| **Study Reference**  **Quality Rating** | **Health Outcome Instruments** | **Health Outcomes** | **Adverse Effects** | **Comments** |
| --- | --- | --- | --- | --- |
| Anderssen, 1995144  ODES (Oslo Diet and Exercise Study)  Fair | NR | Mean change (SE) at 12 mo  **BL 12 mo**  *VO2, mL-kg/minute*  BL DBP>91 mmHg  **IG1** -- -0.5(0.9)  **IG2** -- 1.6 (1.2)\*  **IG3** -- 4.4 (0.7)\*  **CG** -- -2.3 (1.0)  BL DBP 84-91 mmHg  **IG1** -- -0.3 (1.0)  **IG2** -- 2.5 (1.0)\*  **IG3** -- 4.9 (1.1)\*  **CG** -- -2.5 (0.8)  BL DBP<84 mmHg  **IG1** -- -0.1 (0.8)  **IG2 --** 2.0 (1.5)\*  **IG3** -- 4.9 (0.8)\*  **CG** -- -1.3 (0.5)  *\*p<0.05 for IG compared with CG*  **IG1 n analyzed:** 16 (DBP>91), 17 (DBP 84-91), 19 (DBP<84)  **IG2 n analyzed:** 20 (DBP>91), 16 (DBP 84-91), 13 (DBP<84)  **IG3 n analyzed:** 24 (DBP>91), 20 (DBP 84-91), 21 (DBP<84)  **CG n analyzed:** 12 (DBP>91), 16 (DBP 84-91), 15 (DBP<84) | NR | **Subgroup analyses:** Wt change in subset with metabolic syndrome provided in Anderssen 2007 |
| Burke, 2005145  ADAPT  Fair | NR | NR | NR | **Subgroup analyses:** Sex  **Other:** At 40 months, 64/118 (54.2%) completed the study in the CG and 76/123 (61.8%). Due to the high attrition, outcomes at 40 months were not abstracted (weight, waist circumference, SBP, DBP, total cholesterol, HDL, triacylglycerols, glucose, insulin). |
| Christian, 2008146  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** NR |
| Cohen, 1991147  Fair | **QOL**  Instrument used: NR  Range: NR  # of questions: NR  Directionality (higher score=better or worse): NR  **Disability**  Instrument used: NR  Range: NR  # of questions: NR  Directionality (higher score=better or worse): NR  **Depression**  Instrument used: NR  Range: NR  # of questions: NR  Directionality (higher score=better or worse): NR | NR | NR | **Subgroup analyses:** Change in mean arterial pressure, change in number of medications, and visits to physician reported for gainers vs losers  **Other:** Change in number of antihypertensive medications also reported  Of the 18 physicians:  1 had 5 ppts (IG - slight avg weight loss)  1 had 4 ppts (CG-no change on avg)  1 had 3 ppts (CG-slight avg weight gain)  3 had 2 ppts ea  12 had 1 ppt each |
| Cussler, 2008148  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** Analysis also available for baseline observation carried forward, not just completers  **Maintenance trial** |
| Davis, 1992149  Langford, 1991260  Davis, 1989261  TAIM  Fair | **QOL**  Instrument used: Life Satisfaction Scale, Physical Complaints Inventory, Symptom Check List  Range: NR  # of questions: NR  Directionality (higher score = better or worse): NR | Relative Risk (N)  **BL 6 mo**  *Cardiovascular Risk*  Blacks  **IG** -- 1.01 (27)  **CG** -- 1.00 (26)  Whites  **IG** -- 0.91 (57)  **CG** -- 1.00 (53)  Mean at BL, Mean change (SE) at 6 mo  *Pulse rate, beats/minute*  **IG** 79.1 -4.9 (1.0)  **CG** 76.4 -1.8 (1.2)  **IG n analyzed:** 90 (BL), 89 (6 mo);  **CG n analyzed:** 90 (BL, 6 mo)  In addition, specific subscales measured depression, anxiety, sleep disturb-ances, fatigue, and sexual complaints. There was significantly greater improvement in total physical complaints (p<0.002) and sexual problems (p<0.001) in weight reduction groups vs other diet group assignments. However, no diet/drug combo was better than any other or than placebo and usual diet. | NR | **Subgroup analyses:** NR  **Other:** Phase II data not used due to how they randomized patients to the second phase and presentation of results (Davis, 1993, RM #8345) |
| Diabetes Prevention Program Research Group, 1999142  Diabetes Prevention Program Research Group, 2005212  Orchard, 2005262  Diabetes Prevention Program Research Group, 2005205  Diabetes Prevention Program Research Group, 2005207  Ackermann, 2009211  Diabetes Prevention Program  Good | **Depression**  Instrument used: Beck Depression Inventory or current use of antidepressants (BDI ≥11 threshold used for depression)  Range: 0-63  # of questions: NR  Directionality (higher score = better or worse): Higher score = worse  **Anxiety**  Instrument use: Beck Anxiety Inventory  Range: 0-63  # of questions: NR  Directionality: Higher score = worse  **QOL**  Instrument used: Medical Outcomes Study SF-36  Range: NR  # of questions: 36  Directionality: Lower score = worse  Instrument used: Quality of Well-Being Scale (QWB-SA)  Range: NR  # of questions: NR  Directionality: Higher score = better | **BL 12 mo 24 mo 36 mo**  *Depression (BDI>10 or antidepressant use), percent*  Men  **IG** 10.0 7.9 6.7 --  **CG** 9.1 7.5 8.9 --  Women  **IG** 16.1 15.0 15.5 --  **CG** 18.1 17.1 19.6 --  **Men n analyzed\*:** 1029 (BL), 948 (12 mo), 848 (24 mo)  **Women n analyzed\*:** 2158 (BL), 1980 (12 nmo), 1819 (24 mo)  *Cardiovascular disease related deaths, n*  **IG** -- -- -- 2  **CG** -- -- -- 4  *Nonfatal cardiovascular disease events, percent*  **IG** -- -- -- 2.2  **CG** -- -- -- 1.7  *Incidence of nonfatal cardiovascular disease events, events/1000 patient-years*  **IG** - -- -- 9.7  **CG** -- -- -- 7.3  *Note: The small, nonsignificant excess of events in IG consisted of CVD hospitalizations and revascularization procedures.*  *Diabetes mellitus crude cumulative incidence, cases/100 p-y*  IG -- -- -- 4.8  CG -- -- -- 11.0  *Diabetes Mellitus cumulative incidence, percent*  IG 0 -- -- 14.4  CG 0 -- -- 28.9 | **48 mo†**  **Age: All 25-44 45-59 60-85**  *Gastrointestinal symptoms (diarrhea, flatulence, nausea, vomiting), number of events/100 person-years*  **IG** 12.9\* 13.1 14.2 9.7  **CG** 30.7 32.4 30.8 27.8  *Musculoskeletal problems (mostly myalgia, arthritis, arthralgia), number of events/100 person-years*  **IG** 24.1\* 19.9 25.4 28.0  **CG** 21.1 16.1 21.9 26.7  *One or more hospital admissions, percent*  **IG** 15.6 15.4 13.3 20.6  **CG** 16.1 11.1 16.9 21.9  *Rate of hospitalization, number of admissions/100 person-years*  **IG** 8.0 7.5 6.4 12.3  **CG** 7.9 6.3 7.9 10.6  *Median hospital stay, days*  **IG** 3 3 3 3  **CG** 3 3 3 4 | **Subgroup analyses:** Weight and waist circumference at 36 mo by age (although >40% of participants were lost to followup by 36 mo); Subset of 758 participants who had measurements of body fat and body fat distribution by sex at 1 year; Fasting glucose, TG, HDL, BP, waist circumference, and BMI median percent change at 1 year stratified by % weight loss and then sex; Weight loss by race/ethnicity  **Other:** 10-year unblinded followup results available (#8173).  After removal of interaction terms, race (p<0.0001) and gender (p=0.0259) main effects were significant within lifestyle treatment.  IG produced significantly larger percent weight |
| Diabetes Prevention Program Research Group, 1999142  Diabetes Prevention Program Research Group, 2005212  Orchard, 2005262  Diabetes Prevention Program Research Group, 2005205  Diabetes Prevention Program Research Group, 2005207  Ackermann, 2009211  Diabetes Prevention Program  Good |  | **BL 12 mo 24 mo 36 mo**  *Diabetes Mellitus incidence, percent lower from CG (95% CI)*  **IG** 0 -- -- 58 (48, 66)  *Diabetes incidence, cases/100 person-years*  25-44 years  **IG -- -- --** 6.3  **CG** -- -- -- 11.0  45-59 years  **IG**  -- -- -- 4.9  **CG** -- -- -- 10.8  60-85 years  **IG** -- -- -- 3.3  **CG** -- -- -- 10.3  **IG n analyzed:** 1079  **CG n analyzed:** 1082  **BL 12 mo**  *Anxiety, Beck Anxiety Inventory*  **IG** 3.19 (4.48) -0.89 (4.78)  **CG** 3.78 (4.89) -0.25 (4.80)  **IG n analyzed**: 1011 (BL), 998 (12 mos)  **CG n analyzed**: 1012 (BL), 993 (12 mos)  *SF-6D*  **IG** 0.802 (0.106) 0.0004 (0.103)  **CG** 0.788 (0.111) -0.013 (0.106)  *SF-36 Physical Component Score*  **IG** 50.6 (6.9) 1.33 (7.00)  **CG** 50.4 (7.2) -0.04 (7.12)  *SF-36 Mental Component Score*  **IG** 53.7 (7.6) -0.70 (8.67)  **CG** 54.0 (7.4) -1.16 (8.33)  **IG n analyzed:** 1072 (BL), 1017 (12 mos)  **CG n analyzed:** 1079 (BL), 1018 (12 mos)  *Quality of Well-being*  **IG** 0.710 (0.115) 0.022 (0.113)  **CG** 0.700 (0.115) 0.013 (0.124)  **IG n analyzed**: 679 (BL), 268 (12 mos)  **CG n analyzed:** 702 (BL), 252 (12 mos)  *In a fully adjusted model including both IG and weight change, assignment to either IG was not significantly associated with changes in SF-6D at 12 mo vs CG. After adjusting for IG, change in weight were associated with significant changes at 12 mo for SF-6D (p<0.001), PCS-36 (p<0.001), MCS-36 (p=0.04) for ever 5 kg loss; similar associations at 24 mo.*  *\* Not available by IG and CG. Ns are for both IGs (metformin and behavioral counseling) and CG.* | **48 mo†**  **Age: Al 25-44 45-59 60-85**  *Deaths, number/100 person-years*  **IG** 0.10 0.1 0.0 0.31  **CG** 0.16 0.0 0.0 0.86  \* p<0.05 for comparison with CG  † 3.2 yrs for age groups  **IG n analyzed:** 1073 (22-44 yrs: 318; 45-59 yrs: 541; 60-85 yrs: 214)  **CG n analyzed:** 1092 (22-44 yrs: 324; 45-59 yrs: 557; 60-85 yrs: 201)  The rate of musculoskeletal symptoms was highest in the IG-L.  Hospital admissions were more common in the oldest age group, but did not differ by IG or CG. | loss than CG and achieved greater weight loss than the metformin group across the race-gender groups (all p<0.05).  Weight loss, reduction in waist circumference, and percentage of participants who achieved the 7% weight loss goal all increased with increasing age.  Association of weight loss and health utilities is reported which is independent of treatment group |
| Fitzgibbon, 2010204  ORBIT  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** NR |
| Haapala, 2009151  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** NR |
| Hypertension Prevention Trial Research Group, 1990143  HPT  Good | NR | NR | NR | **Subgroup analyses:** NR  **Other:** NR |
| Irwin, 2003152  Frank, 2005263  Mohanka, 2006264  PATH  Good | NR | NR | No injuries were reported as a result of the exercise program | **Subgroup analyses:** Weight and body fat measures stratified by age and BMI at baseline; lipoprotein measures stratified by change in body fat and change in VO2 max; glucose and triglycerides stratified by change in total fat mass and by minutes of exercise per week  **Other:** NR |
| Jeffery, 1993153  Jeffery, 1995289  Trial of Food Provision and Monitary Incentives  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** NR |
| Jones, 1999154  Hansson, 1994265  The HOT Study Group, 1993266  Hypertension Optimal Treatment (HOT) Substudy  Fair | NR | NR | NR | **Subgroup analyses:** Mean (SEM) SBP by target DBP at 3, 6, 12, 18, 24, and 30 months; mean (SEM) DBP by target DBP at BL, 3, 6, 12, 18, 24, and 30 months  **Other:** NR |
| Kastarinen, 2002155  LIHEF Study (Lifestyle Intervention against Hypertension in Eastern Finland)  Fair | NR | NR | NR | **Subgroup analyses:** BP outcomes for those with and without HTN meds  **Other:** NR |
| Kulzer, 2009156  Fair | **QOL**  Instrument used: World Health Organization-Five Well-Being Index (WHO-5)  Range: NR  # of questions: NR  Directionality: Higher score = better  **Depression**  Instrument used: Center for Epidemiologic Studies Depression Scale (CES-D)  Range: NR  # of questions: NR  Directionality: Higher score = worse | Mean (SD)  **BL 12 mo 12 mo change**  *Psychological well-being, WHO-5*  **IG** 15.3 (5.1) 16.7 (4.8) 1.4 (3.9)  **CG** 14.3 (4.9) 14.3 (5.1) 0.0 (4.2)  *Depression, CES-D*  **IG** 12.0 (9.5) 9.8 (7.5) -2.2 (7.7)  **CG** 13.7 (8.2) 11.4 (7.8) -2.3 (6.8) | NR | **Subgroup analyses:** NR  **Other:** NR |
| Langford, 1985157  Wassertheil-Smoller, 1985267  DISH  Fair | NR | NR | NR | **Subgroup analyses:** Race  **Other:** If a patient's drug therapy was restarted because of blood pressure rise as specified, or if drug therapy was restarted by physicians outside the study, this was considered a terminating event and the patient was counted as "withdrawal failure." Other terminating events were strokes, a new myocardial infarction, congestive heart failure, or an elevated creatine level |
| Martin, 2008158  Martin, 2006268  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** Weight change for completers also available; the results were not statistically significant |
| Mayer-Davis, 2004159  POWER  Fair | NR | NR | NR | **Subgroup analyses:** High attenders  **Other:** NR |
| Mensink, 2003160  Mensink, 2003269  Fair | NR | Mean (SE) at BL, Mean change (SE) at 12, 24 mo  **BL 12 mo 24 mo**  *VO2max, L/minute*  **IG** 2.15 (0.1) 0.11 (0.03)\* 0.09 (0.04)\*  **CG** 2.13 (0.1) -0.01 (0.04) -0.03 (0.04)  *\* p<0.05 between groups*  **IG n analyzed:** 55 (BL), 40 (12, 24 mo)  **CG n analyzed:** 59 (BL), 48 (12, 24 mo) | No serious adverse events were observed in the IG during 2 years of followup | **Subgroup analyses:** NR  **Other:** NR |
| Mitsui, 2008161  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** Mean steps per day for IG and CG available in a figure |
| Moore, 2003162  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** NR |
| Narayan, 1998163  Fair | NR | n (percent)  **BL 6 mo 12 mo**  *Abnormal glucose tolerance, 2-hour PG* ≥*7.8 mM*  **IG** 0 (0) 12 (27) 13 (29)  **CG** 0 (0) 4 (9) 5 (11) | NR | **Subgroup analyses:** NR  **Other:** Low attendance at intervention classes; authors note that weekly classes may have been too onerous |
| Parikh, 2010208  Project HEED  Fair | NR | *Incidence of diabetes, cases per person-year*  **IG** 0.36  **CG** 0.33 | NR | Subgroup analyses: NR  Other: IG group reported very limited behavior changes in diet and exercise |
| Perri, 1988164  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** **Maintenance trial**: each group received an intervention for 6 months, but after 6 months the treatment differed |
| Pritchard, 1999165  Fair | NR | **BL 12 mo**  *Daily dose of cardiovascular drug use, n (daily doses; 95% CI)*  **IG1** -- 16 (1.8; 0.8, 2.8)  **IG2** -- 21 (3.2; 1.9, 4.5)  **CG** -- 19 (2.1; 1.4, 2.8)  *Note: No significant differences in the daily doses of cardiovascular drug use.* | NR | **Subgroup analyses:** NR  **Other:** Compared with CG, the cost of an extra kilogram of weight loss for IG1 was $9.76 and for IG1 it was $7.30. |
| Silva, 2009166  Silva, 2008270  Teixeira, 2009271  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** Moderate/vigorous and lifestyle PA associated with 12 mo change in most eating behavior variables (disinhibition, perceived hunger, emotional eating, external eating) and body weight change |
| Simkin-Silverman, 2003167  Simkin-Silverman, 1998272  Kuller, 2001273  Park, 2007274  Women's Healthy Lifestyle Project (WHLP)  Good | NR | NR | IG lost more BMD than CG at total hip, femoral neck, but not at spine or whole body after controlling for age and baseline BMD. Differences disappeared after controlling for weight change. Combining treatment and control groups, women who lost weight showed greatest reductions in hip, neck, and trochanteric sites and women who gained weight showed smallest reductions | **Subgroup analyses:** HDL, LDL, TG, and glucose by hormone use (non- users saw greater increases in LDL and smaller increases in HDL than users in both treatment groups, no diffs in TG, glucose)  **Other:** NR |
| Stevens, 1993146  Whelton, 1992  TOHP Collaborative Research Group, 1992  Trials of Hypertension Prevention Phase I  Good | NR | *Incidence of Hypertension at either 12- or 18-mo, percent (n/N)*  **IG** 6.5 (20/308)  **CG** 13.3 (34/256)  *RR (95% CI):* 0.66 (0.46, 0.94) | NR | **Subgroup analyses:** Weight loss and BP presented by men and women: Group diffs in SBP and DBP seen at all followup time points for men, only SBP at 6-mo for women  Linear regression showed smaller intervention effects for weight change and BP change for black than white participants  **Other:** NR |
| Stevens, 2001169  Hollis, 1995277  TOHP, 1997278  Trials of Hypertension Prevention Phase II  Good | NR | Percent (n) and risk ratio  **6 mo 18 mo 36 mo 48 mo**  *Hypertension*  **IG** 4.2 (25) 16.6 (97) 31.9 (185) 38.5 (211)  **CG** 7.3 (43) 21.1 (124) 39.2 (229) 44.4 (248)  *Risk ratio*  0.58\* 0.78\* 0.81\*\* 0.87  *\* p≤0.05 for CG vs IG*  *\*\* p<0.01*  **IG n analyzed:** 595 (6 mo), 584 (18 mo), 582 (36 mo), 548 (48 mo)  **CG n analyzed:** 589 (6 mo), 588 (18 mo), 577 (36 mo), 559 (48 mo) | NR | **Subgroup analyses:** Weight change by sex and race/ ethnicity (significant group diffs for white men and women through 18 mo, but not white women at 36 mo; black men and women through 6 mo, not at 18 and 36 mo for either black men or women); weight change by # of counseling sessions attend-ed, SBP and DBP by amount of weight lost.  In IG, men had greater net wt loss than women by 1.2 kg at 18 mo and 1.7 kg at 36 mo.  **Other:** NR |
| Svetkey, 2008170  Weight Loss Maintenance Trial PROTOCOL, 2008279  WLM  Good | NR | *Deaths*  **IG1:** 1  **IG2:** 1  **CG:** 1 | NR | **Subgroup analyses:** Report change at 30 mo within 4 race-sex subgroups: no sig interactions with age or sex, and magnitude of observed treatment effects was generally consistent across race-sex subgroups. Change in weight from study entry (Phase I, pre-randomization); maintenance of at least 4 kg weight loss relative to entry weight; no net weight gain from entry; at least 5% loss from entry; no more than 3% gain from randomization  **Other:** NR |
| ter Bogt, 2009171  Fair | NR | NR | NR | **Subgroup analyses:** % change in body weight by gender, age, education, BMI, attempts to lose weight during the past 5 years, visits to NP, treatment recommended  **Other:** NR |
| Tuomilehto, 2001172  Eriksson, 1999280  Lindstrom, 2003281  Uusitupa, 2009282  Finnish Diabetes Prevention Study  Good | NR | **BL 12 m 24 mo 72 mo**  *Diabetes Mellitus, no. cases\**  **IG** -- 5 15(/265=5.7%) 27(/265=10.2%)  **CG** -- 16 37(/257=14.4%) 59(/257=23.0%)  ()=calc  **BL 10.2 years 10.6 years**  *Cardiovascular Disease events\*\**  **IG** -- 57 --  **CG --** 54--  *Deaths\*\*\**  **IG -- --**  6  **CG -- --**  10  *\* Diffs in incidence of DM statistically significant after 2 years. Using all person-years accumulated, cumulative incidence in IG was 58% lower (hazard ratio 0.4, 95% CI 0.3-0.7, p<0.001)*  *\*\*Hazard ratio (95% CI) 1.04 (0.72-1.51), adjusted for age and sex*  *\*\*\*Hazard ratio (95% CI) 0.57 (0.21-1.58), adjusted for age and sex* | NR | **Subgroup analyses:** Incidence of DM by success of attaining intervention goals; Incidence of DM by leisure-time physical activity  **Other:** NR |
| Villareal, 2008173  Villareal, 2006283  Villareal, 2006284  Fair | **QOL**  Instrument used: SF-36\*  Range: NR  # of questions: NR  Directionality (higher score = better or worse): Higher score = better  *\* All 8 domains reported, data abstracted for the three with significant differences between groups* | Mean (SD) at BL, Mean change (SD) at 6 mo  **BL 6 months**  *SF-36 physical function domain*  **IG**  60.0 (21.0) 23.2 (20.9)\*  **CG** 67.0 (15.1) 2.5 (26.4)  *SF-36 role limitations, physical domain*  **IG** 54.4 (43.5) 23.6 (35.9)\*  **CG** 62.5 (44.5) 5.0 (19.7)  *SF-36 change in health domain*  **IG**  38.2 (12.3) 25.3 (13.2)\*\*  **CG** 38.0 (6.3) 0.0 (9.4)  *VO2peak mL/kg per min*  **IG** 16.4 (2.3) 1.7 (1.6)\*  **CG** 15.7 (3.0) 0.3 (1.1)  \* p<0.05 for IG vs CG  \*\* p<0.001 for IG vs CG  **IG n analyzed:** 17  **CG n analyzed:** 10 | **% with adverse effect (calc)**  **%falling during PA sessions:**  **IG CG**  Fell 5.9 (N/A)  0 experienced any a.e. in serum electrolyte concentrations or in renal or liver function test results at 6 mo  Mean (SD) at BL, Percent change (NR) at 12 mo  **BL 12 mo**  *Total hip bone mineral density, g/cm2*  **IG**  0.947 (0.115) -2.4 (2.5)\*  **CG** 0.993 (0.141) 0.1 (2.1)  *Trochanter bone mineral density, g/cm2*  **IG** 0.716 (0.107) -3.3 (3.1)\*  **CG**  0.747 (0.152) -0.2 (3.3)  *Intertrochanter bone mineral density, g/cm2*  **IG** 22.4 (7.0) -2.7 (3.0)\*  **CG**  24.8 (7.8) 0.3 (2.7)  *Lumbar spine bone mineral density, g/cm2*  **IG**  1.107 (0.127) 0.9 (3.1)  **CG**  1.127 (0.132) 1.3 (5.8)  *Whole body bone mineral density, g/cm2*  **IG**  1.151 (0.127) -0.9 (1.7)  **CG**  1.197 (0.138) 0.3 (2.1)  *Spine bone mineral content, g*  **IG**  65.5 (11.6) 2.1 (6.1)  **CG**  67.7 (17.1) 2.1 (4.9)  *Whole body bone mineral content, g*  **IG** 2423 (474) -1.4 (2.5)  **CG** 2606 (669) -1.7 (2.4) | **Subgroup analyses:** NR  **Other:** Changes in body weight correlated directly with changes in BMD at the total hip, trochanter, and intertrochanter sites. |
| Werkman, 2010174  Good | NR | NR | NR | **Subgroup analyses:** Men with low educational attainment (found group diffs in WC at 12-mo only, other outcomes NS)  **Other:** Module 1 was used by 82%, Module 2 was used by 72%, Module 3 was used by 41%, Module 4 was used by 54%, and Module 5 was used by 16% |
| Whelton, 1998175  Appel, 1995285  Chao, 2000286  Kumanyika, 2002287  Trial of Nonpharmacologic Interventions in the Elderly  Good | NR | **12 mo 18 mo 30 mo**  *% free of medication, hypertension, and CV events after initial med withdrawn*  **IG1+IG2**  54.2 48.6 39.2  **CG1+CG2**  42.2 38.6 26.2  Hazard ratio (95% CI): 0.70 (0.57, 0.87)  **IG1+IG2 n analyzed:** 291; **CG1+CG2 n analyzed:** 294  *% with cardiac event*  **IG1 (WL) CG\***  Stroke 0.0 0.6  TIA 0.0 2.3  MI 1.4 1.2  Angina 6.8 5.6  CHF 0.7 0.3  Arrhythmia 1.4 1.2  Other 4.1 5.6  Total CV 14.3 16.7  \*CG is both overweight and nonoverweight usual care  *p>0.05 for IG vs CG, limiting CG to overweight only* | **Subset of 67 overweight women**  No differences in the magnitude of change of bone mineral density of the spine, femoral neck, or total body between the IGs at 12 months (all p>0.30)  When groups were combined, for each pound of weight loss the average decrease of BMD at 6 and 12 months were 0.0006 g/cm, i.e., 0.05%. No sig relationship at distant sites suggesting effects were more pronounced at the spine and not evident at the femoral neck, indicating exercise may be a protective factor for the femoral neck | **Subgroup analyses:** BP for those who were off antihypertensive meds by the last visit; BMD among subset of 67 overweight postmenopausal women (Chao 2000, RM #8229), outcomes by race (Kumanyika 2002, RM #8206)  **Other:** HR (95% CI) for freedom from HTN med, high BP, and CV events by trial end  IG (WL, WL + Na) vs CG: 0.70 (0.57, 0.87), p=0.001 |
| Wood, 1991177  Kiernan, 2001288  Fair | **Depression**  Instrument used: Beck Depression Inventory  Range: 0-63  # of questions: 21  Directionality (higher score = better or worse): worse | Mean (SD) at BL, Mean change (SD) at 12 mo  **BL 12 mo**  *Depression*  Men  **IG1** 4.3 (3.2) 1.1 (3.8)  **IG2** 5.4 (5.0) -0.2 (4.9)  **CG** 5.5 (4.7) -0.7 (2.9)  Women  **IG1** 5.8 (4.1) -1.4 (4.4)  **IG2** 6.0 (4.9) -0.3 (5.8)  **CG** 6.0 (5.9) 0.3 (5.4)  *Aerobic Capacity, mL/kg/min*  Men  **IG1** 34.8 (5.3) 1.6 (5.0)\*\*  **IG2** 33.8 (5.3) 8.6 (5.7)\*\*  **CG** 33.6 (3.8) -0.2 (4.1)  Women  **IG1** 26.6 (4.2) 1.4 (4.1)\*\*  **IG2** 26.5 (4.8) 6.4 (4.8)\*\*  **CG** 27.7 (3.3) 0.0 (4.4)  *Estimated 12-year CHD risk, events/1000 persons*  Men  **IG1** -- -12.9 (23.2)\*\*  **IG2** -- -21.8 (24.1)\*\*\*  **CG** -- 0.6 (15.4)  Women  **IG1** -- -1.0 (4.6)  **IG2** -- -3.5 (5.4)\*\*\*  **CG** -- 1.3 (6.3)  *\*\*p<0.01 for diff between IG and CG;\*\*\*p<0.001* | NR | **Subgroup analyses:** Sex  **Other:** NR |
| Wood, 1988176  Frey-Hewitt, 1990150  Fair | NR | Mean (SD) at BL, mean change (SE) at 12 mo  **BL 12 mo**  *Resting metabolic rate (kcal/hr)*  **IG1** 77.14 (8.03) -6.21 (1.49)\*  **IG2** 75.30 (8.68) -0.95 (1.34)  **CG** 73.33 (10.75) 1.13 (1.39)  *VO2max*  **IG1** 33.81 (4.05) -0.27 (2.97)\*  **IG2** 35.33 (4.88) 4.16 (6.04)  **CG** 33.72 (4.48) -2.41 (3.24)  *\* p≤0.01 for IG vs CG* | NR | **Subgroup analyses:** NR  **Other:** IG1 significantly different from CG at BL for RMR expressed as kcal/kg/hr, may have confused the interpretation of RMR changes for IG1 |
| Woollard, 2003178  Fair | NR | NR | NR | **Subgroup analyses:** NR  **Other:** NR |

**Abbreviations:** ACE=angiotensin-converting enzyme; ADAPT=Activity, Diet, and Blood Pressure Trial; ADL=activity of daily living; AE=adverse event; ASA=aspirin; BDI=Beck Depression Inventory; BL=baseline; BMD=bone mineral density; BMI=body mass index; BP=blood pressure; calc=calculated; CES-D=Center for Epidemiologic Studies Depression Scale; CG=control group; CHD=coronary heart disease; CHF=congestive heart failure; CI=confidence interval; Cl=chloride; CT=computed tomography; CV=cardiovascular; CVD=cardiovascular disease; DASH=Dietary Approaches to Stop Hypertension; DBP=diastolic blood pressure; diff=differ/difference; DISH=Dietary Intervention to Study Hypertension; DM=diabetes mellitus; DMV=Department of Motor Vehicles; DPP=Diabetes Prevention Program; DXA=dual-energy x-ray absorptiometry; ECG=electrocardiography; est=estimated; GP=general practitioner; H/O=history of; HDFP=Hypertension Detection and Followup Program; HDL=high-density lipoprotein; HOMA-IR=homostasis model of insulin resistance; HOT=Hypertension Optimal Treatment; HPT=Hypertension Prevention Trial; HTN=hypertension; IG=intervention group; IQR=interquartile range; ITT=intention to treat; LDL=low-density lipoprotein; med=medication; MI=myocardial infarction; N=no; n=number; NA=not applicable; Na=sodium; NR=not reported; NS=not significant; ODES=Oslo Diet and Exercise Study; OW=overweight; PA=physical activity; PATH=Physical Activity for Total Health; POWER=Pounds Off with Empowerment; PREDIAS=Prevention of Diabetes Self-Management Program; pt=patient; QOL=quality of life; RCT=randomized controlled trial; RMR=resting metabolic rate; SBP=systolic blood pressure; SCORE=Systematic Coronary Risk Evaluation; SDT=Self Determination Theory; SD=standard deviation; SE=standard error; SEM=standard error of the mean; SES=socioeconomic status; sig=significance; SR=sodium reduction; stat=statistics; TAIM=Trial of Antihypertensive Interventions and Management; TG=triglycerides; TIA=transient ischemic attack; TOHP=Trials of Hypertension Prevention; tx=treatment; UC=usual care; US=United States; VO2=maximal oxygen consumption; WC=waist circumference; WHLP=Women’s Healthy Lifestyle Project; WHO=World Health Organization; WL=weight loss; WLM=Weight Loss Management; wt=weight; x=times; Y=yes.