**Table 5b. Risk of bias assessment of studies addressing weight maintenance among adults with or at risk for cardiovascular disease of diabetes mellitus.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **QUESTION\*** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | **Reporting** | | | | | | | | | | | **External validity** | | | **Internal Validity-bias** | | | | | | | **Internal Validity-confounding and selection bias** | | | | | | **Power** |
| **Bibliograph** | | **N** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** |
| **BMI/self-management** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clark, 20041 | | Y | Y | N | N | N | Y | N | N | N | Y | Y | U | U | N | U | U | N | Y | Y | Y | Y | Y | Y | U | N | Y | N | Y |
| Plotnikoff, 20112 | | Y | Y | Y | Y | Y | Y | Y | N | N | N | U | U | Y | U | U | U | U | Y | U | Y | Y | Y | Y | U | Y | N | Y | Y |
| **BMI/Diet** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Meloni, C., 20043 | | 169 | Y | Y | N | N | Y | Y | Y | N | N | N | U | U | U | N | U | Y | N | Y | U | Y | Y | Y | Y | U | N | U | N |
| Razquin, 20104 | | 737 | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | Y | Y | N | N |
| **BMI/Exercise** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Yates, T20105 | | 74 | Y | Y | Y | Y | P | Y | Y | N | Y | Y | U | U | U | U | U | Y | Y | Y | U | Y | Y | Y | Y | U | N | N | N |
| Gram, 20106 | | 68 | Y | Y | Y | Y | Y | Y | Y | Y | N | N | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | U | Y | Y | Y |
| **BMI/combination** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Haruyama, 20097 | | 549 | Y | Y | Y | Y | P | Y | Y | N | Y | Y | Y | Y | Y | N | Y | U | Y | Y | Y | Y | Y | Y | N | N | Y | Y | N |
| Samaras, 19978 | | 26 | Y | Y | Y | Y | Y | N | Y | N | N | N | U | U | Y | U | U | Y | N | Y | Y | Y | Y | U | Y | U | N | U | N |
| Babazono, 20079 | | 99 | Y | Y | Y | Y | P | Y | Y | N | N | N | Y | U | Y | N | U | U | N | Y | N | Y | Y | Y | Y | U | N | N | N |
| Torjesen, 199710 | | 219 | Y | Y | N | Y | P | Y | Y | N | Y | N | U | U | N | N | N | U | N | Y | Y | Y | Y | Y | Y | U | N | N | N |
| Plotnikoff, 20112 | | Y | Y | Y | Y | Y | Y | Y | N | N | N | U | U | Y | U | U | U | U | Y | U | Y | Y | Y | Y | U | Y | N | Y | Y |
| Toobert, 201111 | | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | U | N | Y | N | U | Y | U | Y | N | Y | Y | Y | Y | U | Y | Y | N | Y |
| **Weight/Diet** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Abraira, 198012 | | 30 | Y | Y | Y | Y | P | N | Y | Y | N | N | U | U | Y | N | N | U | N | Y | Y | Y | Y | Y | N | N | N | U | N |
| Razquin, 200913 | | 187 | Y | Y | Y | Y | P | Y | Y | Y | N | N | U | U | U | N | U | U | N | Y | N | Y | Y | U | Y | Y | N | N | N |
| Kumanyika, 200514 | | 1159 | Y | Y | Y | Y | Y | Y | Y | N | N | N | U | U | U | N | Y | N | N | Y | Y | Y | Y | Y | Y | Y | Y | U | Y |
| Meloni, C., 20043 | | 169 | Y | Y | N | N | Y | Y | Y | N | N | N | U | U | U | N | U | Y | N | Y | U | Y | Y | Y | Y | U | N | U | N |
| Razquin, 20104 | | 737 | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | Y | Y | N | N |
| Stefanick, 199815 | | 367 | Y | Y | Y | Y | P | Y | Y | N | Y | Y | U | U | U | N | U | Y | U | Y | U | Y | U | U | Y | U | U | Y | N |
| **Weight/exercise** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Yates, T20105 | | 74 | Y | Y | Y | Y | P | Y | Y | N | Y | Y | U | U | U | U | U | Y | Y | Y | U | Y | Y | Y | Y | U | N | N | N |
| **Weight/ combination** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Samaras, 19978 | | 26 | Y | Y | Y | Y | Y | N | Y | N | N | N | U | U | Y | U | U | Y | N | Y | Y | Y | Y | U | Y | U | N | U | N |
| Babazono, 20079 | | 99 | Y | Y | Y | Y | P | Y | Y | N | N | N | Y | U | Y | N | U | U | N | Y | N | Y | Y | Y | Y | U | N | N | N |
| Gram, 20106 | | 68 | Y | Y | Y | Y | Y | Y | Y | Y | N | N | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | U | Y | Y | Y |
| Hare-Bruun, 200616 | | 376 | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | N | N | U | N | N | U | U | Y | Y | Y | Y | Y | N | N | Y | Y | N |
| Toobert, 201111 | | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | U | N | Y | N | U | Y | U | Y | N | Y | Y | Y | Y | U | Y | Y | N | Y |
| **Waist circumference /Self-management** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clark, 20041 | | Y | Y | N | N | N | Y | N | N | N | Y | Y | U | U | N | U | U | N | Y | Y | Y | Y | Y | Y | U | N | Y | N | Y |
| Plotnikoff, 20112 | | Y | Y | Y | Y | Y | Y | Y | N | N | N | U | U | Y | U | U | U | U | Y | U | Y | Y | Y | Y | U | Y | N | Y | Y |
| **Waist circumference /Diet** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Razquin, 200913 | | 187 | Y | Y | Y | Y | P | Y | Y | Y | N | N | U | U | U | N | U | U | N | Y | N | Y | Y | U | Y | Y | N | N | N |
| Razquin, 20104 | | 737 | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | Y | Y | N | N |
| **Waist circumference/ Combination** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Samaras, 19978 | | 26 | Y | Y | Y | Y | Y | N | Y | N | N | N | U | U | Y | U | U | Y | N | Y | Y | Y | Y | U | Y | U | N | U | N |
| Gram, 20106 | | 68 | Y | Y | Y | Y | Y | Y | Y | Y | N | N | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | U | Y | Y | Y |
| Toobert, 201111 | | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | U | N | Y | N | U | Y | U | Y | N | Y | Y | Y | Y | U | Y | Y | N | Y |
| **Adherence/ exercise** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Gram, 20106 | | 68 | Y | Y | Y | Y | Y | Y | Y | Y | N | N | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | U | Y | Y | Y |
| **QOL/exercise** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Gram, 20106 | | 68 | Y | Y | Y | Y | Y | Y | Y | Y | N | N | U | U | U | U | U | U | N | Y | Y | Y | Y | U | Y | U | Y | Y | Y |
| **QOL/ combination** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Samaras, 19978 | | 26 | Y | Y | Y | Y | Y | N | Y | N | N | N | U | U | Y | U | U | Y | N | Y | Y | Y | Y | U | Y | U | N | U | N |
| **Activity-realted injury/ combination** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Samaras, 19978 | | 26 | Y | Y | Y | Y | Y | N | Y | N | N | N | U | U | Y | U | U | Y | N | Y | Y | Y | Y | U | Y | U | N | U | N |

\*Questions

1. Is the hypothesis/aim/objective of the study clearly described?

2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?

3. Are the characteristics of the patients included in the study clearly described?

4. Are the interventions of interest clearly described?

5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?

6. Are the main findings of the study clearly described?

7. Does the study provide estimates of the random variability in the data for the main outcomes?

8. Have all important adverse events that may be a consequence of the intervention been reported?

9. Have the characteristics of patients lost to follow-up been described?

10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?

11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?

12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?

13. Were the staff, places, and facilities where the patients were treated representative of the treatment the majority of patients receive?

14. Was an attempt made to blind study subjects to the intervention they have received? (We did not use the responses to this question to rate the Risk of Bias given the nature of the interventions)

15. Was an attempt made to blind those measuring the weight outcomes of the intervention? (This item must have been answered Yes for a trial to have low Risk of Bias)

16. If any of the results of the study were based on “data dredging”, was this made clear?

17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?

18. Were the statistical tests used to assess the main outcomes appropriate?

19. Was compliance with the intervention/s reliable?

20. Were the main outcome measures used accurate (valid and reliable)?

21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?

22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?

23. Were study subjects randomized to intervention groups?

24. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?

25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

26. Were losses of patients to follow-up taken into account?

27. Did they report a power calculation?

BMI = Body Mass Index, N=no,P=partially, U=unable to determine, Y=yes

**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. Meloni C, Tatangelo P, Cipriani S et al. Adequate protein dietary restriction in diabetic and nondiabetic patients with chronic renal failure. J Ren Nutr 2004; 14(4):208-13.

4. Razquin C, Martinez JA, Martinez-Gonzalez MA, Fernandez-Crehuet J, Santos JM, Marti A. 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.

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 Medicine 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. Haruyama Y, Muto T, Nakade M, et al. Fifteen-month lifestyle intervention program to improve cardiovascular risk factors in a community population in Japan. Tohoku J Exp Med 2009; 217(4):259-69.

8. 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.

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

10. 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.

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

12. 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.

13. 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. Eur J Clin Nutr 2009; 63(12):1387-93.

14. 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.

15. 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.

16. Hare-Bruun H, Flint A, Heitmann B. Glycemic index and glycemic load in relation to changes in body weight, body fat distribution, and body composition in adult Danes. Am J Clin Nutr 2006; 84(4):871-9.