

Randomized Controlled Trials in Nutrition

This is a collection of high quality research studies in nutrition, about some of the topics we cover on this website.

All of these studies are published in respected, peer-reviewed journals.

All of the studies on this page are randomized controlled trials in humans, unless otherwise noted!

Low-Carbohydrate vs. Low-Fat Diets

A low carb diet is based on foods that contain a low amount of carbohydrate. Foods that are high in sugars and starches are replaced with foods that are high in protein and fat.

A low fat diet, is based on foods that contain a low amount of fat, typically under 30% of total calories. Foods like fruits, vegetables and whole grains are emphasized.

The studies below are controlled trials where people are randomized to either a low-carb or a low-fat diet. The outcomes measured are usually body weight and risk factors for disease.

1. Krebs NF, et al. [Efficacy and safety of a high protein, low carbohydrate diet for weight loss in severely obese adolescents](#). J Pediatr. 2010 Aug;157(2):252-8.
2. Hernandez, et al. [Lack of suppression of circulating free fatty acids and hypercholesterolemia during weight loss on a high-fat, low-carbohydrate diet](#). Am J Clin Nutr March 2010 vol. 91 no. 3 578-585.
3. Brinkworth GD, et al. [Long-term effects of a very-low-carbohydrate weight loss diet compared with an isocaloric low-fat diet after 12 mo](#). Am J Clin Nutr. 2009 Jul;90(1):23-32.
4. Volek JS, et al. [Carbohydrate restriction has a more favorable impact on the metabolic syndrome than a low fat diet](#). Lipids. 2009 Apr;44(4):297-309.
5. Tay J, et al. [Metabolic effects of weight loss on a very-low-carbohydrate diet compared with an isocaloric high-carbohydrate diet in abdominally obese subjects](#). J Am Coll Cardiol. 2008 Jan 1;51(1):59-67.
6. Keogh JB, et al. [Effects of weight loss from a very-low-carbohydrate diet on endothelial function and markers of cardiovascular disease risk in subjects with abdominal obesity](#). Am J Clin Nutr. 2008 Mar;87(3):567-76.
7. Shai I, et al. [Weight loss with a low-carbohydrate, Mediterranean, or low-fat diet](#). N Engl J Med. 2008 Jul 17;359(3):229-41.
8. Dyson PA, et al. [A low-carbohydrate diet is more effective in reducing body weight than healthy eating in both diabetic and non-diabetic subjects](#). Diabet Med. 2007

Dec;24(12):1430-5.

9. Halyburton AK, et al. [Low- and high-carbohydrate weight-loss diets have similar effects on mood but not cognitive performance.](#) Am J Clin Nutr. 2007 Sep;86(3):580-7.
10. Gardner CD, et al. [Comparison of the Atkins, Zone, Ornish, and LEARN diets for change in weight and related risk factors among overweight premenopausal women: the A TO Z Weight Loss Study: a randomized trial.](#) JAMA. 2007 Mar 7;297(9):969-77.
11. McClernon FJ, et al. [The effects of a low-carbohydrate ketogenic diet and a low-fat diet on mood, hunger, and other self-reported symptoms.](#) Obesity (Silver Spring). 2007 Jan;15(1):182-7.
12. Nickols-Richardson SM, et al. [Perceived hunger is lower and weight loss is greater in overweight premenopausal women consuming a low-carbohydrate/high-protein vs high-carbohydrate/low-fat diet.](#) J Am Diet Assoc. 2005 Sep;105(9):1433-7.
13. Meckling KA, et al. [Comparison of a low-fat diet to a low-carbohydrate diet on weight loss, body composition, and risk factors for diabetes and cardiovascular disease in free-living, overweight men and women.](#) J Clin Endocrinol Metab. 2004 Jun;89(6):2717-23.
14. JS Volek, et al. [Comparison of energy-restricted very low-carbohydrate and low-fat diets on weight loss and body composition in overweight men and women.](#) Nutr Metab (Lond). 2004; 1: 13.
15. Yancy WS Jr, et al. [A low-carbohydrate, ketogenic diet versus a low-fat diet to treat obesity and hyperlipidemia: a randomized, controlled trial.](#) Ann Intern Med. 2004 May 18;140(10):769-77.
16. Aude YW, et al. [The national cholesterol education program diet vs a diet lower in carbohydrates and higher in protein and monounsaturated fat: a randomized trial.](#) Arch Intern Med. 2004 Oct 25;164(19):2141-6.
17. Brehm BJ, et al. [A randomized trial comparing a very low carbohydrate diet and a calorie-restricted low fat diet on body weight and cardiovascular risk factors in healthy women.](#) J Clin Endocrinol Metab. 2003 Apr;88(4):1617-23.
18. Sondike SB, et al. [Effects of a low-carbohydrate diet on weight loss and cardiovascular risk factor in overweight adolescents.](#) J Pediatr. 2003 Mar;142(3):253-8.
19. Samaha FF, et al. [A low-carbohydrate as compared with a low-fat diet in severe obesity.](#) N Engl J Med. 2003 May 22;348(21):2074-81.
20. Foster GD, et al. [A randomized trial of a low-carbohydrate diet for obesity.](#) N Engl J Med. 2003 May 22;348(21):2082-90.

Low-Carb and Type II Diabetes:

21. Guldbrand, et al. [In type 2 diabetes, randomization to advice to follow a low-carbohydrate diet transiently improves glycaemic control compared with advice to follow a low-fat diet producing a similar weight loss.](#) Diabetologia. 2012 Aug;55(8):2118-27.

22. Westman EC, et al. [The effect of a low-carbohydrate, ketogenic diet versus a low-glycemic index diet on glycemic control in type 2 diabetes mellitus](#). Nutr Metab (Lond). 2008 Dec 19;5:36.
23. Daly ME, et al. [Short-term effects of severe dietary carbohydrate-restriction advice in Type 2 diabetes – a randomized controlled trial](#). Diabet Med. 2006 Jan;23(1):15-20.

Main Results: Low-carb diets usually lead to more weight loss than low-fat diets, even when the low-fat groups are calorie restricted while the low-carb groups are not.

Low-carbohydrate diets also significantly improve major risk factors for diseases like cardiovascular disease and type II diabetes.

Meta-Analyses of Low-Carb Diet Studies

These studies are [meta-analyses](#) of randomized controlled trials of low-carbohydrate diets.

1. Santos F, et al. [Systematic review and meta-analysis of clinical trials of the effects of low carbohydrate diets on cardiovascular risk factors](#). Obesity Reviews, 13: 1048–1066.
2. Hession M, et al. [Systematic review of randomized controlled trials of low-carbohydrate vs. low-fat/low-calorie diets in the management of obesity and its comorbidities](#). Obesity Reviews, 10: 36–50.
3. Westman EC, et al. [Low-carbohydrate nutrition and metabolism](#). Am J Clin Nutr August 2007 86: 2 276-284

Main Results: Same as above. Low-carb diets lead to more weight loss and further improvements in metabolic health compared to the low-fat diet that is usually recommended by nutritionists and governments around the world.

The Paleolithic Diet

Randomized controlled trials of [the paleolithic diet](#) (commonly known as the paleo diet or caveman diet).

1. Jönsson T, et al. [Beneficial effects of a Paleolithic diet on cardiovascular risk factors in type 2 diabetes: a randomized cross-over pilot study](#). Cardiovascular Diabetology 2009, 8:35.
2. Lindeberg S, et al. [A Palaeolithic diet improves glucose tolerance more than a Mediterranean-like diet in individuals with ischaemic heart disease](#). Diabetologia. 2007 Sep;50(9):1795-807.

Main Results: The paleo diet has favorable effects on body weight and major risk factors. However, the studies available are very small so the results must be taken with a grain of salt.

Vitamin D3 Supplementation

A deficiency in Vitamin D is very common today, especially in countries where there is little sun

throughout most of the year.

Vitamin D3 and cancer:

1. Lappe JM, et al. [Vitamin D and calcium supplementation reduces cancer risk: results of a randomized trial](#). Am J Clin Nutr. 2007 Jun;85(6):1586-91.

Vitamin D, fractures and falls:

2. **Meta-analysis:** Bischoff-Ferrari HA, et al. [Fracture prevention with vitamin D supplementation: a meta-analysis of randomized controlled trials](#). JAMA. 2005 May 11;293(18):2257-64.
3. Trivedi DP, et al. [Effect of four monthly oral vitamin D3 \(cholecalciferol\) supplementation on fractures and mortality in men and women living in the community: randomised double blind controlled trial](#). BMJ 2003;326:469.
4. Broe KE, et al. [A higher dose of vitamin d reduces the risk of falls in nursing home residents: a randomized, multiple-dose study](#). J Am Geriatr Soc. 2007 Feb;55(2):234-9.

Vitamin D3 and Influenza A Infections:

5. Urashima M, et al. [Randomized trial of vitamin D supplementation to prevent seasonal influenza A in schoolchildren](#). Am J Clin Nutr May 2010.

Main Results: Vitamin D supplementation reduces risk of falls and fractures in the elderly at higher doses. May reduce risk of cancer and respiratory infections.

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There is no cherry picking here. All relevant studies are included.