**Table 21b. Weight change outcomes in interventional studies on CVD\_T2DM**

| **Author, year** | **Arm** | **Outcome defined** | **Baseline N** | **Baseline weight, mean** | **N at 12 months** | **Weight, 12 months, mean** | **Change from BL** | **Final measure, months** | **N at Final Measure** | **Weight, final measure, mean** | **Change from BL** | **Measure of Association** | **Test for Trend** | **Variables Adjusted for** | **Comment** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Diet Interventions** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Razquin, 20109 | 1 | kg | 196 | Mean : 74.5.3SE: 11.8 |  |  |  | 36 | Not reported | SE : 0.3Mean change : -0.10 |  | Arm 1 N=196Arm 2 N=30236-mo body weight change (36 mo vs baseline)0.202 (95% CI: -0.593 to 0.997)P=0.618 |  |  |  |
|  | 2 |  | 302 | Mean : 75.6SE: 11.9 |  |  |  | 36 | Not reported | MeanSE: 0.2Mean change : -0.21 |  |  |  |  |  |
|  | 3 |  | 239 | Mean : 74.6SE: 10.3 |  |  |  | 36 | Not reported | MeanSE : 3.8Mean change : -0.07 |  |  |  |  |  |
| Abraira, 198010 | 2 | abs weight in kg;  |  | Mean : 63.0 | Mean change : 0.74 |  | Mean change : 0.94 |  |  |  |  | Mean between-group change at 12 mo: -0.8 (reference=unmeasured diet) | note "no significant changes in either group" |  | % change in weight reported at 12 mo and 24 mo; abstracted 12- and 24- mo data from Fig 1 using Engauge  |
|  | 3 |  |   | mean : 64.4 | mean change : 1.58 |  | mean change : 0.96 |  |  |  |  |  |  |  |  |
| **Physical Activity Interventions** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Yates, 20105 | 1 | kg | 26 | mean : 82.7, SD : 14.7 | n : 26 | Mean: 81.9 | Mean: -0.8, 95%CI: -2.3 to 0.6 |  |  |  |  |  |  | Other : baseline weight |  |
|  | 2 |  | 24 | mean: 80.7, SD: 17.2 | n : 24 | Mean: 81.2 | Mean: 0.5, 95% CI: -1.2 to 2.2 |  |  |  |  | Arm 1 N =26Arm 2 N=24Mean between-group difference from baseline1.4 (95% CI: -0.8 to 3.5)P=0.199Reference=Arm 1 |  |  |  |
|  | 3 |  | 24 | mean : 82.8,SD : 14.6 | n : 24 | Mean: 82.3 | Mean: -0.5, 95% CI: -2.1 to 1.1 |  |  |  |  | Arm 1 N =26Arm 3 N=24Mean between-group difference from baseline0.3 (95% CI: -1.8 to 2.5)P=0.749Reference=Arm 1 |  |  |  |
| Anderssen, 199511 | 1 | kg | 43 | Mean: 89.3, SEM: 2.1 | n: 43 | Mean: 90.4 | Mean: 1.1, SEM: 0.4 |  |  |  |  |  |  |  |  |
|  | 2 |  | 49 | Mean: 89.7, SEM: 1.7 | n: 49 | Mean: 88.8 | Mean: -0.9, SEM: 0.7 |  |  |  |  | Mean between-group difference from baseline -295% CI: -3.4 to -0.6, P=0.007 |  |  |  |
| **Combination Interventions** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Kumanyika, 200512 | 1 | kg | 577 |  |  |  |  | 36 | NR | SD : 5.3Mean change : 1.8 |  |  | None of these weight changedifferences attained statistical significance |  | Within ethnicity-gender subgroups, changes were smaller in the active intervention versus control for men and larger for women. Weight change differences were not statistically significant overall or in subgroups. |
|  | 2 |   | 582 |   |  |  |  | 36 | NR | SD : 5.2Mean change : 1.7 |  | Mean between-group change: -0.1, SE: 0.31, P=0.75Reference=arm1 |  |  |  |
| Samaras, 19977 | 1 | kg at 12 mo minus baseline | 13 | Mean : 98.2SE : 3.4 | Check if this is the last timepoint reported | Mean : 0.79SE : 1.09 |  |  |  |  |  |  | No between-arm difference on ANOVA or Mann Whitney |  | Measures at 12 months are "changes since baseline measures) |
|  | 2 |  | 13 | Mean : 83.0se : 3.6 | Check if this is the last reported timepoint | Mean : 0.14se : 1.09 |  |  |  |  |  |  |  |  |  |
| Babazono, 20078 | 1 | kg | 41 | Mean : 58.6SD : 9.1 | N : 41check if this is the last timepoint reported | Mean : 58.1SD : 8.8 | -0.5 |  |  |  |  |  | no statistically significant differences in body weight between the two groups at baseline or after 1 yr follow up |  |  |
|  | 2 |  | 46 | Mean : 58.5SD : 9.7 | N : 46Check if this is the last reported timepoint | Mean : 57.1SD : 9.5 | -1.4 |  |  |  |  | Mean between-group change from baseline: -0.9 |  |  |  |
| Gram, 20106 | 1 | kg | 22 | Mean : 99SD : 15 | N: 20check if this is the last timepoint reported | Mean : 98.8SDSE: 3.2 |  |  |  |  |  | Arm 1 N= 20Arm 2 N=24 |  |  |  |
|  | 2 |  | 24 | Mean : 93.6SD : 14.8 | N: 24Check if this is the last reported timepoint | Mean : 92.5SDSE: 3.2 | Mean difference between Groups-1.26 (95%CI -3.09 to : 0.58)Se: 0.9 |  |  |  |  |  |  |  |  |
|  | 3 |  | 22 | Mean : 88.9SD : 14.3 | N : 21Check if this is the last reported timepoint | Mean : 87.1SDse : 3.3 | Mean between Group difference: -1.1, SE: 1.1, 95%CI: -3.31 to 1.11 |  |  |  |  |  |  |  |  |
| Stefanick, 199813Women | 1 | kg | 45 | Mean: 69.6, SD: 10.5 (for all 4 arms) | 45 |  | Mean: 0.8, SD: 4.2 |  |  |  |  | P<0.001 from ANOVA comparing weight change across all 4 arms |  |  | P values adjusted for multiple comparisons using Bonferroni’s adjustment |
|  | 2 |  | 43 |  | 43 |  | Mean: -0.4, SD: 2.5 |  |  |  |  | Mean between-group difference (95% CI): -1.2 (-2.6 to 0.2)Reference=arm1 |  |  |  |
|  | 3 |  | 46 |  | 46 |  | Mean: -2.7, SD: 3.5 |  |  |  |  | P<0.05 versus Arm 2, P<0.001 versus Arm 1;Mean between-group difference (95% CI): -3.5 (-5.1 to -1.9)Reference=arm1 |  |  |  |
|  | 4 |  | 43 |  | 43 |  | Mean: -3.1, SD: 3.7 |  |  |  |  | P<0.01 versus Arm 2, P<0.001 versus Arm 1Mean between-group difference (95% CI): -3.9 (--5.6 to -2.2)Reference=arm1 |  |  |  |
| Stefanick, 199813Men | 1 | kg | 46 | Mean: 84.2, SD: 10.8 (for all 4 arms) | 46 |  | Mean: 0.8, SD: 2.7 |  |  |  |  | P<0.001 from ANOVA comparing weight change across all 4 arms |  |  |  |
|  | 2 |  | 47 |  | 47 |  | Mean: -0.6, SD: 3.1 |  |  |  |  | Mean between-group difference (95% CI): -1.4 (--2.6 to -0.2)Reference=arm1 |  |  |  |
|  | 3 |  | 49 |  | 49 |  | Mean: -2.8, SD: 3.5 |  |  |  |  | P<0.05 versus Arm 2, P<0.001 versus Arm 1Mean between-group difference (95% CI): -3.6 (--4.9 to -2.3)Reference=arm1 |  |  |  |
|  | 4 |  | 48 |  | 48 |  | Mean: -4.2, SD: 4.2 |  |  |  |  | P<0.001 versus Arm 2, P<0.001 versus Arm 1Mean between-group difference (95% CI): -5.0 (--6.4 to -3.6)Reference=arm1 |  |  |  |

Abs = Absolute; ANOVA = Analysis of Variance test; BL = Baseline; Kg= kilogram; N = Sample Size; SD = Standard Deviation; SEM = Standard Error of the Mean

**References**

 1 Clark M, Hampson SE, Avery L, et al. Effects of a tailored lifestyle self-management intervention in patients with Type 2 diabetes. Br. J. Health Psychol. 2004; 9(3):365-79.

 2 Plotnikoff RC, Pickering MA, Glenn N et al. The effects of a supplemental, theory-based physical activity counseling intervention for adults with type 2 diabetes. J Phys Act Health 2011; 8(7):944-54.

 3 Zazpe I, Sanchez-Tainta A, Estruch R, et al. A large randomized individual and group intervention conducted by registered dietitians increased adherence to Mediterranean-type diets: the PREDIMED study. J Am Diet Assoc 2008; 108(7):1134-44; discussion 1145.

 4 Torjesen PA, Birkeland KI, Anderssen SA, et al. Lifestyle changes may reverse development of the insulin resistance syndrome. The Oslo Diet and Exercise Study: a randomized trial. Diabetes Care 1997; 20(1):26-31.

 5 Yates T, Davies MJ, Gorely T, et al. The effect of increased ambulatory activity on markers of chronic low-grade inflammation: evidence from the PREPARE programme randomized controlled trial. Diabetic Med 2010; 27(11):1256-63.

 6 Gram B, Christensen R, Christiansen C, et al. Effects of nordic walking and exercise in type 2 diabetes mellitus: A randomized controlled trial. Clin. J. Sport Med. 2010; 20(5):355-61.

 7 Samaras K, Ashwell S, Mackintosh AM, et al. Will older sedentary people with non-insulin-dependent diabetes mellitus start exercising? A health promotion model. Diabetes Res Clin Pract 1997; 37(2):121-8.

 8 Babazono A, Kame C, Ishihara R, et al. Patient-motivated prevention of lifestyle-related disease in Japan: A randomized, controlled clinical trial. 2007; 15(2).

 9 Razquin C, Martinez JA, Martinez-Gonzalez MA, et al. A mediterranean diet rich in virgin olive oil may reverse the effects of the-174g/c il6 gene variant on 3-year body weight change. Mol. Nutr. Food Res. 2010; 54(SUPPL. 1):S75-S82.

 10 Abraira C, de Bartolo M, Myscofski JW. Comparison of unmeasured versus exchange diabetic diets in lean adults. Body weight and feeding patterns in a 2-year prospective pilot study. Am J Clin Nutr 1980; 33(5):1064-70.

 11 Anderssen SA, Haaland A, Hjermann I, et al. Oslo Diet and Exercise Study: a one year randomized intervention trial; effect on hemostatic variables and other risk factors. Nutr Metab Cardiovasc Dis 1995; 5:pp 189-200.

 12 Kumanyika SK, Cook NR, Cutler JA et al. Sodium reduction for hypertension prevention in overweight adults: further results from the Trials of Hypertension Prevention Phase II. Journal of Human Hypertension 2005; 19(1):33-45.

 13 Stefanick ML, Mackey S, Sheehan M, et al. Effects of diet and exercise in men and postmenopausal women with low levels of HDL cholesterol and high levels of LDL cholesterol. N Engl J Med 1998; 339(1):12-20.

 14 Razquin C, Martinez JA, Martinez-Gonzalez MA, et al. A 3 years follow-up of a Mediterranean diet rich in virgin olive oil is associated with high plasma antioxidant capacity and reduced body weight gain. European Journal of Clinical Nutrition 2009; 63(12):1387-93.

 15 Toobert DJ, Strycker LA, King DK, et al. Long-term outcomes from a multiple-risk-factor diabetes trial for Latinas: inverted exclamation markViva Bien! Transl Behav Med 2011; 1(3):416-26.