicable
[†] Duration of followup after the intervention = 1 year
[‡] Duration of followup after the intervention = 8 months

Table 7. Description of interventions in studies among adult populations using environmental approaches

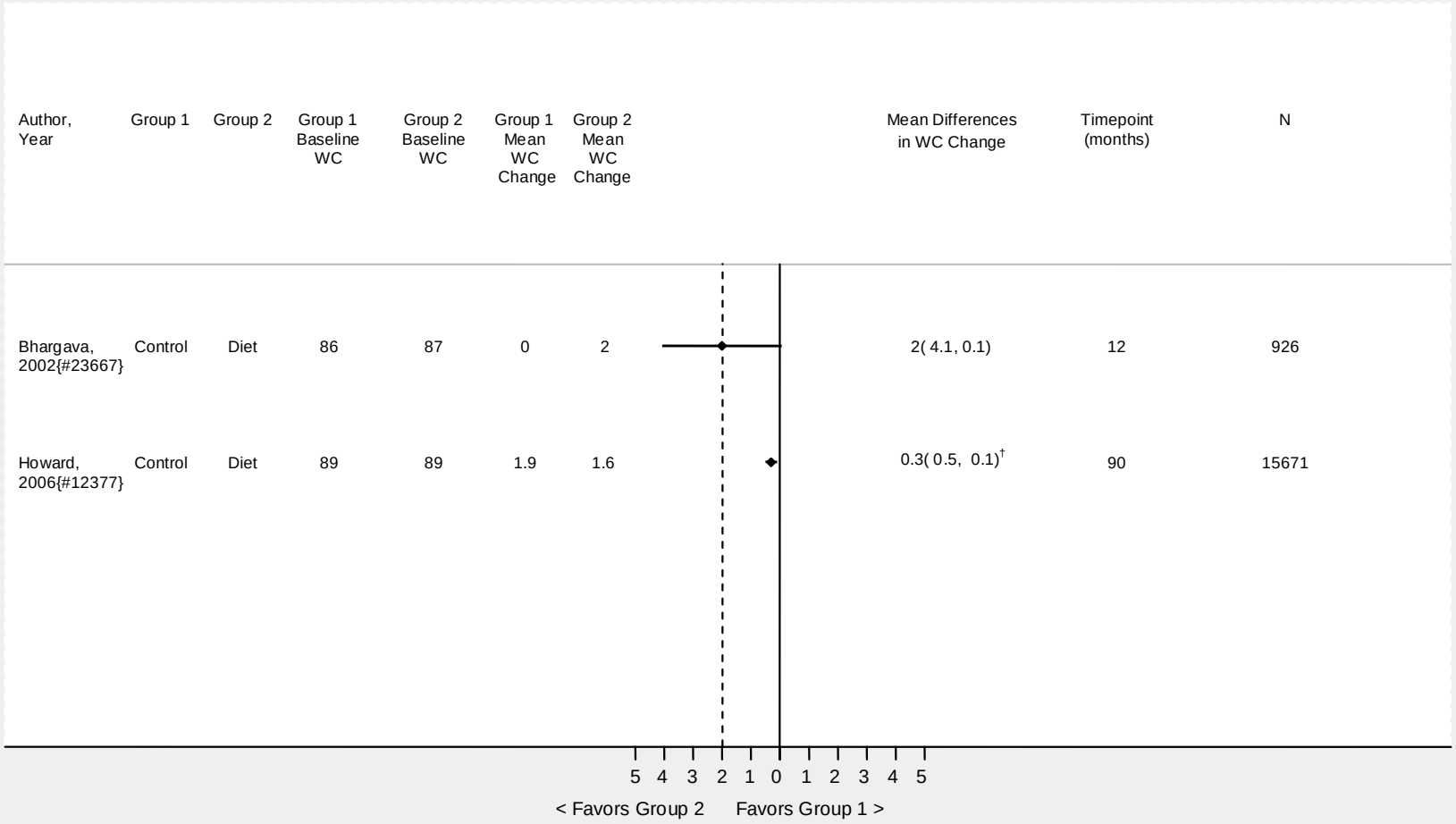
Author, Year Duration	Primary Aim	Control	Active Combination intervention
Fortmann, 1981[47] 30 months	Reduce CVD risk	No intervention	Self management • 10 week counseling program for participant +/ spouse delivered in small groups and individual home sessions focused on personal analysis of behavior, modeling new healthy behaviors, and skills building (high risk subgroup of arm 3). Diet • Direct mailing of dietary educational information including pamphlets and cookbooks focused on reducing saturated fat, cholesterol, salt, sugar, and alcohol intake, and calorie restriction (arms 2 & 3) Physical Activity • Direct mailing of exercise educational information focused on increasing physical activity (arms 2 & 3) Environmental • Mass media campaign on CVD risk factors that used TV, radio, newspaper, and billboards (arms 2 & 3)

Figure 3. Differences in weight change for dietary interventions among adults from the general population



† Abstracted from figure
‡ Adjusted for age, race/ethnicity, baseline BMI, change in dietary and physical activity patterns over time
kg: kilogram
If the study did not report an estimate of variability, no confidence intervals were generated.
Dotted line indicates a clinically meaningful change of 2.5kg

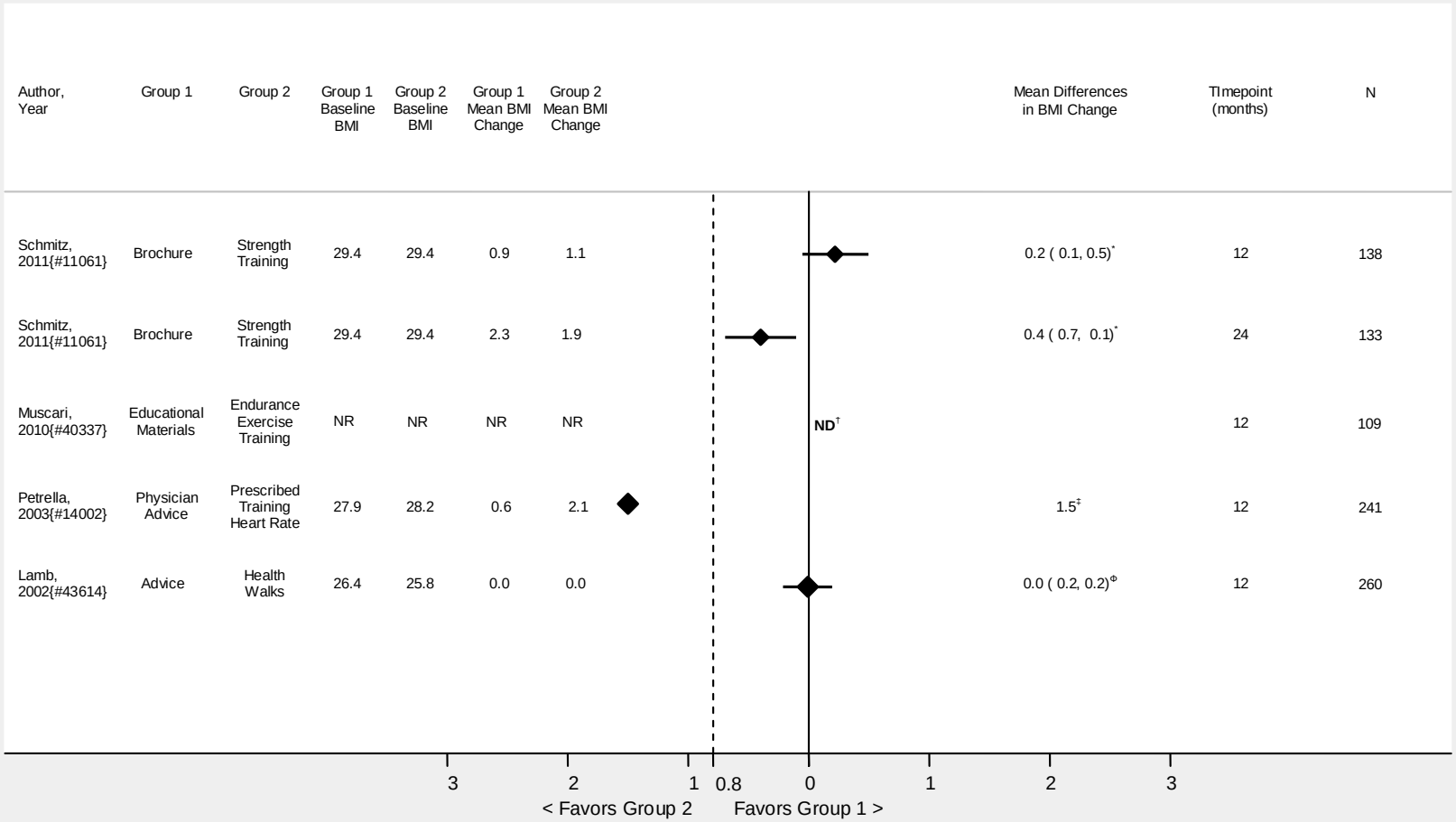
Figure 4. Differences in waist circumference change for dietary interventions among adults from the general population



Mean differences in waist circumference change (cm) from baseline to timepoint for the general population (Group 2 Group 1)

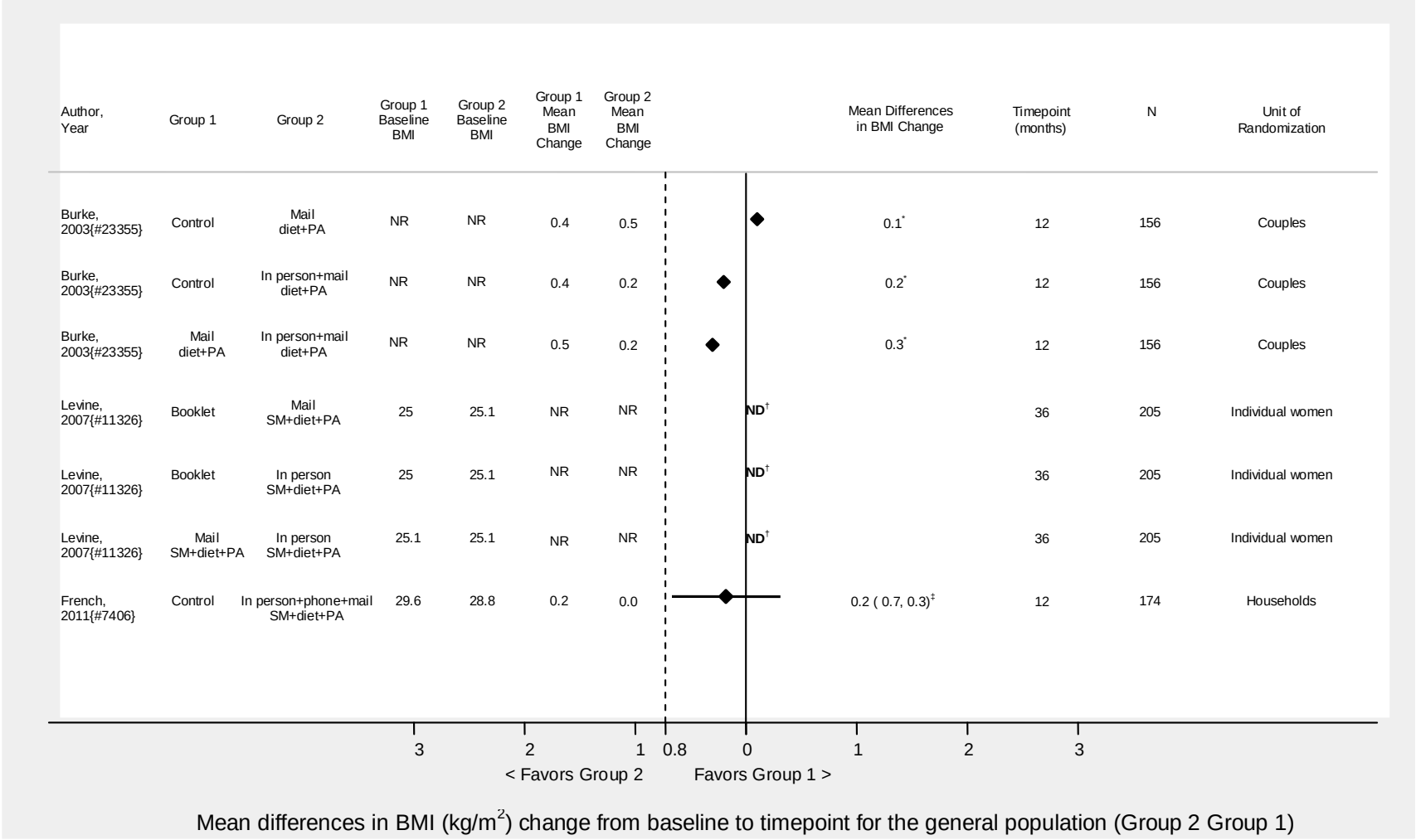
† Adjusted for age, race/ethnicity, baseline BMI, change in dietary and physical activity patterns over time
cm: centimeter; WC: waist circumference
Dotted line indicates a clinically meaningful change of 2 cm

Figure 5. Differences in BMI change for physical activity interventions among adults from the general population



*Adjusted for race/ethnicity, baseline activity, marital status and kilocalorie intake
† Reported no difference between groups without providing values
‡ Adjusted for pre randomization levels of undefined baseline factors
Φ Intention to treat analysis
BMI: body mass index; kg/m^2: kilogram/meter^2; ND: reported no difference between groups without providing values; NR: not reported
If the study did not report an estimate of variability, no confidence intervals were generated. Dotted line indicates a clinically meaningful change of 0.8 BMI units

Figure 6. Differences in BMI change for combination interventions among adults from the general population



* Abstracted from figure; adjusted for age, sex and correlation within couples
† Reported no difference between groups without providing values
‡ Adjusted for age, gender, smoking, household configuration, income, education, race and correlation within households
BMI: body mass index; kg/m^2: kilogram/meter^2; ND: reported no difference between groups without providing values; NR: not reported; PA: physical activity; SM: self management.
If the study did not report an estimate of variability, no confidence intervals were generated. Dotted line indicates a clinically meaningful change of 0.8 BMI units

Work based Approaches to Weight Maintenance in Adults

Study Characteristics

Four interventional trials (73,102 participants) took place in work settings. The results from these trials were reported in 5 articles. Both recruitment and the intervention occurred in the workplace.[70 73] One trial occurred in the military (124,367 eligible active duty air force members; 68,591 members analyzed), which we considered a workplace.[70] One trial occurred at sites within a chemical company (10.281 eligible employees; 3152 employees recruited at baseline; 3119 analyzed)[72 74], another occurred at different hospitals (1983 employees randomly selected; 806 recruited at baseline; 731 analyzed)[73], and the final trial occurred at a variety of different employers (553 employees recruited at baseline; 458 analyzed)[71]. All four of the work based interventional studies were multicenter trials. One trial was randomized,[73] the other three used non randomized, quasi experimental designs (Appendix E, Evidence Table 6).[70 72]

The duration of the interventions ranged from 12 to 24 months. The earliest year of recruitment was 2002,[70] and the latest year of recruitment was 2006 (Appendix E, Evidence Table 6).[72]

Three studies were located in the United States[70 72 73] and one in Europe (Appendix E, Evidence Table 9).[71]

Three studies stated their goals were to prevent weight gain.[70 71 73] while Another study's goal was to reduce overweight and obesity (Appendix E, Evidence Table 6).[72]

Population Characteristics

Interventional Studies

Inclusion criteria varied between the four work based interventional studies. The number of women that were included in each study varied considerably between studies, although it seems a likely reflection of the sex distribution in each worksite. For example, women made up less than 15 percent of the military study and 30 percent of the chemical company study population.[70 72] A population of hospital workers comprised over 75 percent women (Appendix E, Evidence Table 7).[73]

The mean age of participants that were included in each study also seemed likely to be a reflection of the age distribution of that worksite. For example, mean age was in the early thirties for the military population[70] and in the mid forties for the chemical company population.[72] In a sample of employees from a variety of worksites in the Netherlands, the mean age was in the upper thirties.[71] Race/ethnicity, education, and smoking status were not consistently reported across studies (Appendix E, Evidence Table 7).

Approaches

All work based intervention studies used a combination of approaches including self management (n=2), diet (n=3), and physical activity (n=3). Three of the work based interventions also included specific environmental changes as a part of their combination approach.[71 73] The specifics of each intervention and approach are described prior to the results by Key Question (Table 8; Appendix E, Evidence Table 8).

Outcomes

Key Points

- **BMI**
  - No difference in BMI change between a combination of self management, dietary, physical activity and environment level interventions and the comparison groups (low strength of evidence).
  - No studies were identified for maintenance of BMI with self management, diet, or physical activity interventions alone in the work setting (insufficient strength of evidence).
- **Weight**
  - No difference in prevention of weight gain between a combination of self management, dietary, physical activity and environment level interventions and the comparison groups (low strength of evidence).
  - No studies were identified for maintenance of weight with self management, diet, or physical activity interventions alone in the work setting (insufficient strength of evidence).
- **Waist circumference**
  - No difference in waist circumference change between a combination of self management, dietary, physical activity and environment level interventions and the comparison groups (low strength of evidence).
  - No studies were identified with self management, diet, or physical activity interventions alone in the work setting (insufficient strength of evidence).
- **Adherence**
  - Awareness and use of the environmental interventions was poor (low strength of evidence).
  - No studies were identified with self management, diet, or physical activity interventions alone in the work setting (insufficient strength of evidence).
- **Other outcomes**
  - No studies identified (insufficient strength of evidence).

Key Questions 1 through 5. What is the comparative effectiveness of self management, dietary physical activity, orlistat, or combination approaches that do not involve an environment level intervention for the prevention of weight gain in adults?

No work based intervention studies reported on a single modality of intervention. All studies used a combination of interventions, including an environment level intervention and and are reported under Key Question 6.[70 71]

Key Question 6: What is the comparative effectiveness of a combination of self management, dietary, and physical activity approaches combined with environment level approaches for the prevention of weight gain in adults?

All work based approaches to weight management used a combination of approaches, including both individual level interventions targeting self management, diet, and physical activity as well as environment level interventions.

The work based interventional study in the setting of a chemical company evaluated the effectiveness of site specific environmental changes to promote healthy eating and physical activity in combination with a workplace health promotion program that provided individually

tailored programming on self management, diet, and exercise.[72] The study considered this worksite health promotion program as usual care, as it was in place at both the control and intervention sites. The environmental changes were considered the intervention.

The work based interventional study in the hospital evaluated the effects of a combined individual and environment level program.[73] Environment level changes included promotional materials and group events to promote healthy eating and physical activity, along with individual level education on diet and exercise through displays, workshops, and newsletters. The control group for this study received no intervention.

The work based interventional study that was implemented in a variety of worksites in the Netherlands[71] combined individual level self management interventions with environmental level changes. The self management intervention emphasized education, skills training, goal setting, and self monitoring with respect to energy balance, which was supported via a web based tool. The environmental changes implemented varied between worksites. Each intervention was selected and implemented by key personnel at each site. The control group received no intervention.

The work based interventional study in the military evaluated the effects of a self management intervention that included completion of two personal energy plan workbooks supplemented with weekly educational emails on healthy eating habits and physical activity.[70] The control group in this study received no intervention.

BMI Change

Three studies evaluated change in BMI at 12 and 24 months.[71 73] No study found a clinically significant between group difference in BMI change at 12 or 24 months.[71 73] In two of these studies, both control and intervention maintained their BMI over time (Figure 7; Appendix E, Evidence Table 9).

Weight Change

Three studies reported on weight change.[70 72] No clinically meaningful differences were reported between the intervention and control groups. Both the control and intervention groups maintained their weight over 2 years in one study.[71] The military based study only provided results among subgroups,[70] which are presented in the section below (Figure 8; Appendix E, Evidence Table 9).

Waist Circumference Change

One study evaluated waist circumference as an outcome.[71] This study reported a statistically significant between group difference favoring the intervention group at 12 and 24 months, although the difference was not clinically significant (1.5 cm at both 12 and 24 months) (Appendix E, Evidence Table 9).

Adherence

One study reported adherence to the intervention.[73] This study created a participation score (with a range of zero to100, where higher scores indicate greater participation) that was based on survey responses to questions regarding awareness and use of the environmental interventions. The 12 month mean participation score was 15.8 and the 24 month mean participation score was 18.1 among intervention sites (Appendix E, Evidence Table 9).

Clinical Outcomes

No studies reported on mortality, quality of life, cardiovascular disease, diabetes, cancer, sub fertility, degenerative joint disease or liver disease.

Adverse Events

No studies reported on adverse effects such as burden of intervention, nutritional deficiencies, eating disorders, or activity related injury.

Subgroups

The study in the military setting reported the 12 month mean change in weight among subgroups of men and women.[70] Women in the intervention group lost a mean of 0.1 kg, whereas women in the control group gained 0.4 kg. The difference between these two groups was statistically significant; however, a difference of 0.5 kg is not clinically relevant (Appendix E, Evidence Table 9). The study in the chemical company setting performed a stratified analysis by gender, which did not reveal any significant interaction between the intervention and gender[74]. No other subgroup analyses were performed in the other studies.

Applicability

The work based studies occurred in different populations and used different intervention strategies. Effective work based interventions may be specific to the dynamics of particular work environments.

Interpretation

There were no differences in BMI, weight or waist circumference change between the groups. One study provided a health promotion plan for both the intervention and control sites and added environment level reminders about diet and physical activity at the intervention site. Both the control and intervention groups maintained weight over 2 years.

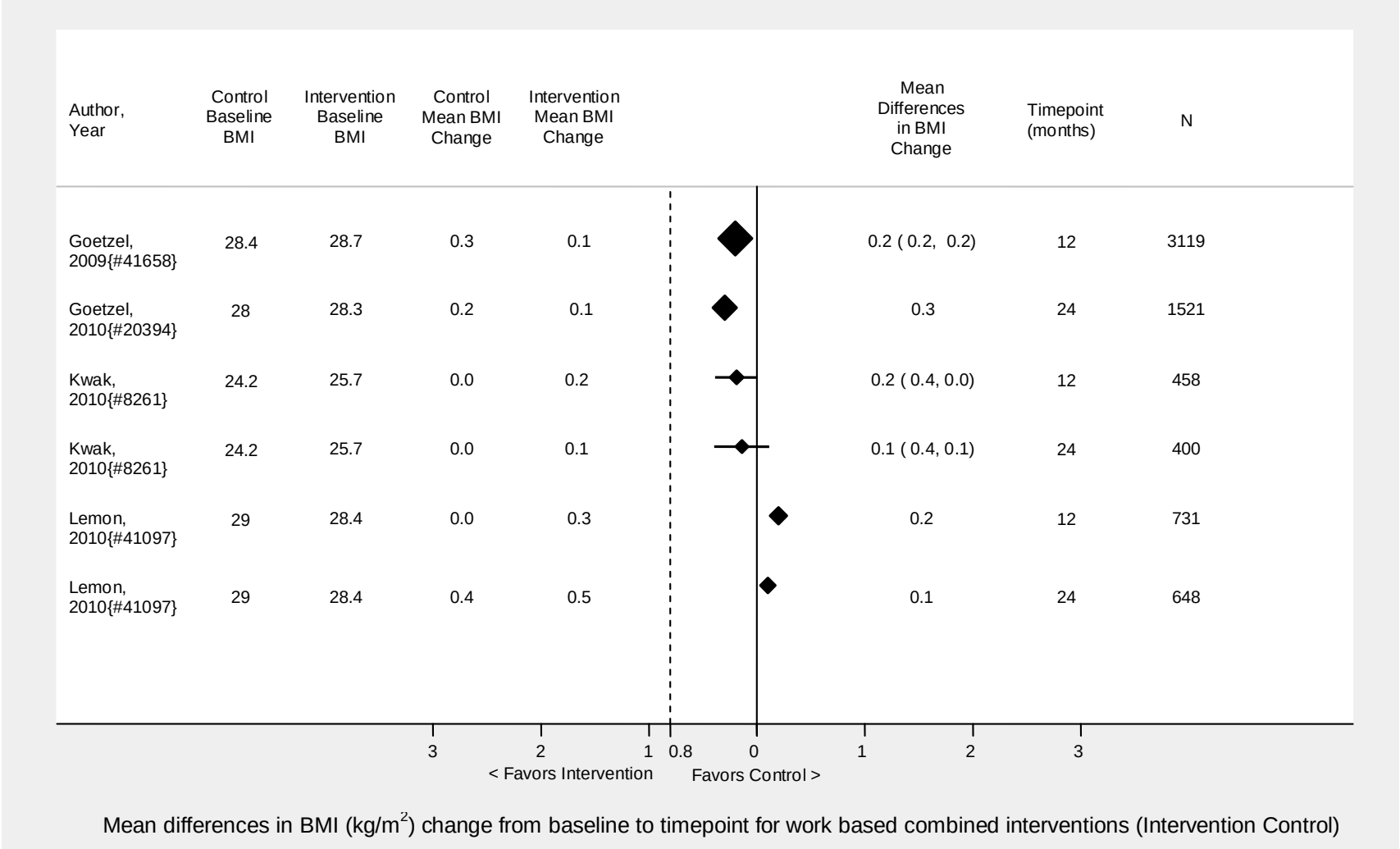
Table 8. Description of interventions in studies among adult populations in work settings

Author, Year Duration	Primary Aim	Control	Active Combination intervention
Goetzel, 2009[74] Goetzel, 2010[72] 24 months	Reduce overweight and obesity	Usual care with individually focused health promotion programs	Diet • Usual care for individual dietary counseling Physical Activity • Usual care physical activity programs Environment • Environmental changes to support an increase in employees' physical activity, improve their eating habits, and manage their weight through environmental prompts and point of choice messaging • Key personnel recruited to set worksite health goals and train worksite leaders on health promotion
Kwak, 2010[71] 12 months	Prevent weight gain	No intervention	Self management • Receipt of In Balance box with pedometer, measuring tape, calorie guide, and instructions for food and exercise diaries • Access to In Balance website including Weight Co@ch instrument that provides personalized advice to maintain weight • CD ROM based training including education on energy balance behaviors, skills training, goal setting • Self monitoring Environment • Key worksite personnel selected and implemented different environmental interventions at each site such as changing food products available at the cafeteria, workshops, signs promoting healthy eating and physical activity, forming lunchtime walking or cycling groups

Table 8. Description of interventions in studies among adult populations in work settings (continued)

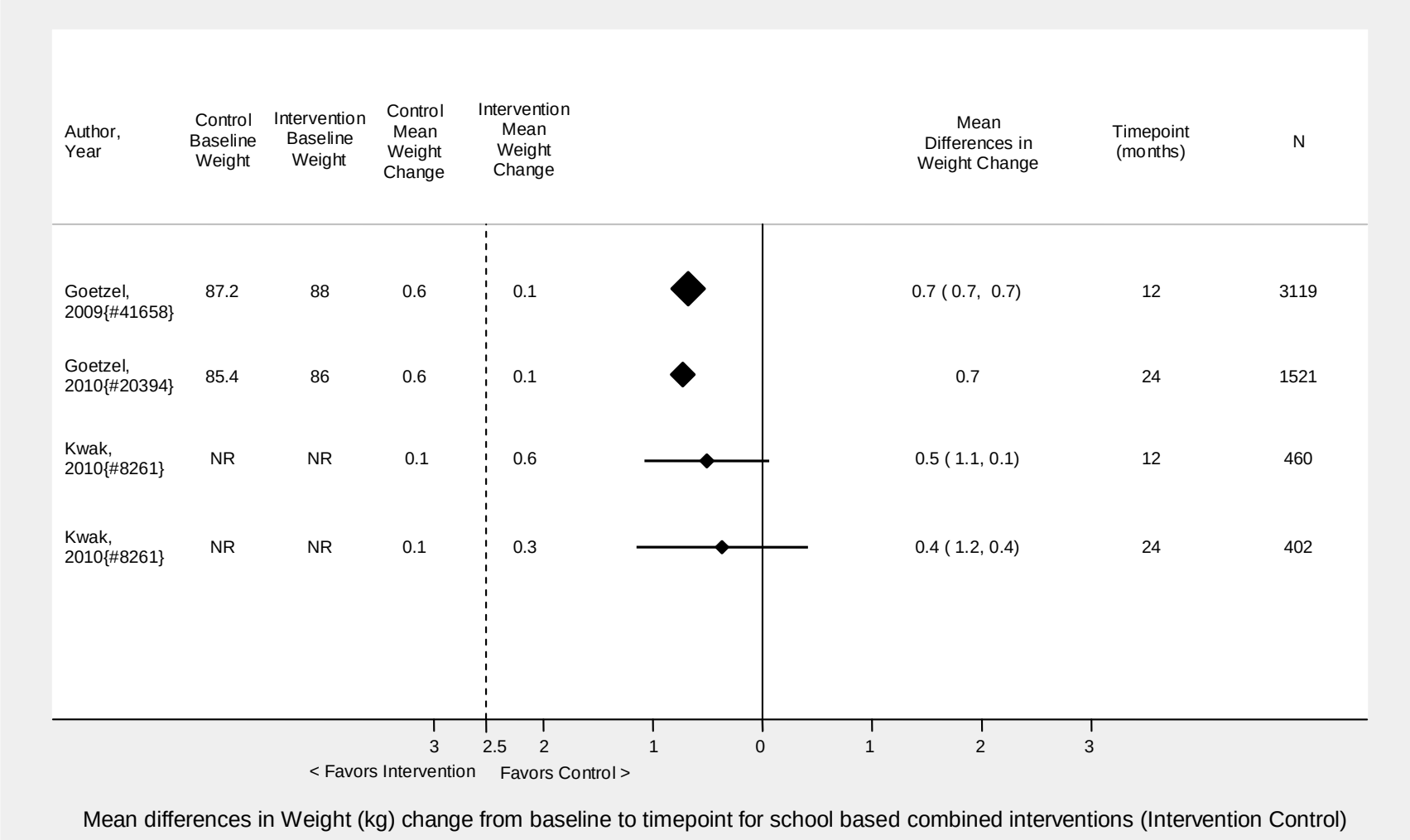
Author, Year Duration	Primary Aim	Control	Active Combination intervention
Lemon, 2010[73] 24 months	Prevent weight gain	Usual care/no intervention	Diet • Weekly displays on nutrition education • Weekly newsletter via email that included education on a healthy weight topic, a recipe, and quick tip Physical Activity • Weekly displays on exercise education • Monthly strength training workshop where individuals were given a simple routine and a resistance band Environment • Promotional signs to encourage healthy eating included nutritional information for food and beverages in the cafeteria, new healthy menu options, special cafeteria events, onsite farmer's market, healthy potlucks • Promotional signs to encourage physical activity included stairway signs, indoor and outdoor walking routes, and walking groups • Periodic campaigns and challenges targeting physical activity, healthy eating, and weight with group and individual prizes
Robbins, 2006[70] 12 months	Prevent weight gain	Usual care	Self management • Completion of personal energy plan workbooks Diet • Email on healthy eating habits every other week Physical Activity • Email on physical activity every other week

Figure 7. Differences in BMI change for combination interventions among adults in a work setting



BMI: body mass index; kg/m^2: kilogram/meter^2
If the study did not report an estimate of variability, no confidence intervals were generated.
Dotted line indicates a clinically meaningful change of 0.8 BMI units

Figure 8. Differences in weight change for combination interventions among adults in a work setting



kg: kilogram; NR: not reported
If the study did not report an estimate of variability, no confidence intervals were generated.
Dotted line indicates a clinically meaningful change of 2.5kg

College Based Approaches to Weight Maintenance in Adults

Study Characteristics

Two interventional trials (155 participants) took place in a college setting.[75,76] One trial was reported in two publications.[75] Both interventions were randomized trials at a single school. The duration of the interventions ranged from 16 to 24 months. The earliest year of recruitment was 1997[76] and the latest year of recruitment was 2002.[75] One trial occurred in the United States[76] (40 students randomized; 34 analyzed) and the other trial took place in Canada (115 students randomized; 105 analyzed). [75]

The stated study goal for both of the studies was the prevention of weight gain (Appendix E, Evidence Table 10).

Population Characteristics

Interventional Studies

The trials had similar populations.[75 76] The mean age was 19 years and the majority of participants were White. Both studies included only freshman and sophomore college students. One study examined only women,[76] while the other study included both women and men (Table 9; Appendix E, Evidence Table 111).[75]

Approaches

Both college based interventional studies used a combined approach to target weight maintenance in the intervention group including diet and exercise education. One study also included education on self management (Appendix E, Evidence Table 12).

Outcomes

Key Points

- **BMI**
  - No difference in BMI change between a combination of self management, dietary, and physical activity interventions and the comparison groups in the college setting (low strength of evidence).
  - No studies were identified for maintenance of BMI with self management, diet, or physical activity interventions alone in the college setting (insufficient strength of evidence).
- **Weight**
  - No difference in weight change between a combination of self management, dietary, and physical activity interventions and the comparison groups in the college setting (low strength of evidence).
  - No studies were identified for maintenance of weight with self management, diet, or physical activity interventions alone in the college setting (insufficient strength of evidence).
- **Waist circumference**

- No difference in waist circumference change between a combination of self management, dietary, and physical activity interventions and the comparison groups in the college setting (low strength of evidence).
- No studies were identified for maintenance of waist circumference with self management, diet, or physical activity interventions alone in the college setting (insufficient strength of evidence).

- **Adherence**
  - Less than half of participants attended at least 60 percent of intervention seminars (low strength of evidence).
  - No other studies were identified (insufficient strength of evidence).
- **Other outcomes**
  - No study identified (insufficient strength of evidence).

Key Questions 1 through 4. What is the comparative effectiveness of self management, dietary, physical activity or orlistat approaches for the prevention of weight gain in adults?

No college based intervention studies reported on self management, dietary, physical activity or orlistat interventions. Both studies included a combination intervention as reported with Key Question 5.[67 75]

Key Question 5: What is the comparative effectiveness of a combination of self management, dietary, physical activity, and medication approaches for the prevention of weight gain in adults?

Both trials targeted freshman or sophomore students to provide them education on diet and exercise. One trial evaluated the effects of a 4 month college course on the science of nutrition, exercise, physiology, and metabolism on weight gain prevention.[76] The course included both lectures and laboratory exercises on these topics. The other trial evaluated the effects of a 24 month weight gain prevention program using small groups to increase knowledge on diet and exercise, as well as self management principles including problem solving, goal setting, and monitoring strategies. [75] The control group participants for both of these trials received no information or intervention. [75 76]

BMI Change

Both trials evaluated change in BMI.[75 76] Neither study reported a clinically meaningful difference in weight gain prevention based on BMI (Figure 9; Appendix E, Evidence Table 13).

Weight Change

Both trials reported on weight change[75 76] The 24 month weight gain prevention program among college students had a statistically significant effect on weight change.[75] The between group differences at 12 and 24 months were 1.4 kg and 1.3 kg and are not considered clinically significant. The college course intervention had a between group difference of 3.2 kg at 16 months; however, this result was not statistically significant (Figure 10).[76]

Waist Circumference Change

One trial reported on waist circumference.[75] There was no difference in waist circumference change between the intervention and the control groups at 2 years (Appendix E, Evidence Table 16).

Adherence

Adherence to the intervention was reported in one trial.[75] This study defined adherence as attending more than 60 percent of seminars during a 12 month period. During year 1 adherence was 53 percent and fell to 26 percent during year 2 (Appendix E, Evidence Table 13).

Clinical Outcomes

No studies reported on mortality, quality of life, cardiovascular disease, diabetes, cancer, sub fertility, degenerative joint disease or liver disease.

Adverse Events

No studies reported on adverse effects such as burden of intervention, nutritional deficiencies, eating disorders, or activity related injury.

Subgroups

One study evaluated the effects of the intervention among those with BMI $\leq$24 kg/m^2 and higher BMIs(>24 kg/m^2) at baseline.[76] There were no differences in 16 month BMI change between control and intervention participants who had lower BMIs at baseline. However, the higher BMI intervention group (n=11) lost 1.4 kg as compared with higher BMI controls (n=6) who gained 9.2 kg, which was statistically significant (Appendix E, Evidence Table 13).

Applicability

Interventions included only freshman and sophomore college students. The overall generalizability of the findings is limited, due to the limited number of interventional studies in the college setting.

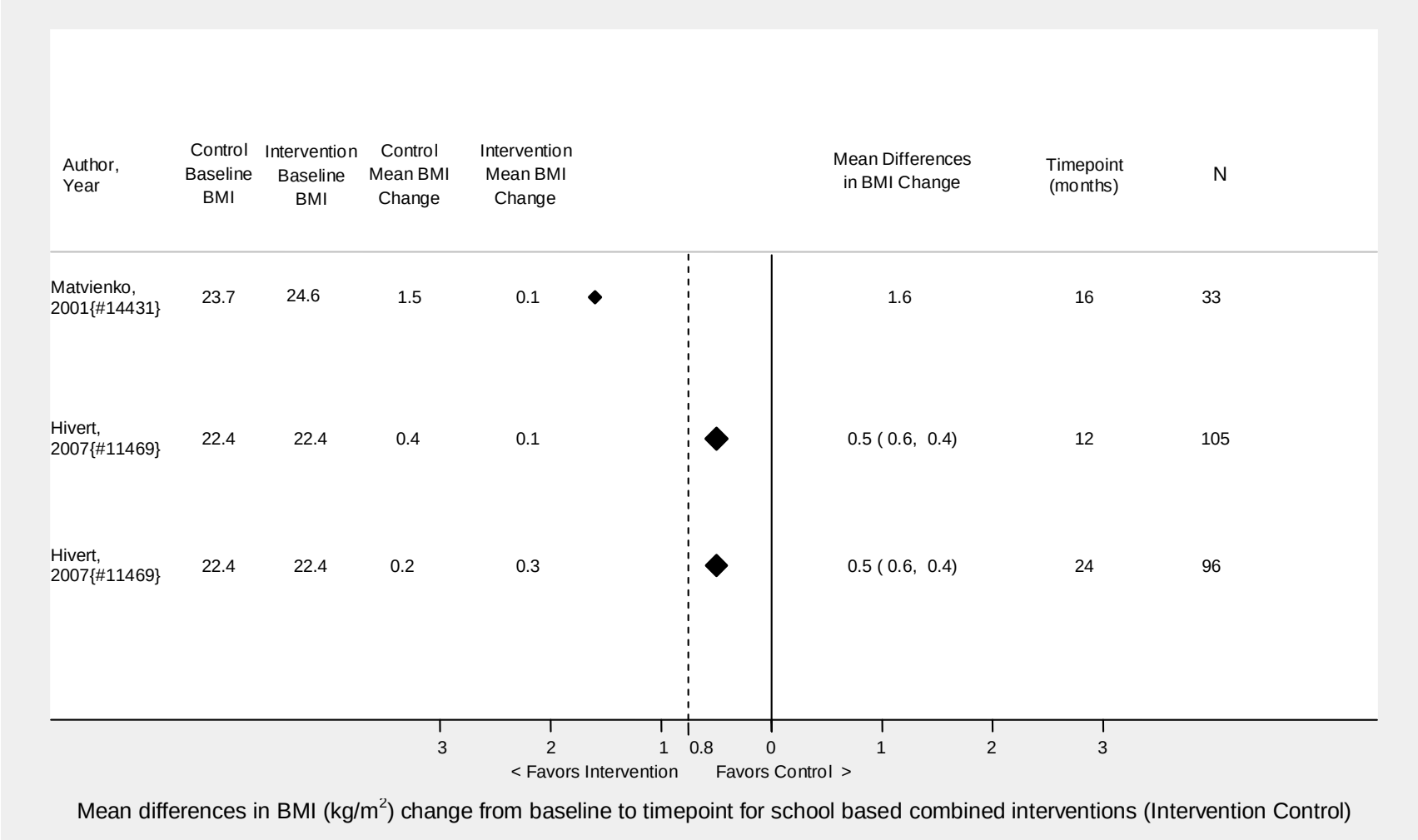
Interpretation

Combined interventions in the college setting did not have a significant effect on weight gain prevention. However, these interventions may be effective among students with higher BMI at baseline.

Table 9. Description of interventions in studies among adult populations in college based settings

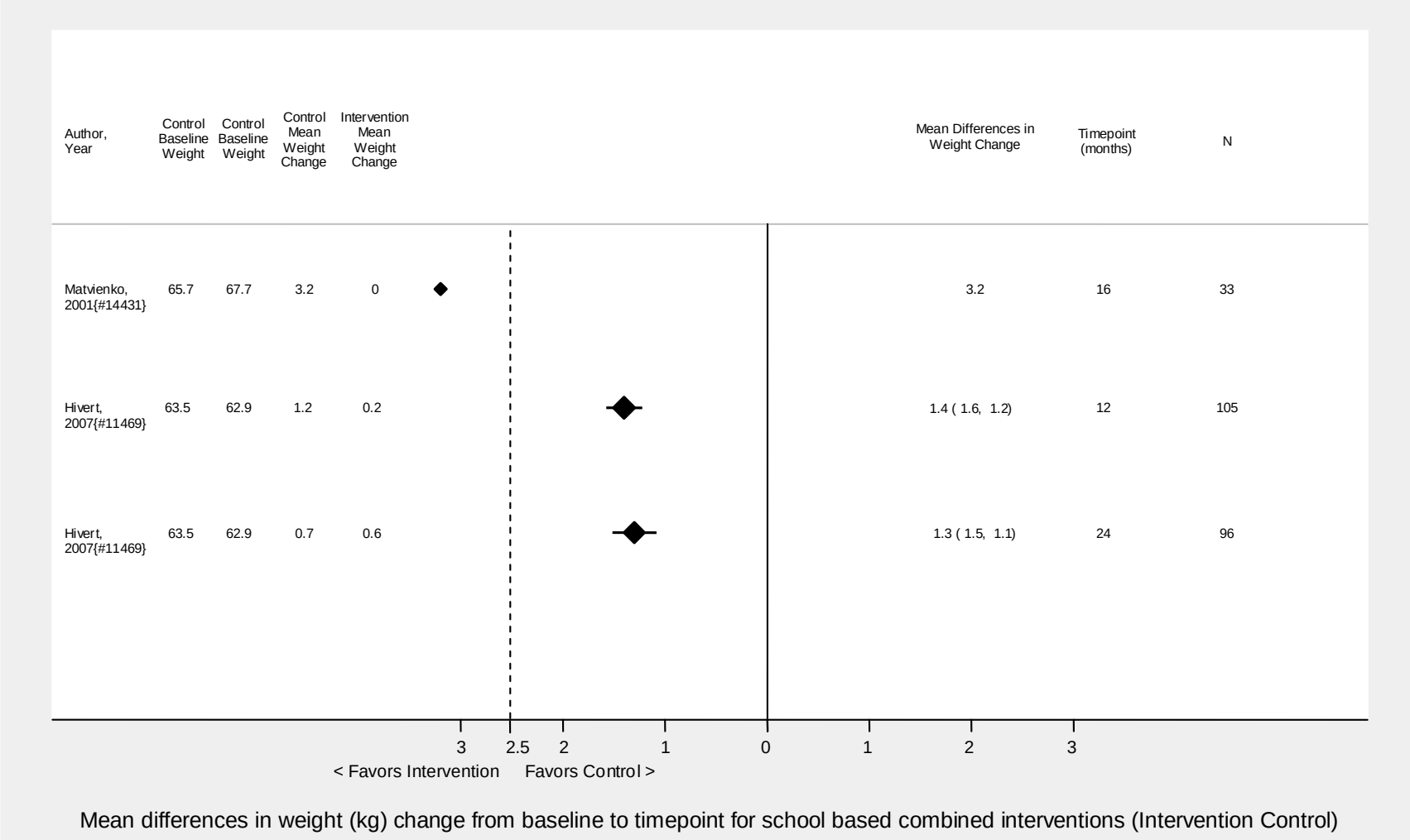
Author, Year Duration	Primary Aim	Control	Active Combination intervention
Hivert, 2007[75] 24 months	Prevent weight gain	No intervention	Small group sessions Self management • Increasing knowledge on weight gain • Problem solving • Goal setting • Monitoring strategies Diet • Increasing knowledge on national recommendations on diet Physical Activity • Increasing knowledge on national recommendations on exercise
Matvienko 2001[76] 4 months	Prevent weight gain	No intervention	College course Diet • Lectures to increase knowledge of nutrition science including physiology and metabolism • Laboratory exercises including body composition measurements, serving sizes, food sensory exercises, and food preparation methods Physical Activity • Lectures to increase knowledge of exercise science including physiology and metabolism

Figure 9. Differences in BMI change for combination interventions among adults in a college setting



BMI: body mass index; kg/m^2: kilogram/meter^2; ND: report no difference between groups (did not provide values); NR: not reported; PA: physical activity; SM: self management.
If the study did not report an estimate of variability, no confidence intervals were generated.
Dotted line indicates a clinically meaningful change of 0.8 BMI units

Figure 10. Differences in weight change for combination interventions among adults in a college setting



Mean differences in weight (kg) change from baseline to timepoint for school based combined interventions (Intervention Control)

kg: kilogram
If the study did not report an estimate of variability, no confidence intervals were generated.
Dotted line indicates a clinically meaningful change of 2.5kg

Weight Maintenance in Adults at Risk for or with Cardiovascular Disease or Diabetes Mellitus

Study Characteristics

Nine randomized clinical trials (trials)[77 88] and one non randomized clinical trial[89] evaluated the effect of self management, dietary, and/or physical activity interventions on weight maintenance in adults at risk for or with established cardiovascular disease or diabetes mellitus. One of the included trials, the Oslo Diet and Exercise Study (ODES), reported relevant results in two published articles,[77 78] and another, The PREDIMED (Prevencion con Dieta Mediterranea) Study, reported relevant results in three published articles (Appendix E, Evidence Table 14).[83 84 86]

One trial was conducted in Australia,[85] one in Asia,[79], two in the United States,[82 89] and five in Europe. [77 78 80 81 83 84 88] Five of the 10 trials did not report years of recruitment.[80 81 85 87 89] Of those reporting on time of recruitment, three recruited between 2001 and 2007[79 86 88] and two recruited between 1990 and 1992. [77 78 82] Two trials were conducted at more than one site,[82 84 86] and the others were conducted at a single study site. [77 81 85 87 89] Six trials recruited participants from a clinical setting [80 81 83 87 89]. Other settings for recruitment included a cohort study,[77 78] insurance plan,[79] and diabetes screening program.[88] Two trials did not report on the recruitment setting (Appendix E, Evidence Table 14).[82 87]

Four trials restricted inclusion exclusively to those with diabetes mellitus.[80 81 85 89] Of these studies, one excluded patients not on insulin,[89] and one excluded those without a stable diabetes medication regimen.[81]

Six trials were conducted in participants with risk factors for cardiovascular disease or diabetes mellitus such as dyslipidemia, elevated blood pressure, elevated BMI, or elevated hemoglobin A_{1c} (HbA_{1c}).[77 79 82 84 86 88] Of these six trials, four excluded participants with known cardiovascular disease,[77 78 82 84 86 87] and three excluded participants with diabetes.[77 78 82 87] One trial required all participants to have impaired glucose tolerance (Appendix E, Evidence Table 14).[88]

Most articles did not report on total followup period; [79 84 86 88] when reported, followup periods ranged from 1 to 2 years.[77 78 85 89]

Weight maintenance was a stated goal in a single article (Appendix E, Evidence Table 14).[89]

Population Characteristics

The 10 trials enrolled or randomized 3,830 participants. [77 82 85 89] Two trials did not report the sex of the study population.[77 78 89] Women comprised 31 to 62 percent of the study population in the other articles.[79 89] Three trials did not report on the age of participants.[77 78 82 89] In another trial, the reported mean age by sex was 56.9 years for women and 47.8 years for men.[87] Mean age ranged from 59.5 to 68.2 in the other trials.[79 81 83 86 88] Only two trials reported on race and ethnicity; black participants comprised 17 percent of the study population in one trial,[82] and 26 percent of participants in another trial were Asian or Pacific Islander (Appendix E, Evidence Table 15).[88]

Education was reported qualitatively in a one trial in which roughly one half of participants were college graduates.[82] In the PREDIMED Study, 73 to 76 percent of participants had less than

a high school education in the control and two active diet intervention arms.[86] Smoking was reported in two trials with 11 and 19 percent of participants current smokers.[77 88]One study excluded current smokers (Appendix E, Evidence Table 18).[85]

Roughly half of the participants in the PREDIMED Study had diabetes,[86] and in another study, 14 to 20 percent of participants had diabetes.[79]. All participants were on insulin in one study of patients with diabetes (Appendix E, Evidence Table 15).[89]

Interventions

We did not identify any trials evaluating the effect of orlistat on weight maintenance in adults. One trial compared a self management intervention to a control group,[80] two trials evaluated dietary interventions,[83 84 86 89] two evaluated physical activity interventions,[83 84 86 87 89] and five trials evaluated a combination of a self management, dietary, or physical activity interventions (Tables 10 13; Appendix E, Evidence Table 16).[79 81 82 85 87]

Outcomes

Key Points

- **BMI**
  - Goal setting to improve dietary and physical activity patterns resulted in less weight gain at one year compared to no intervention (low strength of evidence).
  - No differences reported between dietary, physical activity or combination interventions and control groups (low strength of evidence).
- **Weight**
  - A combination of diet and exercise resulted in decreased weight at one year compared to no intervention (low strength of evidence).
  - No differences between self management, dietary or physical activity interventions and control groups (low strength of evidence).
- **Waist circumference**
  - Goal setting to improve dietary and physical activity patterns decreased waist circumference at one year compared to no intervention (low strength of evidence).
  - Endurance exercise decreased waist circumference compared to no intervention (low strength of evidence).
  - A combination of self management, aerobic activity and strength training resulted in less of an increase in waist circumference compared to control (low strength of evidence).
  - No difference between dietary interventions and control groups (low strength of evidence).
- **Adherence**
  - Adherence to endurance exercise three times per week was 57 percent over one year (low strength of evidence).
  - Adherence to a combination of self management and physical activity interventions ranged from 64 to 100 percent (low strength of evidence).
  - Trials of self management and dietary interventions did not report adherence (insufficient strength of evidence).
- **Quality of life**

- There was no difference in quality of life between an intervention that included a combination of self management and physical activity compared to control (low strength of evidence).
- Trials of self management, dietary and physical activity interventions did not report adherence (insufficient strength of evidence).

Key Question 1. What is the comparative effectiveness of self management approaches for the prevention of weight gain in adults?

A single RCT of 100 participants evaluated the effects of a 6 month self management intervention relative to usual care on BMI and waist circumference maintenance in overweight adults with diabetes.[80] The self management intervention focused on goal setting to improve dietary and physical activity patterns (Table 1).[80] Assessment of diet and physical activity was used to identify and address barriers to meeting lifestyle goals.[80]

Participants in this self management intervention attended three in person sessions and had three telephone contacts.[80] Four other trials included self management as a component of the active intervention strategy and are described below in the section on studies evaluating a combination of intervention types (Table 10; Appendix E, Evidence Table 17).[79 81 82 85]

BMI Change

At 12 months, mean BMI had increased by 1.42 kg/m^2 in the usual care arm and remained stable (mean change from baseline, 0.34 kg/m^2) in the self management intervention arm.[80] This difference in mean change in BMI from baseline between the groups did not reach statistical significance ((1.8; 95 percent CI 0.2 to 3.7, p=0.075) for the self management intervention compared with usual care) (Appendix E, Evidence Table 17).[80 80] All randomized participants were included in the analysis (N=100).[80]

Weight Change

There were no self management interventions in this population that measured waist circumference as an outcome.

Waist Circumference Change

At 12 months, mean waist circumference had increased by 2.4 cm in the usual care arm and decreased by 1.5 cm in the self management intervention arm.[80] This difference in mean change in waist circumference from baseline between the groups did not reach statistical significance (3.9 cm, 95 percent CI, 2.1 to 9.9 cm, p=0.21) (Appendix E, Evidence Table 17).[80] All randomized participants were included in the analysis (N=100).[80]

Adherence

There were no self management interventions in this population that measured adherence as an outcome.

Clinical Outcomes

The included study did not report on mortality, cancer, cardiovascular disease outcomes, hemoglobin A1c, sub fertility, degenerative joint disease, liver disease, or quality of life.

Adverse Events

The included study did not report on burden of the intervention, nutritional deficiencies, eating disorders, activity related injury, or other adverse events.

Subgroups

The included study did not report results by baseline weight, gender, age, life events, race, ethnicity, cultural group, income, socioeconomic status, educational attainment, or family history of obesity.

Applicability

This evaluation of a self management intervention is applicable to patients with diabetes. The intervention was not very intensive and should be generalizable to the adult population with diabetes.

Interpretation

BMI and waist circumference increased in the control group and decreased slightly in the active intervention group. These relative differences between groups were clinically, but not statistically, significant.

Key Question 2. What is the comparative effectiveness of dietary approaches for the prevention of weight gain in adults?

Two intervention studies (enrolled/randomized N=1806) evaluated the effects of a dietary intervention compared with another dietary intervention or to a control group on weight maintenance in adults at risk for or with established cardiovascular disease or diabetes.[86 89] In a non randomized trial conducted at a single Veterans Administration (VA) outpatient diabetes clinic in the 1970s, patients with diabetes who were on insulin therapy were assigned to either 1) the American Diabetes Association (ADA) exchange diet which specified a daily caloric goal and carbohydrate distribution or 2) the standard "diabetic maintenance diet" which emphasized avoidance of simple sugars but set no specific daily caloric goal or pattern of carbohydrate intake.[89]

Patients in both groups received education about their assigned diet over 24 months during regularly scheduled quarterly clinic visits with a dietician.[89] In The PREDIMED Study, participants with diabetes or at least three cardiovascular disease risk factors were randomized to 1) a Mediterranean diet with virgin olive oil, 2) a Mediterranean diet with mixed nuts, or 3) a control group in which they received printed materials and met with a dietician once for recommendations on following an American Heart Association diet.[86]

Participants randomized to the Mediterranean diet groups met individually once a quarter with study dieticians for motivational interviews and in group education sessions on the

Mediterranean diet.[86] Participants also received either free virgin olive oil or mixed nuts based on their study group.[86] Table 2 and Appendix Table X provide additional details on these interventions.

Three additional studies included a dietary component in their active intervention and are described below in the section on studies studying a combination of intervention types (Table 11).[79 82 87]

BMI Change

Similar proportions of participants the two dietary interventions and usual care arms (approximately 40 percent) experienced a decrease in BMI during the first 12 months of the PREDIMED Study (1,551 analyzed of 1,776 randomized participants; Appendix E, Evidence Table 17) (p=0.464).[86]

Weight Change

In the VA based study (enrolled and analyzed N=30), weight increased with both diets but less so in the ADA diet group (mean between group difference in weight for the ADA versus standard diet group: 0.8 kg at 12 months), and by 24 months both groups had gained nearly 1 kg (Figure 11).[89] In a sub analysis of 737 participants from the PREDIMED Study, compared with the control group, participants in the olive oil based group lost an average of 0.1 (95 percent CI, 0.1 to 0.2), p<0.0001 for weight loss) kg and the nut based group had gained 0.03 kg at 36 months (Figure 3).[84] The average weight loss at 36 months was 0.1 kg less in the nut based compared with olive oil based intervention arm (Appendix E, Evidence Table 17).[84]

Waist Circumference Change

In another PREDIMED Study sub analysis, which included a random sample of participants completing the study (N=187), baseline waist circumference was significantly higher in the olive oil based Mediterranean diet group compared with the control group (98.8 cm vs. 93.8 cm, p=0.005); baseline waist circumference was 96.7 cm in the nut based Mediterranean diet group.[83] Waist circumference increased by 0.1 cm in the control group and decreased by 0.6 in the olive oil based and 0.2 cm in the nut based groups by 36 months (Figure 12).[83] Compared with the control group, participants in the olive oil based group and the nut based group experienced an average decrease in waist circumference of 0.7 (95 percent CI, 2.4 to 0.9 cm, p=0.38) and 0.3 (95 percent CI, 1.8 to 1.1 cm, p=0.65) cm at 36 months, and the average decrease in waist circumference was 0.4 (95 percent CI, 1.1 to 1.9 cm, p=0.59) cm less in the nut based compared with olive oil based intervention arm (Appendix E, Evidence Table 17).[83]

Adherence

There were no dietary interventions in this population that measured adherence as an outcome.

Clinical Outcomes

The included studies did not report on mortality, cancer, cardiovascular disease outcomes, hemoglobin A1c, sub fertility, degenerative joint disease, liver disease, or quality of life.

Adverse Events

The included studies did not report on burden of the interventions, nutritional deficiencies, eating disorders, activity related injury, or other adverse events.

Subgroups

The included studies did not report results by baseline weight, gender, age, life events, race, ethnicity, cultural group, income, socioeconomic status, educational attainment, or family history of obesity.

Applicability

Dietary intervention trials were conducted in patients with or at risk for cardiovascular disease and diabetes. All enrolled participants in one study,[89] and roughly 50 percent in the other[86] had diabetes. One study was conducted in male veterans during regularly scheduled visits at a VA specialty clinic, and the other was intensive with quarterly meetings and detailed dietary instruction. Also, the impact of diabetes medication use in the PREDIMED Study was unclear. The high prevalence of diabetes, diabetes medication use, and variation in study site and intervention limit the generalizability of these studies.

Interpretation

Dietary interventions do not prevent weight gain in patients with or at risk for cardiovascular disease and diabetes . It is unknown if adherence could have affected the results, as adherence was not reported in the included trials.

Key Question 3. What is the comparative effectiveness of physical activity approaches for the prevention of weight gain in adults?

Two trials evaluated the effect of a physical activity intervention relative to a control intervention on weight maintenance in adults at risk for cardiovascular disease or diabetes (Table 3).[77 78 88] These trials randomized 195 participants, and provided results for 166 participants.[77 78 88] In the Pre diabetes Risk Education and Physical Activity Recommendation (PREPARE) trial, participants in the active interventions attended a 180 minute group informational session about exercise, which addressed barriers to walking at baseline. Participants were subsequently followed up for 10 minute visits at 3 and 6 months to review their progress.[88] In one of the two active intervention arms, participants also received a pedometer to help them meet the recommended number of steps per day.[88] In the Oslo Diet and Exercise Study (ODES), participants in the active intervention arm attended supervised endurance exercise sessions three times per week.[77]

Four additional trials included a physical activity component in their active interventions and are discussed below in the section on studies evaluating a combination of intervention types (Table 12).[79 81 85 87]

BMI Change

Studies provided results on 166 of 195 randomized participants for analyses of BMI change.[78 88] In the ODES, the physical activity intervention resulted in a slight decrease in BMI, whereas the usual care group experienced a slight increase in BMI.[78] The mean between group difference in BMI at 12 months with usual care group as reference was 0.7 (95 percent CI 0.8 to 0.6, $p<0.001$) kg/m^2 (Figure 5).[78] In the PREPARE trial, mean BMI changes at 12 months were

negligible across the three arms of the study. Compared with usual care, between group differences (95 percent CI) in BMI for the PREPARE and PREPARE and pedometer active interventions were 0.2 (0.5 to 0.9, p=0.575) kg/m^2 and 0.5 kg/m^2 (0.3 to 1.2, p=0.212) at 12 months (Figure 13; Appendix E, Evidence Table 17).[88]

Weight Change

Studies provided results on 166 of 195 randomized participants for analyses of weight change.[78 88] In the ODES, weight increased by 1.1 kg in the usual care arm and decreased by 0.9 kg in the physical activity intervention arm. The between group mean difference in weight was 2.0 kg (95 percent CI, 3.4 to –0.6, p=0.007) over 12 months for the active group compared with the control (Figure 6).[77] Weight changes at 12 months between arms were negligible in the PREPARE trial.[88] Compared with usual care, between group differences in weight for the PREPARE and PREPARE and pedometer active interventions were 0.3 (95 percent CI, 1.8 to 2.5, p=0.749) kg and 1.4 (95 percent CI 0.8 to 3.5, p=0.199) kg at 12 months (Figure 14; Appendix E, Evidence Table 17).[88]

Waist Circumference Change

In the ODES, waist circumference increased by 0.9 cm in the usual care arm and decreased by 1.9 cm in physical activity intervention arm. The between group mean difference in weight at 12 months was 2.8 (95 percent CI 4.3 to 1.3, p=0.0003) cm for the active compared with the control group (Appendix E, Evidence Table 17).[77]
Results on waist circumference were provided for 92 of 97 randomized participants.[77]

Adherence

Exercise adherence (attendance at exercise sessions) was 57 percent in the physical activity intervention arm of the ODES (Appendix E, Evidence Table 17).[77] Results on adherence were provided for 49 of 54 participants randomized to the active exercise intervention arm of the ODES.[77]

Clinical Outcomes

The included studies did not report on mortality, cancer, cardiovascular disease, diabetes, sub fertility, degenerative joint disease, liver disease, or quality of life.

Adverse Events

The included studies did not report on burden of the interventions, nutritional deficiencies, eating disorders, activity related injury, or other adverse events.

Subgroups

The included studies did not report results by baseline weight, gender, age, life events, race, ethnicity, cultural group, income, socioeconomic status, educational attainment, or family history of obesity.

Applicability

Results from the included trials on physical activity interventions are applicable to patients at risk for diabetes and cardiovascular disease. One intervention was particularly intensive with participants exercising on site three times per week for one year[77] while the other was less intense with three in person visits over 6 months.[88]

Interpretation

Even with modest adherence to the intervention (57 percent), participants in the three times per week endurance exercise training group experienced a decrease in waist circumference over one year.

The relative effects of the physical activity interventions in the studies were consistent with the relative intensities of the interventions. Participants in the ODES were more likely to benefit from the endurance exercise three times per week,[77] where results were similar in the active and control arms of the PREPARE trial with an information session intervention .[88]

Key Question 4: What is the comparative effectiveness of orlistat for the prevention of weight gain in adults?

There were no studies in this population that measured the impact of orlistat on weight maintenance.

Key Question 5. What is the comparative effectiveness of a combination of self management, dietary, physical activity, and medication approaches for the prevention of weight gain in adults?

Five trials (N=1704 randomized) evaluated the effect of a combination of a self management, dietary, or physical activity interventions on weight maintenance in adults with or at risk for cardiovascular disease or diabetes.[79 81 82 85 87] Two trials evaluated the effect of a self management intervention combined with physical activity in patients with diabetes, and both trials emphasized increasing physical activity and goal setting (Table 4).[81 85] The trials of Hypertension Prevention Phase II (TOHP II) evaluated the effect of a sodium reduction strategy employing dietary and self management in overweight people with suboptimal blood pressure (Table 4).[82] The Diet and Exercise for Elevated Risk (DEER) trial compared the effects of a dietary intervention, physical activity intervention, and a combination diet and physical activity intervention in men and women with elevated LDL and low HDL (Table 4),[87] This trial provided results stratified by sex.[87] A single trial compared the effect of the combination of a dietary, physical activity, and a self management intervention compared with a control intervention in people with elevated blood pressure or elevated HbA_{1c} (Table 13).[79]

BMI Change

Studies provided results on 178 of 193 randomized participants for analyses of BMI change.[79 81 85] Relative to control, the combination of physical activity with self management strategies in two studies resulted in small decreases in BMI ranging from 0.4 to 0.7 kg/m^2 at 12 months (Figure 12).[81 85] For the intervention that emphasized both aerobic activity and strength training, compared with the control, the between group difference in BMI was almost clinically and statistically significant: 0.7 (1.4 to 0.0, p=0.049) kg/m^2.[81] In the trial comparing the

combination of self management, physical activity, and diet with control, both arms experienced a small decrease in weight, and this decrease was 0.4 kg/m^2 more in the active intervention arm (statistical significance of the between group change not reported; Figure 15) (Appendix E, Evidence Table 17).[79]

Weight Change

Studies provided results on 1,337 of 1,352 randomized participants for analyses of weight change.[79 81 82 85] Relative to the control, the combination of physical activity with self management strategies resulted in small decreases in weight ranging from 0.7 to 1.3 kg at 12 months which were not significant (Figure 13).[81 85] In the RCT comparing the combination of self management, physical activity, and diet to control, both arms experienced a small decrease in weight at 12 months, but this decrease was 0.9 kg more in the active intervention arm (statistical significance of the between group change not reported (Figure 13).[79] Mean weight increased slightly in the control and sodium reduction arm of TOHP II at 36 months, but this difference was not significant. The between group difference in weight was 0.1 kg (95 percent CI 0.7 to 0.5), p=0.75 (Figure 16; Appendix E, Evidence Table 17).[82]

Waist Circumference Change

Relative to the control, the combination of physical activity with self management strategies resulted in a small decreases in waist circumference at 12 months in one RCT.[81] In the intervention that emphasized both aerobic activity and strength training, compared with the control the between group difference in waist circumference was significant: 2.4 (95 percent CI, 4.7 to 0.0 cm, p=0.047) (Appendix E, Evidence Table 17).[81] This study provided results on 65 of 68 randomized participants.[81]

Adherence

Two trials combining self management and physical activity interventions reported on adherence.[81 85] Attendance at intervention sessions was 63.5 percent and 64.6 percent in the active intervention arms for one trial[81] and 100 percent in the other trial (Appendix E, Evidence Table 17).[85] Studies provided results on 58 of 59 randomized to an active intervention for analyses of adherence.[81 85]

Quality of Life

The authors reported no significant differences in SF 36 results between arms in one study (Appendix E, Evidence Table 17).[81] This study provided results on 65 of 68 randomized participants for this analysis.[81]

Other Clinical Outcomes

The included studies did not report on mortality, cancer, cardiovascular disease, diabetes, sub fertility, degenerative joint disease, or liver disease.

Adverse Events

The included studies did not report on burden of the interventions, nutritional deficiencies, eating disorders, activity related injury, or other adverse events.

Subgroups

In the DEER Trial, men and women experienced small increases in weight in the control group and decreases in weight in the three active intervention arms (exercise alone, diet alone, or diet and exercise; Figure 20); these changes in weight by treatment arm were clinically and statistically significant ($p<0.001$.[87] Both the diet intervention and the combination of diet and exercise intervention modestly decreased weight relative to the control and exercise alone groups.[87] In the TOHPII, race and sex stratified analyses showed that changes in weight were smaller in the sodium reduction arm for men and larger for women, but these weight change differences were not statistically significant; numeric results were not provided (Appendix E, Evidence Table 17).[82]

The included studies did not report results by baseline weight, age, life events, income, socioeconomic status, educational attainment, or family history of obesity.

Applicability

Results from the two trials evaluating the combination of physical activity and self management are applicable to patients with diabetes.[81 85] Most interventions were intensive and required multiple in person visits.

Interpretation

Effective interventions for persons with diabetes or at risk of diabetes were more successful at decreasing waist circumference than preventing weight gain. Endurance exercise training, a combination of diet and physical activity and a combination of self management, diet and physical activity were more effective at decreasing waist circumference than control. Goal setting alone prevented weight gain as measured by BMI. A combination of diet and exercise led to weight loss.

The two studies with the most intensive exercise interventions had interventions lasting for 4 to 6 months with outcome data reported at 12 months.[81 85] A third study that incorporated physical activity was the least intensive and did not have supervised exercise sessions.[79] The more intensive interventions were more likely to prevent weight gain.

Table 10. Description of self management intervention among adult patients with or at risk for cardiovascular disease and diabetes

Author, year Duration of intervention	Primary Aim	Control Group	Self Management Intervention
Clark, 2004[80] Duration 6 months	Set and attain individualized diet and physical activity goals using motivational interviewing	Usual care/no intervention.	• 30 minute in person session at baseline to set lifestyle goals and address barriers to meeting goals • 10 minute in person session at 3 and 6 months to problem solve and set additional goals if initial goals met • 3 telephone contacts at 1, 3, and 7 weeks after initial assessment

Table 11. Description of diet interventions among adult patients with or at risk for cardiovascular disease and diabetes

Author, year **Name of Study** **Duration of intervention**	**Primary Aim**	**Control Group**	**Diet Intervention 1**	**Diet Intervention 2**
Zazpe, 2008[86] Razquin, 2010[84] Razquin, 2010[83] PREDIMED Duration 36 months	Change dietary composition to Mediterranean diet	Received leaflet about the American Heart Association dietary recommendations and single meeting with a dietician about this diet	• Mediterranean diet composition with emphasis on virgin olive oil • Quarterly individual sessions with dietician with personalized motivational interviewing • Group educational sessions • Free access to study center dietician • Free provision of olive oil	• Same as Diet Intervention 1 but with free provision of mixed nuts instead of olive oil
Abraira, 1980[89] Duration 24 months	Increase peak oxygen consumption through endurance exercise	None	Standard diabetic diet: • Three meals + bedtime snack • Strict avoidance of refined sugars • Consumption of starches • Avoidance of saturated fat • No exchange system • No caloric goal • No specific carbohydrate distribution • Quarterly visits with dietician	American Diabetes Association Diet: • Daily caloric goal • Daily meal pattern planned and distributed through a food exchange • Three meals + bedtime snack • Carbohydrate distribution: breakfast (30 percent), lunch (30 percent), dinner (30 percent), and snack (10percent). • Moderate restriction of both refined sugars and carbohydrates • Quarterly visits with dietician

* Study name listed only if applicable

Table 12. Description of physical activity interventions among adult patients at risk for cardiovascular disease and diabetes

Author, year **Name of Study** **Duration of intervention**	**Primary Aim**	**Control Group**	**Physical Intervention 1**	**Physical Activity Intervention 2**
Yates, 2010[88] PREPARE Duration 6 months	Increase physical activity through walking	Printed information about impaired glucose tolerance and physical activity by mail	• Single in person, 180 min group, session at baseline consisting of information about impaired glucose tolerance and counseling about perceived effectiveness of exercise, walking self efficacy beliefs, barriers to walking, and self regulatory strategies • 10 minute review of progress in person at 3 and 6 months • Received steps per day goal and pedometer	• Same as Physical Activity 1 but no pedometer given
Anderssen, 1995[77] Torjesen, 1997[78] ODES Duration12 months	Increase peak oxygen consumption through endurance exercise	Usual care/no intervention	• Supervised exercise sessions lasting 60 minutes three times per week • Goal to attain improve peak VO_2 by targeting 60 80percent of peak heart rate	

Table 13. Description of combination interventions among adult patients at risk for cardiovascular disease and diabetes

Author, year Duration of intervention	Primary Aim	Control Group	Active Intervention 1	Active Intervention 2	Active Intervention 3
Samaras, 1997[85] Duration 6 months	Increase physical activity	Usual care/no intervention	Physical Activity Component: • Monthly in person aerobic exercise session with exercise physiologist • Goal to achieve 50 percent of VO_{2max} (by perceived exertion) • Exercise sessions available to intervention subjects after initial 6 month intervention period Self Management Component: • Monthly in person session with staff for education; coping skills; improving confidence, self esteem, decision making; and goal setting • Received hand outs, videos, activity meters, and log books for goal setting and review of progress	• Not applicable	• Not applicable

Table 13. Description of combination interventions among adult patients at risk for cardiovascular disease and diabetes (continued)

Author, year Duration of intervention	Primary Aim	Control Group	Active Intervention 1	Active Intervention 2	Active Intervention 3
Gram, 2010[81] Duration 4 months	Increase physical activity in daily life	Received standard written information on exercise and advice to be physically active upon enrollment	Physical Activity Component: • In person exercise sessions lasting 45 minutes supervised by physiotherapist • Focus on strength training and aerobic exercise • Access to exercise equipment • Goal to achieve more than 40 percent of VO_{2max} (by perceived exertion) • Encouraged to increase activity outside of training sessions • Received information on physical training in their neighborhoods at end of intervention period Self Management Component: • Received tailored advice • In person interviews at 0, 8, 16, and 24 weeks to assist with goal setting	Physical Activity Component: • In person exercise sessions lasting 45 minutes supervised by physiotherapist which occurred outdoors on forest paths • Focused on Nordic walking • Received walking sticks with individualized stick length • Goal to achieve more than 40 percent of VO_{2max} (by perceived exertion) with Nordic walking • Encouraged to increase activity outside of training sessions • Received information on physical training in their neighborhoods at end of intervention period Self Management Component: Same as Active Intervention 1	• Not applicable

Table 13. Description of combination interventions among adult patients at risk for cardiovascular disease and diabetes (continued)

Author, year Duration of intervention	Primary Aim	Control Group	Active Intervention 1	Active Intervention 2	Active Intervention 3
Babazono, 2007[79] Duration12 months	Increase fruits/vegetables and physical activity	Received result of health exam; leaflet about exercise; and had conventional health center visits (3) without additional services	Diet Component: • Increased fruits/vegetables • Decreased salt, oil, sugar, and alcohol • Increased time for meals and eat more slowly Physical Activity Component: • Challenge cards to increase activity Self Management Component: • Received results about health exam • 5 in person sessions at health center to set personal diet and physical activity goals; problem solve; and receive advice • 3 health center visits • 2 home visits	• Not applicable	• Not applicable

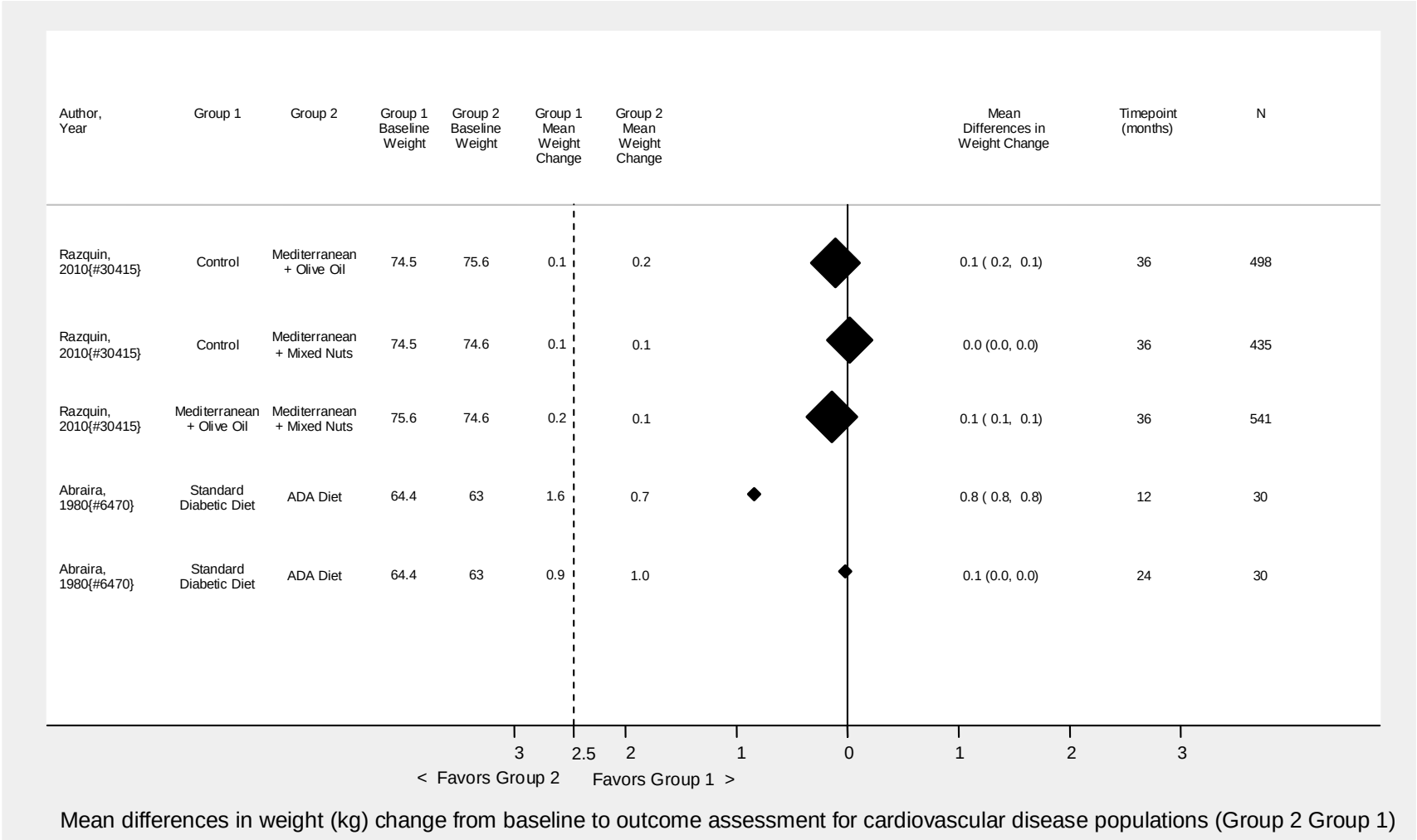
Table 13. Description of combination interventions among adult patients at risk for cardiovascular disease and diabetes (continued)

Author, year Duration of intervention	Primary Aim	Control Group	Active Intervention 1	Active Intervention 2	Active Intervention 3
Stefanick, 1998[87] Duration 9 11 months	Follow NCEP diet and/or increase aerobic exercise	Usual care/no intervention: asked to maintain usual diet and exercise	Diet: • Follow NCEP Step 2 diet 12 week adoption phase • One individualized counseling session • 8 one hour group lessons Maintenance phase • Monthly contact with dietician by mail, telephone, or in person individual or group meetings	Physical Activity: • Aerobic exercise 6 week adoption phase • Single private meeting with exercise staff • In person, supervised, one hour exercise session 3 times per week Maintenance phase • 10 miles of walking/jogging each week • Option to continue supervised exercise sessions • Required monthly group session • Optional Home based activities	• Active Intervention 1 + Active Intervention 2 (Diet + Physical Activity)

Table 13. Description of combination interventions among adult patients at risk for cardiovascular disease and diabetes (continued)

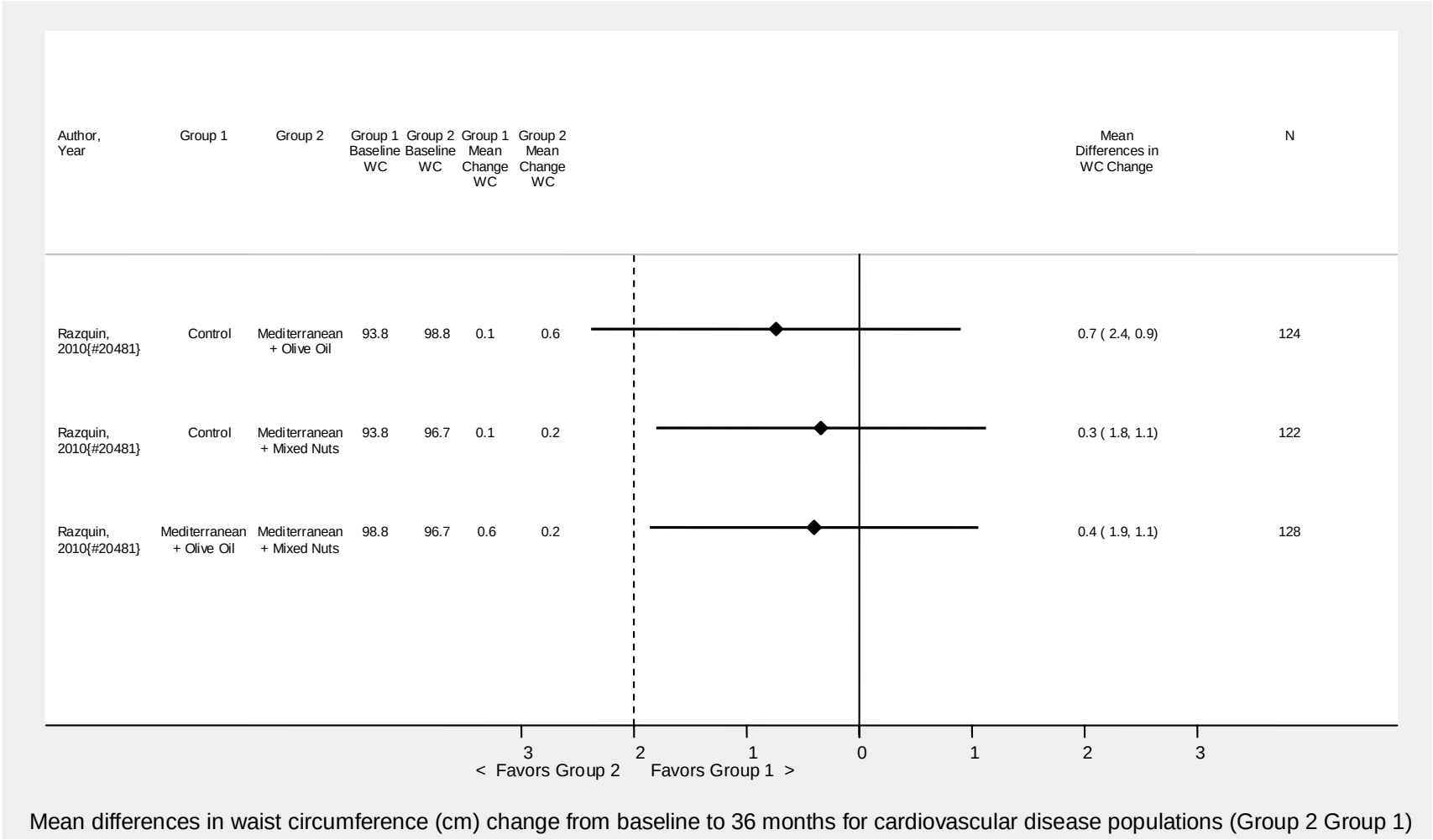
Author, year Duration of intervention	Primary Aim	Control Group	Active Intervention 1	Active Intervention 2	Active Intervention 3
Kumanyika, 2005[82] Duration 36 48 months	Consume <1800 mg of sodium per day	Usual care/no intervention	Diet Component • Consume <1800 mg Na+/day • No change in caloric or other dietary intake Self Management Component Intensive phase • Initial individual counseling session • 10 weekly group 60 to 90 minute sessions Transitional phase • 4 monthly group sessions • Additional intervention sessions as needed • Individual in person, telephone and mail contacts as needed • Relapse prevention techniques • Feedback on changes in urine sodium • Self monitoring • Counselor and peer support	• Not applicable	• Not applicable

Figure 11. Differences in weight change for diet interventions among adults at risk for or with cardiovascular disease or diabetes mellitus



ADA: American Diabetic Association; kg: kilogram
Dotted line indicates a clinically meaningful change of 2.5kg

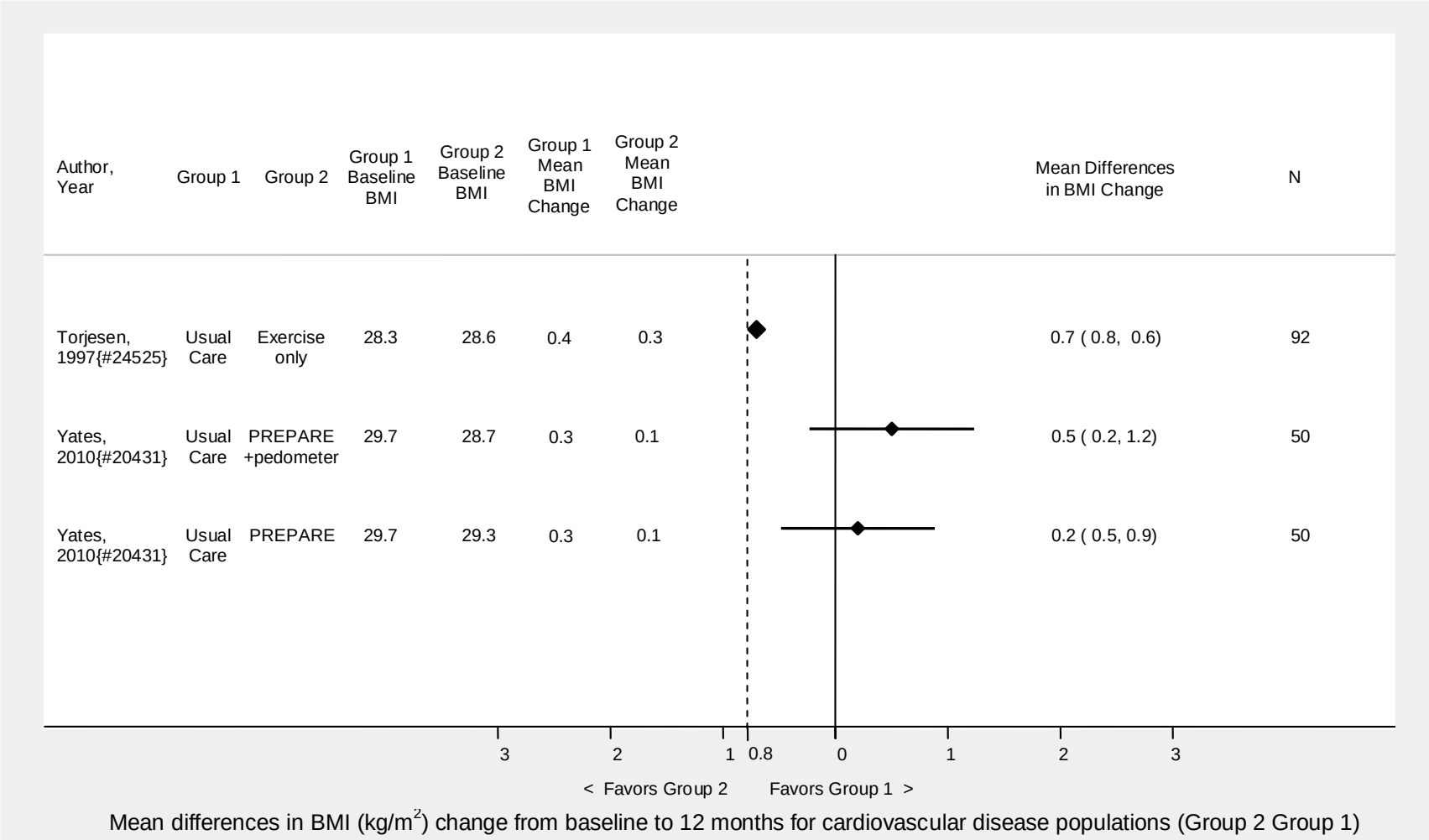
Figure 12. Differences in waist circumference change for diet interventions among adults at risk for or with cardiovascular disease or diabetes mellitus



Mean differences in waist circumference (cm) change from baseline to 36 months for cardiovascular disease populations (Group 2 Group 1)

cm: centimeter; WC: waist circumference
Dotted line indicates a clinically meaningful change of 2 cm

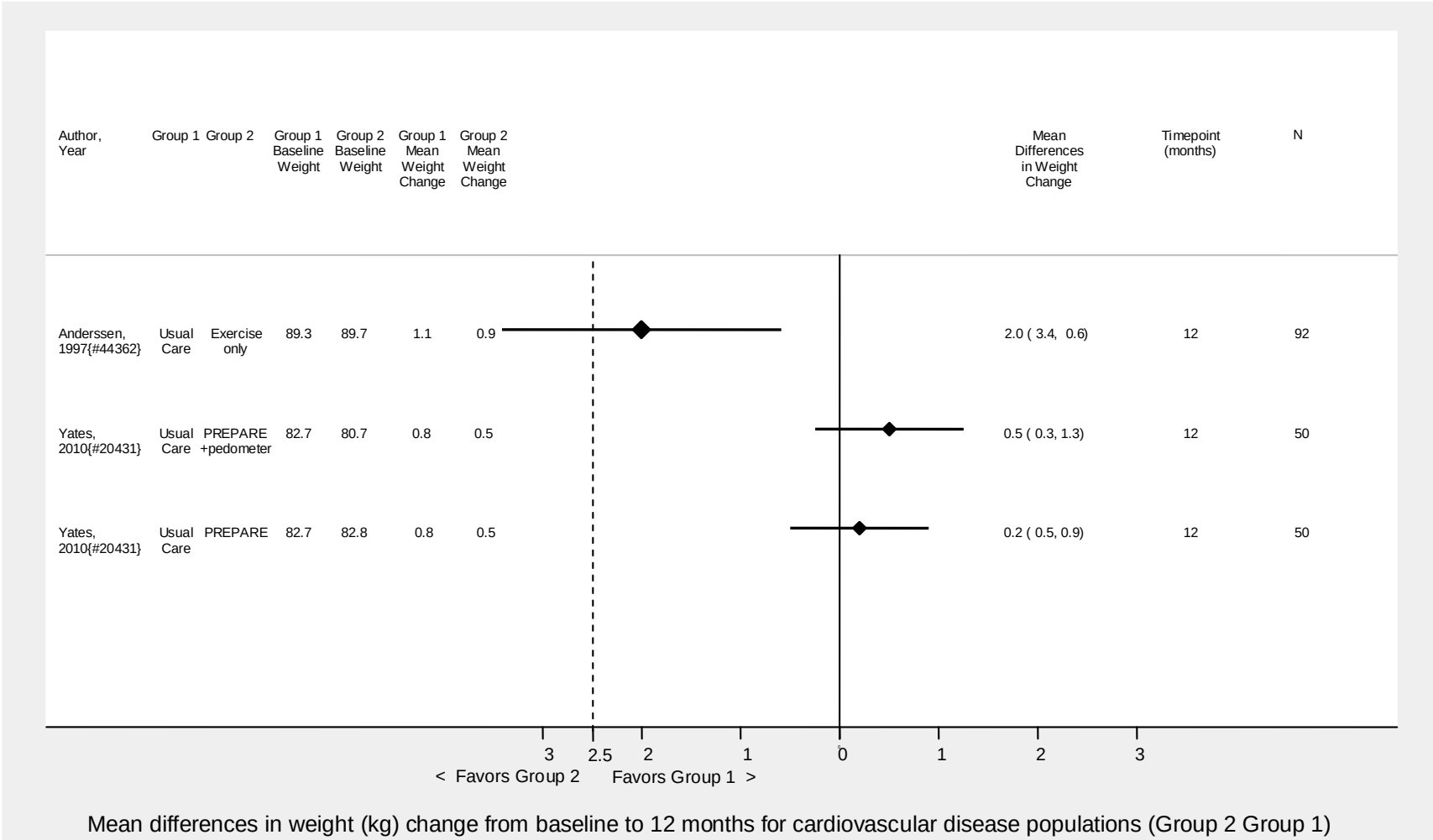
Figure 13. Differences in BMI change for physical activity interventions among adults at risk for or with cardiovascular disease or diabetes mellitus



Mean differences in BMI (kg/m^2) change from baseline to 12 months for cardiovascular disease populations (Group 2 Group 1)

BMI: body mass index; kg/m^2: kilogram/meter^2
If the study did not report an estimate of variability, no confidence intervals were generated.
Dotted line indicates a clinically meaningful change of 0.8 BMI units

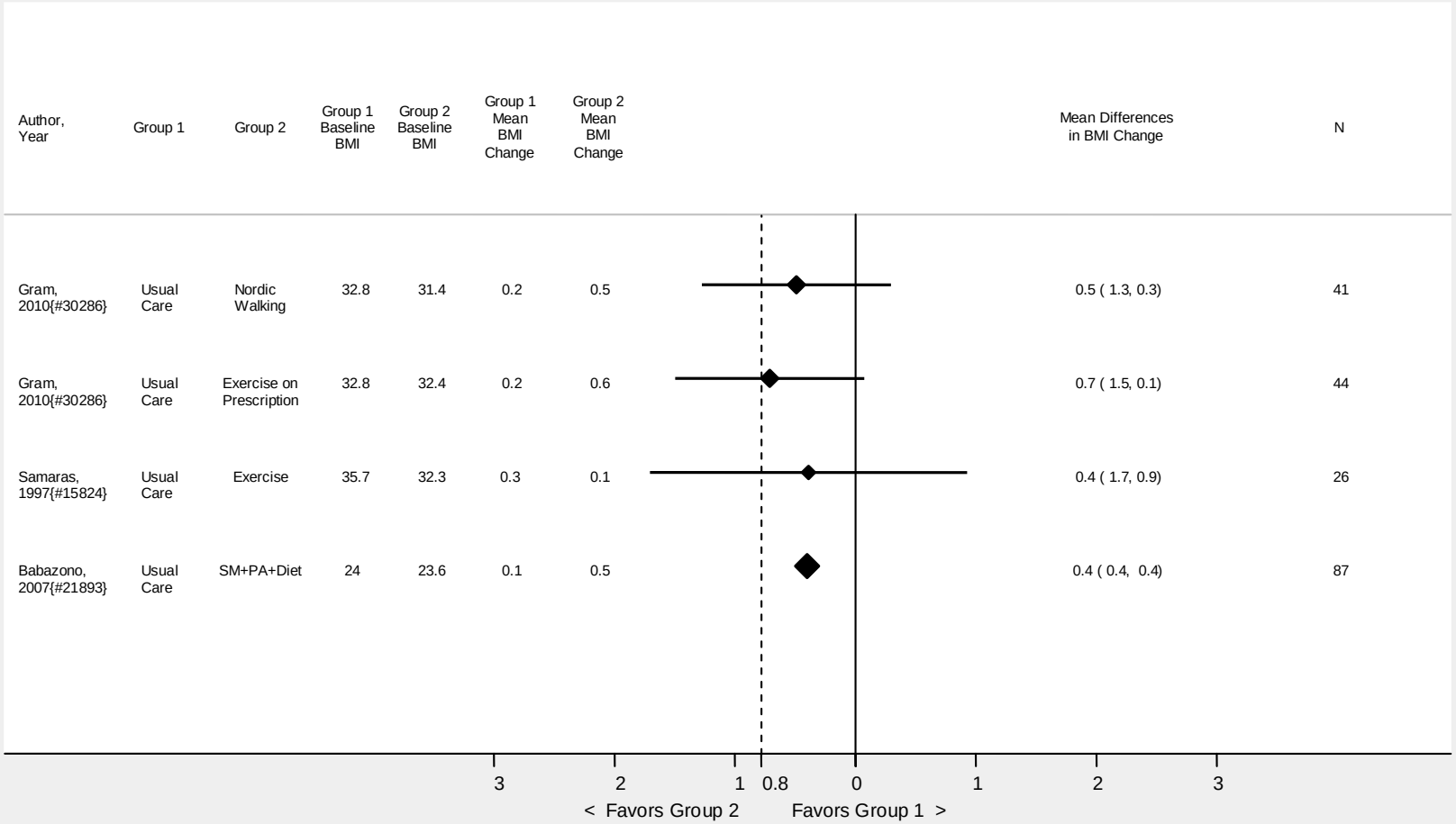
Figure 14. Differences in weight change for physical activity interventions among adults at risk for or with cardiovascular disease or diabetes mellitus



Mean differences in weight (kg) change from baseline to 12 months for cardiovascular disease populations (Group 2 Group 1)

kg: kilogram
Dotted line indicates a clinically meaningful change of 2.5kg

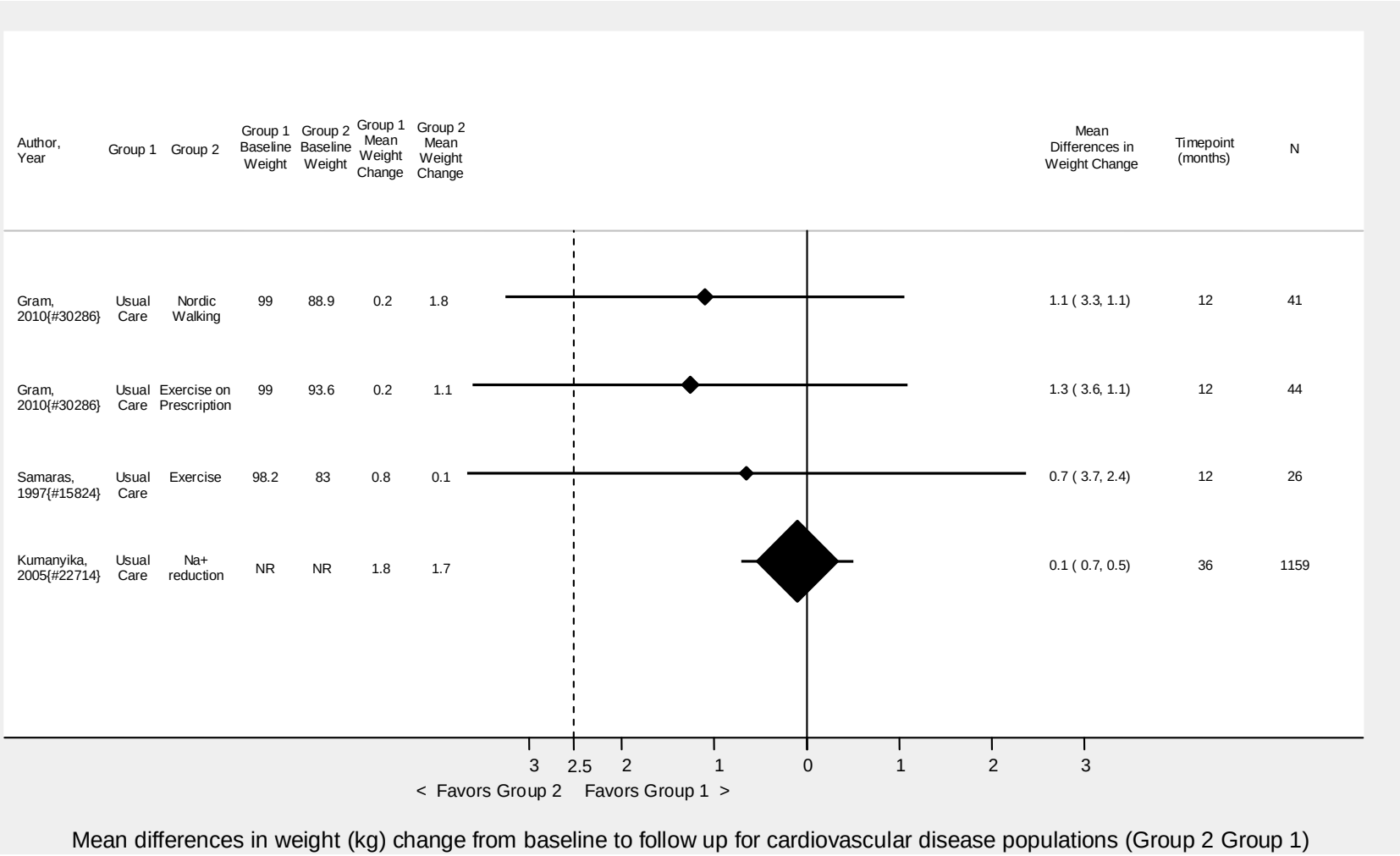
Figure 15. Differences in BMI change for combination interventions among adults at risk for or with cardiovascular disease or diabetes mellitus



Mean differences in BMI (kg/m^2) change from baseline to 12 months for cardiovascular disease populations (Group 2 Group 1)

BMI: body mass index; kg/m^2: kilograms/meter^2; PA: physical activity; SM: self management
Dotted line indicates a clinically meaningful change of 0.8 BMI units

Figure 16. Differences in weight change for combination interventions among adults at risk for or with cardiovascular disease or diabetes mellitus



Mean differences in weight (kg) change from baseline to follow up for cardiovascular disease populations (Group 2 Group 1)

kg: kilogram; Na+: sodium; NR: not reported
Dotted line indicates a clinically meaningful change of 2.5kg

Weight Maintenance in Adults with Cancer

Study Characteristics

Data on prevention of weight gain in adults with cancer were reported in three interventional studies (reported in 4 articles) (baseline n=2,671; 2,362 analyzed)[90 93] and one observational study (baseline n=1,966; 1,657 analyzed) (Appendix F, Evidence Table 18).[94]

Interventional Studies

All three of the interventional studies were randomized trials. [90 93] One trial was reported in two publications.[92 93] The duration of the interventions was 12 months in all studies. One trial followed participants for an additional 48 months.[91] One trial was conducted at multiple sites,[91] two at single sites,[90 93] and all were in the United States.[90 91 93] Participants were recruited from clinical settings in two trials,[90 91] and from the community in one trial.[93] The first years of recruitment were 1994,[91] 1999,[93] and unreported.[90] One trial stated the specific goal of assessing weight maintenance (Appendix F, Evidence Table 18).[90]

Observational study

One observational study was included.[94] Patients were recruited at five months after cancer diagnosis and followed through 36 months after diagnosis (31 months of total followup).[94] The study was a subanalysis of an Australian study to identify predictors of colorectal cancer before and after a screening program. Participants with histologically confirmed colorectal cancer that was reported to a citywide cancer registry during 2003 and 2004 were recruited (Appendix F, Evidence Table 18).[94]

Population Characteristics

Interventional Studies

Inclusion criteria based on age, timing of cancer diagnosis, and previous treatment for cancer were common. One trial included women with a first degree relative with breast cancer.[92 93] The other trials recruited women with newly diagnosed cancer.[90 91] One trial recruited women within 365 days of surgery for breast cancer.[91] The other trial included women who had not yet received chemotherapy or radiation treatment for breast cancer, colon cancer, or lymphoma and whose treatment plan would include chemotherapy and a steroid.[90] One trial included all adult women,[90] another women aged 48 through 79 years,[91] and another included only premenopausal, healthy women between 21 and 50 years of age.[92 93] Two trials had ethnically diverse populations,[91 93] and trial study did not report the race or ethnicity of participants.[90] White participants accounted for 75 and 85percent of the participants in these two trials.[91 93] The percentage of participants with a college degree ranged from 49 to 83 percent and was reported in all trials (Appendix F, Evidence Table 19).

No trial restricted inclusion of subjects based on weight or BMI. One trial required that participants were consuming at least 20 percent of their calories from fat,[91] one required that fat intake was greater than 25percent of calories and fruit and vegetable intake of less than or equal to 5 servings per day,[93] and one required baseline exercise of under 120 minutes per week.[90] One trial reported smoking status; 50 percent of women were never smokers (Appendix F, Evidence Table 19).[91]

Observational Study

The observational study had very few exclusion criteria.[94] All English speaking individuals who could respond to a phone interview aged 20 to 80 years old at the time of diagnosis were included. Underweight women were excluded. Sixty one percent of participants were male, 72 percent of whom were 60 years or older. Forty six percent had a technical college or university degree. Forty percent were never smokers and seven percent were current smokers at five months after cancer diagnosis.[94]

At baseline, five months after cancer diagnosis, 45 percent of participants were a healthy weight, 37 percent were overweight and 18 percent were obese trials (Appendix F, Evidence Table 19).

Interventions

Three trials reported on dietary interventions for prevention of weight gain.[90 93] Two trials focused on dietary changes (one including a self management approach) and the other trial focused on physical activity. The goal of one trial was to reduce percentage calories from fat to 15 percent while otherwise maintaining a nutritionally adequate diet.[91] Participants were randomized to receive counseling with a dietician every three months with specific emphasis on fat reduction (intervention group) or counseling sessions with a goal of achieving adequate vitamin and mineral intake (comparison group) trials (Appendix F, Evidence Table 21).[91]

Another trial randomized participants to one of four diet groups: control (asked to follow their usual diet), low fat diet (<15percent of calories from fat), high fruits and vegetables diet (9 servings/day), or a combination of low fat and high fruits and vegetables diet.[93]

Another trial randomized women to home based endurance exercise, resistance exercise or control trials (Appendix F, Evidence Table 20).[90]

Outcomes

Key Points

- **BMI**
  - Television viewing does not result in clinically meaningful weight gain among individuals with colorectal cancer (low strength of evidence).
  - Dietary interventions aimed at decreasing the percentage of calories from fat decreases BMI at up to 5 years (low strength of evidence).
- **Weight**
  - Low fat, high fruits and vegetables or a combination of the two diets does not meaningfully reduce weight gain among premenopausal women with a family history of breast cancer (low strength of evidence).
  - Home based aerobic and resistance exercise decreases weight gain over one year in women with cancer (moderate strength of evidence).
- **Adherence**
  - Adherence to low fat, high fruits and vegetable diets and exercise is possible in women with cancer (low strength of evidence). Continued adherence to a high fruits and vegetables diet is greater than to a low fat diet.
- **Adverse effects**
  - Combination interventions have no adverse effects (low strength of evidence).

Key Question 1. What is the comparative effectiveness of self management approaches for the prevention of weight gain in adults?

One observational study measured television viewing among individuals with primary colorectal cancer.[94] Participants were asked how often they spent watching television during the previous month (Table 14).

BMI Change

The study enrolled 1,966 people at baseline (5 months after diagnosis) and analyzed 1,202 people at 24 months and 1,028 at 36 months.[94] BMI was 0.7 kg/m^2 (95 percent CI, 0.3 to 1.1) greater at 24 months among individuals reporting five or more hours of television per day compared with less than three hours per day of baseline television viewing after adjustment for baseline BMI, sex, age, education, smoking, cancer stage, mode of treatment, co morbidities and physical activity level. At 36 months, those individuals with more than five hours per day had an adjusted BMI 0.6 kg/m^2 greater (95 percent CI, 0.1 to 1.1) than the less than 3 hours of television per day group. These findings were statistically significant ($p<0.001$ at 24 months and $p=0.01$ at 36 months), but not clinically significant (Appendix E, Evidence Table 21).

Weight Change

No study reported on weight change.

Waist Circumference Change

There were no studies reporting on self management interventions and waist circumference change.

Adherence

There were no studies reporting on self management interventions and adherence.

Clinical Outcomes

No study reported on mortality, cancer, CVD, sub fertility, diabetes, degenerative joint disease, liver disease, QOL

Adverse Events

No study reported on burden of intervention, nutritional deficiencies, eating disorder, activity related injury, adverse effect of medication, other

Subgroups

No study reported results by baseline weight, gender, age, life events, race, ethnicity, cultural group

Applicability

The results apply to individuals with colorectal cancer in whom obesity and physical inactivity have been associated with worse long term survival.

Interpretation

Greater hours spent viewing television does not appear to affect weight gain among individuals with colorectal cancer.

Key Question 2: What is the comparative effectiveness of dietary approaches for the prevention of weight gain in adults?

One trial randomized premenopausal women with a family history of breast cancer to one of four diet groups for one year: control (asked to follow their usual diet), low fat diet (<15percent of calories from fat), high fruits and vegetables diet (9 servings/day), or a combination of low fat and high fruits and vegetables diet (Table 15).[92 93]

BMI Change

There were no studies reporting on diet interventions and BMI change.

Weight Change

Women randomized to the low fat diet lost 0.9 kg more than the control group at one year. The high fruits and vegetables group gained 1.4 kg more than the control group. The group eating a combination of a low fat and high fruits and vegetables diet lost 0.2 more kg than the control group.[93] None of these differences was clinically meaningful (Figure 17; Appendix E, Evidence Table 21).

Waist Circumference Change

There were no studies reporting on diet interventions and waist circumference change.

Adherence

All groups including the control group increased their fruit and vegetable intake at one year.[93] The groups assigned to increase fruit and vegetable consumption had the greatest increases in consumption of seven additional servings per day compared to less than 1 additional serving in the control and low fat groups. The percentage of calories from fat increased in the control group by one percent. The decrease in calories from fat was 16 percent in the low fat group, two percent in the high fruits and vegetables group and 15 percent in the combination group. Forty percent of women in the low fat group, and 20 percent of women in the combination group dropped out of the study. Retention was greater than 90 percent in the high fruits and vegetables and control groups (Appendix E, Evidence Table 21).[93]

Clinical Outcomes

No study reported on mortality, cancer, CVD, sub fertility, diabetes, degenerative joint disease, liver disease, QOL

Adverse Events

No study reported on burden of intervention, nutritional deficiencies, eating disorder, activity related injury, adverse effect of medication, other

Subgroups

No study reported results by baseline weight, gender, age, life events, race, ethnicity, cultural group

Applicability

The results apply to premenopausal women. The women in this trial may be more likely to make dietary changes than the general population because of their family history of breast cancer.

Interpretation

Low fat and high fruits and vegetables diet alone or combined do not prevent weight gain over one year. Adherence to dietary changes are possible in women with breast cancer. However, increasing fruits and vegetables resulted in greater continued study participation than a low fat diet.

Key Question 3: What is the comparative effectiveness of physical activity approaches for the prevention of weight gain in adults?

One trial compared the effect of a home based exercise intervention on weight gain, body fat, and aerobic capacity.[90] The study included women with a diagnosis of breast cancer, lymphoma, or colon cancer who exercised fewer than 120 minutes per week and who were chemotherapy naïve, but were planning to begin chemotherapy including a steroid as a part of the treatment. Subjects were randomized to aerobic exercise, resistance exercise, or control (Table 16).

BMI Change

No study reported on BMI change.

Weight Change

The control group participants gained 5.9 kg during the one year intervention period, whereas women in both exercise groups lost weight.[90] The prevention of weight gain in the exercise group was clinically and statistically significant. The aerobic exercise group gained 8.5 kg less than the control group. The difference in weight gain was 6.3 kg less for the resistance exercise group (Appendix E, Evidence Table 21).

Waist Circumference Change

No study reported on waist circumference change.

Adherence

The intervention reported on adherence to the intervention overall.[90] Seventy nine percent of women assigned to the aerobic exercise arm adhered to the intervention, compared with 65 percent of resistance exercise participants at one year (Appendix E, Evidence Table 21).

Clinical outcomes

No study reported on mortality, cancer, CVD, sub fertility, diabetes, degenerative joint disease, liver disease, QOL

Adverse Events

No study reported on burden of intervention, nutritional deficiencies, eating disorder, activity related injury, adverse effect of medication, other

Subgroups

No study reported results by baseline weight, gender, age, life events, race, ethnicity, cultural group

Applicability

The results apply to women with cancer.

Interpretation

Women beginning chemotherapy with steroids can prevent weight gain with home based exercise. The strength of evidence is moderate.

Key Question 4: What is the comparative effectiveness of orlistat for the prevention of weight gain in adults?

No studies assessed the impact of orlistat on weight maintenance in populations with cancer..

Key Question 5: What is the comparative effectiveness of a combination of self management, dietary, physical activity, and medication approaches for the prevention of weight gain in adults?

One trial (2,437 baseline; 2,164 analyzed) compared a combination of self management and a low fat diet (15 percent reduction in fat) to no change in fat consumption.[91] Both the intervention and control group participants received dietary counseling. The dietary counseling included individual sessions for both groups and optional group counseling for the intervention group. The counseling included information on monitoring fat intake, goal setting, social support and relapse prevention and management (Table 17).

BMI Change

BMI decreased in the intervention group and did not change in the control group. BMI met the threshold for clinical and statistical significance at years one, three and five. BMI was 0.8 units lower in the intervention group than controls at years 1 (95 percent CI, 0.3 to 1.3) and 3 (95 percent CI, 0.2 to 1.3) and 1.1 units lower at year five (95 percent CI, 0.4 to 1.9) (Appendix E, Evidence Table [91]

Weight Change

The individuals in the group received fewer calories from fat had clinically significant weight loss (2.7 kg; 95 percent CI, 0.9 to 4.5) after five years compared to the those in the control group.[91] Weight loss at years one and three were statistically, but not clinically significant (Appendix E, Evidence Table 21).[91]

Waist Circumference Change

No study reported on waist circumference change.

Adherence

The study reported that 80% of participants provided dietary data for at least three time periods after the baseline assessment. At year five, approximately 39% of the intervention group and 44% of the control group reported dietary intake. (Appendix E, Evidence Table 21).[91]

Clinical Outcomes

No study reported on mortality, cancer, CVD, sub fertility, diabetes, degenerative joint disease, liver disease, QOL

Adverse Events

The group receiving decreased calories from fat intervention was reported to have had adverse events were associated with the dietary intervention) (Appendix E, Evidence Table 21).[91]

Subgroups

No study reported results by baseline weight, gender, age, life events, race, ethnicity, cultural group

Applicability

The results apply to women with breast cancer.

Interpretation

A dietary fat reduction intervention that included self management counseling results in clinically meaningful prevention of weight gain. The women were adherent to the intervention through five years of followup. The strength of evidence was low.

Table 14. Description of self management interventions among adults with cancer

Author year Study name* Duration of intervention*	Primary Aim	Group 1	Group 2	Group 3
Wijndaele, 2009[94]			Active Australia survey to calculate weekly physical activity	Association between television time and BMI

* Study name listed only if applicable

Table 15. Description of dietary interventions among adults with cancer

Author year Study name Duration of intervention*	Primary Aim	Group 1	Group 2
Djuric 2002[93] The Nutrition and Breast Health Study Duration 12 months	Study the effect of a dietary fat and fruit/vegetable intake on biomarkers of cancer risk	Received information on Food Guide Pyramid from national Dairy Council	3 diet arms: low fat, high fruits/vegetables, combination low fat high fruits/vegetables. One on one counseling with dietiticans, monthly group meetings, written materials

* Study name listed only if applicable

Table 16. Description of physical activity interventions among adults with cancer

Author year Study name* Duration of intervention*	Primary Aim	Group 1	Group 2	Group 3
Schwartz 2009[90] Duration 12 months	Compare differences in body composition changes among women newly diagnosed with cancer beginning chemotherapy and receiving a steroid.	Usual Care	Aerobic exercise Physical activity education, one time session, individual moderate intensity exercise 4x per week for 20 minutes.	Resistance exercise Physical activity education, one time session, individual moderate intensity exercise 4x per week for 20 minutes.

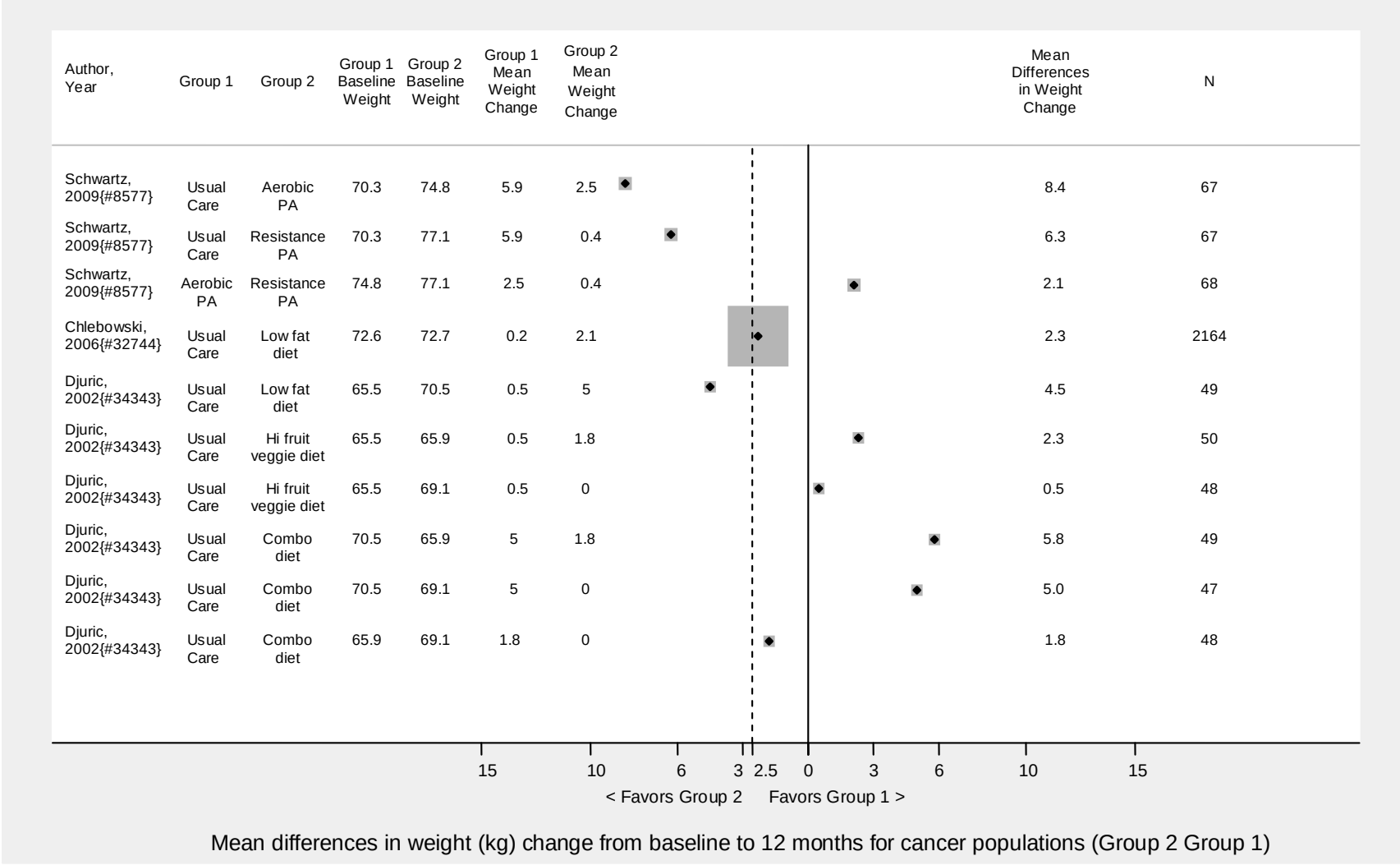
* Study name listed only if applicable

Table 17. Description of combination interventions among adults with cancer

Author year Study name Duration of intervention*	Primary Aim	Group 1	Group 2
Chlebowski 2006[91] The Women's Intervention Nutrition Study (WINS) Duration 60 months	Reduce fat intake in women with resected, early stage breast cancer receiving conventional cancer management	Maintained usual diet. Had contact with dietician at baseline and every 3 months plus written materials	Reduction of fat intake to 15percent while maintaining nutritional adequacy. Individual in person counseling sessions biweekly plus dietician visits every 3 months

* Study name listed only if applicable

Figure 17. Differences in weight change among adults with cancer



Combo Diet = low fat + high fruits & vegetables
kg: kilogram; PA: physical activity
If the study did not report an estimate of variability, no confidence intervals were generated.; Dotted line indicates a clinically meaningful change of 2.5kg

Weight Maintenance in Adults with Mental Illness

Study Characteristics

Data on prevention of weight gain in adults with mental illness were reported in two trials (163 randomized; 150 analyzed).[95 96] The interventions occurred for three[96] and six[95] months. One study assessed patients 18 months after the intervention ended.[95] The other study measured weight at the end of the two year intervention.[96] No observational studies were identified (Appendix E. Evidence Table 22).

Interventional Studies

A specific weight maintenance goal was reported in one trial [96]. One trial occurred at multiple households in Scotland.[95] The Spanish trial was clinic based and did not report the number of clinics involved.[96] The starting year of enrollment was 2002 in the one study that reported enrollment period (Appendix E. Evidence Table 22).[96]

Population Characteristics

Interventional Studies

The Spanish study aimed to prevent weight gain among individuals taking medications for their first episode of psychosis.[96] The Scottish study provided fruits and vegetables to group homes for schizophrenics.[95] The majority of patients were men (71percent and 75percent, respectively) and under 50 years old (mean age 27 and 45 years, respectively). Neither study made restrictions on weight for eligibility (Appendix E. Evidence Table 23).

Interventions

The Scottish study provided fruits and vegetables (5 servings per household member per day), fruits and vegetables plus lessons on preparing food, or no intervention to group homes.[95] The Spanish study provided individual sessions on behavior management and education on diet and exercise (Appendix E. Evidence Table 24).

Outcomes

Key Points

- **BMI**
  - Providing fruits and vegetables to households of people with schizophrenia does not prevent weight gain (low strength of evidence).
  - A behavioral intervention combined with education on diet and exercise does not prevent anti psychotic medication associated weight gain (low strength of evidence).
- **Weight Change**
  - A behavioral intervention does not prevent anti psychotic associated weight gain (low strength of evidence).

Key Questions

Key Question 1: What is the comparative effectiveness of self management approaches for the prevention of weight gain in adults?

No studies addresses self management interventions in populations with mental illness.

Key Question 2: What is the comparative effectiveness of dietary approaches for the prevention of weight gain in adults?

An interventional study of individuals with schizophrenia examined the impact of provision of free fruits and vegetables with and without instruction in meal planning and food preparation compared with usual care on eating habits.[95] Mean followup was 18 months.

BMI change

The trial (102 randomized; 91 analyzed) reported no significant differences in BMI between groups at 18 months from the start of the intervention years (Appendix E, Evidence Table 25).[95]

Weight change

No study reported dietary intervention impacts on weight change in populations with mental illness.

Waist circumference change

No study reported dietary intervention impacts on waist circumference change in populations with mental illness.

Clinical outcomes

No study reported on mortality, cancer, CVD, sub fertility, diabetes, degenerative joint disease, liver disease, QOL

Adherence

No study reported dietary intervention impacts on adherence in populations with mental illness.

Adverse events

No study reported on burden of intervention, nutritional deficiencies, eating disorder, activity related injury, adverse effect of medication, other

Subgroups

No study reported results by baseline weight, gender, age, life events, race, ethnicity, cultural group

Applicability

The results are applicable to group homes of patients with mental illness, particularly schizophrenia.

Interpretation

Provision of free fruits and vegetables to group homes of individuals with schizophrenia did not prevent weight gain. The strength of evidence is low.

Key Question 3: What is the comparative effectiveness of physical activity approaches for the prevention of weight gain in adults?

No studies addressed physical activity interventions in populations with mental illness.

Key Question 4: What is the comparative effectiveness of orlistat for the prevention of weight gain in adults?

No studies addressed orlistat in populations with mental illness.

Key Question 5: What is the comparative effectiveness of a combination of self management, dietary, physical activity, and medication approaches for the prevention of weight gain in adults?

One trial (61 randomized, 59 analyzed) of individuals within 6 weeks of a first psychotic episode used a combination of self management, diet, and physical activity approaches for weight gain prevention.[96] Subjects were randomized to one of three antipsychotic medications (5 to 20 mg/day olanzapine, 3 to 6 mg/day risperidone, or 3 to 9 mg/day haloperidol) then randomized to either a 3 month behavioral intervention or usual care. The behavioral intervention included individual sessions addressing energy intake and activity behaviors. Subjects received dietary counseling and counseling on an exercise program over 10 to 14 individual sessions, and body weight was measured at baseline, weekly for three months, and at four, six, 12, and 24 months of followup.

BMI change

Individuals in both the intervention and control groups gained 3.7 kg/m2 during 12 months of followup.[96] At 24 months, the intervention group gained 0.5 kg/m2 less than the control group (3.7 kg/m2 gained in the intervention group) years (Appendix E, Evidence Table 25).

Weight change

At 24 months, individuals in the behavioral intervention group gained 10.0 kg compared to 11.5 kg in the control group.[96] The difference in weight gain between groups is not clinically meaningful between years (Appendix E, Evidence Table 25).

Waist circumference change

No study reported on combination interventions impact on waist circumference change.

Clinical outcomes

No study reported on mortality, cancer, CVD, sub fertility, diabetes, degenerative joint disease, liver disease, QOL

Adherence

No study reported on combination interventions impact on adherence.

Adverse events

No study reported on burden of intervention, nutritional deficiencies, eating disorder, activity related injury, adverse effect of medication, or other adverse events

Subgroups

No study reported results by baseline weight, gender, age, life events, race, ethnicity, cultural group

Applicability

The results of the combination intervention apply to individuals taking anti psychotic medications associated with weight gain.

Interpretation

All of the individuals on antipsychotic medications gained weight. An intervention providing behavioral techniques and information on diet and exercise did not prevent weight gain during the two years of intervention.

Discussion

Key Findings and Implications

The evidence supports that prevention of weight gain in adults is challenging. Very few interventions or approaches led to clinically meaningful changes in BMI, weight or waist circumference. When adherence was reported, it tended to be poor (less than 80 percent adherence). Poor adherence may have been one reason for the lack of effectiveness observed across interventions and populations. The interventions that prevented weight gain, or the interventions examined when no intervention was effective in a population, are described by population below.[97] The strength of evidence for all observed comparisons is provided in Table 18. No comparison was graded as having a high strength of evidence. Three comparisons were graded as having a moderate strength of evidence. All others have low or insufficient evidence. The strength of evidence is low for many comparisons because the studies were not designed to measure weight maintenance and the study staff that measured weight in the intervention studies may have been aware of the participants' exposure groups.

Evidence

Adults from the General Population

The strength of evidence is low but supports that watching less television, eating fewer meals prepared outside of the home, avoiding potato chips and French fries, monitoring heart rate during exercise and increasing the duration of exercise over time contribute to weight maintenance (Table 14; Appendix F, Tables 1a b).

Environment level Approaches.

The strength of evidence is low that media campaigns and greater neighborhood walkability do not prevent weight gain (Appendix F, Tables 2a b).

Workplace based Approaches

The strength of evidence is low that workplace based approaches do not prevent weight gain (Appendix F, Tables 3a b).

College based Approaches

The strength of evidence is moderate that for credit coursework about nutrition and weight prevent weight gain during the intervention and the subsequent year (Appendix F, Tables 4a b).

Adults at risk for or With Cardiovascular Disease or Diabetes Mellitus

The strength of evidence is low but supports that goal setting and strategies involving a multimodal approach prevent weight gain (Appendix F, Tables 5a b).

Adults with Cancer

The strength of evidence is moderate to support aerobic and resistance exercise performed at home prevents weight gain among women with cancer. The strength of evidence is low that dietary interventions aimed at decreasing the percentage of calories from fat prevent weight gain among women with cancer (Appendix F, Tables 6a b).

Adults with Mental Illness

The strength of evidence is low that neither providing fruits and vegetables to group homes for people with schizophrenia nor individual counseling for individuals with psychoses prevents weight gain (Appendix F, Tables 7a b).

Populations without Evidence

No study included only individuals with normal weight at baseline; individuals with a family history of obesity; or socioeconomically disadvantaged individuals.

Despite the attention on primary prevention of obesity[98 101 102 103 105] there is little evidence to recommend specific interventions that will achieve this goal. Existing recommendations are frequently based on intermediate measures of changes in diet or physical activity. For example, the recommendations by the Centers for Disease Control and Prevention for community interventions to prevent obesity acknowledge that the evidence to support the recommendations were not based on studies of at least one year duration that measured weight as an outcome, but on short term changes in food choices or use of environmental modifications to facilitate physical activity.[98]

The World Health Organization European Ministerial Conference on Counteracting Obesity recommended that primary care providers play a more active role in preventing obesity.[101] Although the American Medical Association recommends the prevention of inappropriate weight gain,[106] reimbursement for the time required to provide weight maintenance counseling for the non obese is not supported by Medicare.[107,108] The lack of reimbursement may at least partly explain the low adherence with these recommendations by providers. An analysis of the Behavioral Risk Factor Surveillance Survey data in 2003 indicated that only 2.6 percent of individuals with a BMI between 18 and 25 received advice to maintain their current weight by a healthcare provider.

Although evidence is limited to support factors associated with weight gain prevention, the theoretical rationale to prevent weight gain is sound given the robust evidence that obesity is associated with poor health outcomes,[910 16] is costly,[19] and is difficult to reverse.[109]

Three of the interventions targeted populations experiencing life changes such as attending college[75] or beginning to cohabitate with a partner.[55] During these periods of change, individuals may be more likely to be open to lifestyle modification or more likely to be adherent to the changes. Although these interventions did not uniformly result in weight maintenance compared to control or result in higher levels of adherence, designing interventions to be implemented during these and other life changes (*e.g.*, post partum, retirement, relocating to a new region) may be considered in future research.

Identifying an individual's interest level in an intervention prior to recommending a weight maintenance strategy may also be of interest. Many studies randomized participants to an

intervention followed by multiple in person visits, phone calls and mailings. One trial opted to provide patients with up to three phone invitations to participate in a walking program compared to an information session. Only 33 percent of those invited to walk, took part in walk.[52] Allowing the option of participating in an intervention (rather than required visits, phone calls, etc) demonstrates that individuals who consent to participate in a weight related study may not have the motivation to participate in the particular intervention of interest. Combining a time when a person is already in a period of change with an intervention that an individual is motivated to participate in may be an area for future research.

Table 18. Summary of the Strength of Evidence*

	BMI	Weight change	Waist circumference	Progression to overweight or obese	Adherence	Quality of Life	Mortality	Adverse events
General population								
Self management	Insufficient	**Low Less TV viewing favored**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	**Low No difference**	**Low Dietary change favored**	**Low Dietary change favored**	**Low Dietary change favored**	Insufficient	Insufficient	**Low No difference**	Insufficient
Physical activity	**Low Physical activity favored**	**Low No difference**	**Low No difference**	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	**Low No difference**
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low No difference**	**Low No difference**	**Low No difference**	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient
Environment level	**Low No difference**	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
College based								
Self management	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Physical activity	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Moderate No difference**	**Moderate No difference**	**Low No difference**	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient
Environment level	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Workplace based								
Self management	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Physical activity	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low No difference**	**Low No difference**	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient

Table 18. Summary of the Strength of Evidence* (continued)

	BMI	Weight change	Waist circumference	Progression to overweight or obese	Adherence	Quality of Life	Mortality	Adverse events
With or at risk for cardiovascular disease or diabetes mellitus								
Self management	**Low Goal setting favored**	**Low No difference**	**Low Goal setting favored**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	**Low No difference**	**Low No difference**	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Physical activity	**Low No difference**	**Low No difference**	**Low Endurance exercise favored**	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low Diet and exercise favored**	**Low Diet and exercise favored**	**Low No difference**	Insufficient	**Low No difference**	Insufficient	Insufficient
Cancer								
Self management	**Low No difference**	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Diet	**Low Decreasing fat favored**	**Low No difference**	Insufficient	Insufficient	**Low Adherence was good**	Insufficient	Insufficient	Insufficient
Physical activity	Insufficient	**Moderate Home exercise favored**	Insufficient	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	Insufficient
Orlistat	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Combination	**Low No difference**	**Low No difference**	Insufficient	Insufficient	**Low Adherence was poor**	Insufficient	Insufficient	**Low No adverse events**

* No studies were identified that assessed the impact of orlistat on weight maintenance (Key Question 4).

Important Unanswered Questions

Which of the Key Questions Remain Unanswered?

We had a particular interest in identifying evidence about preventing weight gain among individuals with normal weight at baseline, but found no relevant studies. Similarly, we identified no studies addressing prevention of weight gain among overweight or obese individuals or socioeconomically disadvantaged individuals that met our inclusion criteria. Only one intervention was applied at a community level and this trial was more than 20 years old. Three studies used a cell phone or web based technology as part of a combination intervention.[67 70 71] None of these combination interventions prevented weight gain. No comparisons involved orlistat, which is available over the counter, and is sometimes used for weight maintenance despite having only a weight loss indication.

Is Weight Maintenance Relevant if the Majority of the Population is Overweight or Obese?

One study specifically stated that participants would have preferred assistance losing weight rather than maintaining weight.[54] The investigators conducting that study stated that they had difficulty recruiting women in the normal weight range and had to expand the study to include overweight women. Presently, the majority of the U.S. population is overweight or obese, so weight loss interventions may be more appropriate than weight maintenance interventions for most of the population. However, changes that prevent weight gain may be more effective in the normal weight population than in the overweight and obese population. This, however, remains unknown.

What are the Motivators to Maintain Weight Among Those Who are not Overweight?

In this review, we did not review attitudes about weight change. However, understanding what motivates individuals to maintain a healthy weight may inform interventions. Identifying these motives will be particularly important for individuals who are not overweight. Targeting weight maintenance advice based on one's motives may help increase adherence to modify behaviors and prevent weight gain.[110]

Findings in Relationship to what is Already Known

One previous systematic review has addressed weight gain prevention in adults.[34] The authors included randomized interventional trials that had a stated goal of primary prevention of obesity among those with BMI under 30 kg/m^2 at baseline (or mean BMI less than 30 kg/m^2 at baseline) or weight loss among those with a BMI of 25 to 30 kg/m^2 at baseline, had at least three months of followup after the start of the intervention, reported on weight or BMI change and were published between 1996 and 2006. Nine trials were included. Only two of those trials were included in the current review. The other trials did not have followup of at least one year or they allowed participants to have a weight loss goal. Their conclusion from that review was that the

body of evidence is too small to compare the effectiveness of interventions for obesity prevention.

Despite the interest in preventing weight gain and obesity, there is little evidence to support long term interventions. Previous reviews on physical activity,[111] fruit and vegetable consumption,[112] and psychological models and behavior change methods[113] have come to similar conclusions. A workshop on food technology to prevent obesity also commented that long term studies to support eating behaviors and interventions are lacking.[114]

Applicability

Interventions to prevent weight gain have been implemented in a variety of populations and settings. Observational studies to identify predictors of weight gain have focused on the general population and individuals with cancer. The interventions and approaches described in this review apply to a variety of populations. The settings of the intervention were much more limited. We had hoped to identify more environment level interventions. Unfortunately, many studies about environment level interventions were cross sectional designs and did not meet the criteria for our review.

Because adherence was poor in many interventions, the results may have been more useful if they had been reported by adherence status. For example, if participants who adhered to an intervention were more likely to maintain weight than the non adherent participants, we may have been able to make more recommendations based on the evidence. Adherence may explain why we observed effective strategies resulting from observational studies rather than intervention studies in the general population.

Implications for Clinical and Policy Decisionmaking

These results may help provide an evidence base for future practice guidelines to influence individual decision making, patient management, and policy decisions. However, we suspect that the strength of evidence for most comparisons is too low to support guidelines.

Behavior change is difficult for individuals whose goal is weight maintenance, just as behavior change is difficult for those attempting to lose weight. Avoiding potato chips and French fries is a simple, low cost intervention that prevented weight gain. College coursework on healthy diets and physical activity also prevented weight gain. The more intensive interventions, such as increasing exercise intensity over time to prevent weight gain, reported few adverse events. Although these intensive interventions did not result in strong evidence to promote their adoption, there is no evidence that *not* adopting a weight maintenance strategy is preferable.

Limitations of the Comparative Effectiveness Review Process

The strength of evidence was low or insufficient for almost all comparison outcome relationships. There are several reasons for these low evidence grades based on how we assessed each study's quality and graded the strength of evidence. We feel, however, that this is a fair appraisal of the risk of bias in these studies.

1) Intervention trials were frequently downgraded for lack of blinding, for not reporting the blinding of outcome assessors, or for not accounting for losses to followup. We included in this review only observational studies that accounted well for confounding and for losses to followup to ensure that we included only the highest quality observational studies.

2) Very few interventions had a stated goal of weight maintenance or weight gain prevention. We excluded studies that explicitly mentioned that at least some of the patients had a goal of weight loss. The best known weight gain prevention trial was excluded for this reason (Pound of Prevention).[97] Only one of the included observational studies was nested within a cohort whose original design had a weight related outcome of interest.[62]

3) Very few studies reported standard errors or confidence intervals for the between group differences in change in a weight related outcome over time. When the majority of studies did not report a measure of variability, we graded the body of evidence as imprecise. In some instances, the studies did not report a mean difference or point estimate stating *there was no significant difference in weight change between the groups*.

Limitations of the Evidence Base

Many studies did not report a weight related goal and were included. We may have inadvertently included some trials that had a goal of weight loss but that did not say so explicitly in the published paper. Studies labeled as weight maintenance among overweight and obese individuals may not have been solely targeting weight maintenance, but implicitly implied weight loss. We excluded studies that included specific aims of "weight change" associated with power calculations for an expected decrease in weight among the intervention group. However, some studies did not report power calculations or an expected direction of weight change. These studies were necessarily included.

Controls had better weight maintenance than expected. In many studies, the weight maintenance was better in the control groups than is expected in a general population. Many control groups had no increase in weight over time. In the general United States population, adults gain about 0.5 kg per year.[5] It is possible that the knowledge that one will be evaluated on weight regularly may help individuals to maintain weight without an intensive intervention. This may support the use of weight surveillance interventions in a workplace or primary care setting.

Concern exists that encouraging normal weight individuals to focus on weight may lead to body image issues or eating disorders.[115] The frequency of this adverse event was not estimable, as none of the included intervention studies reported on this outcome. However, some believe that there is a spectrum of eating behaviors with disorders such as anorexia nervosa and bulimia nervosa that may be triggered by weight maintenance interventions. It is possible that interventions to promote healthful eating, physical activity and weight maintenance may decrease disordered eating but this is not known. [116] The evidence provides no support presently.

Future Research Needs

We suggest that most comparisons and outcomes that have low or insufficient evidence are potential future research needs. In particular, we recommend future research examine interventions to prevent weight gain among normal weight individuals and, separately, overweight and obese individuals. Interventions for individuals taking anti psychotic medications are also a high priority given that participants in one trial gained 10 kg in the first year of medication use. Different degrees of intensity of the interventions in varied populations should be compared. Less intensive interventions may be possible given that control groups responded nearly as well as intervention groups in most of the studies that we included.

There are design and reporting considerations that should be considered for future studies. Observational cohorts should make measuring weight a stated goal in their protocols. Intervention trials should be of sufficient duration to assess the efficacy of interventions for

preventing weight gain. We suggest that one year should be a minimum duration of follow up for these interventions. Longer follow up will make it easier to identify true effectiveness as most individuals only gain 0.5 kg per year.

Conclusions

The evidence provides some, although limited, support for interventions to prevent weight gain. Effective interventions included ones that involve minor behavior change (*e.g.*, decreasing television viewing and eating fewer potatoes) or more major changes (*e.g.*, endurance exercise training in a gym at least three times per week). More studies are needed to evaluate the comparative effectiveness of these interventions.

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