

CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Low Carbohydrate Diet Interventions for Diabetes: Clinical Effectiveness and Guidelines

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Research Questions

1. What is the clinical effectiveness regarding the use of a low carbohydrate diet in obese adults with diabetes?
2. What are the evidence-based guidelines regarding the use of a low carbohydrate diet in obese adults with diabetes?

Key Findings

Two systematic reviews with meta-analyses, 13 randomized controlled trials, and one non-randomized study were identified regarding the clinical effectiveness of low carbohydrate diets for obese adults with type II diabetes or prediabetes. Additionally, one evidence-based guideline was identified.

Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. The search was limited to English language documents published between Jan 1, 2012 and Apr 6, 2017.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Obese adults with diabetes (either pre-diabetic or type II diabetes)
Intervention	Q1: Low carbohydrate diet Q2: Low carbohydrate diet interventions
Comparator	Q1: Standard treatment (i.e., another intervention and/or medication) Q2: Not applicable
Outcomes	Clinical effectiveness, including glucose control and weight loss, guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews,

and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

Two systematic reviews with meta-analyses, 13 randomized controlled trials, and one non-randomized study were identified regarding the clinical effectiveness of low carbohydrate diets for obese adults with type II diabetes or prediabetes. Additionally, one evidence-based guideline was identified. No relevant health technology assessments were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

Two systematic reviews with meta-analyses,¹⁻² 13 randomized-controlled trials,³⁻¹⁵ and one non-randomized study¹⁶ were identified regarding the clinical effectiveness of low carbohydrate diets for obese adults with type II diabetes or prediabetes. Detailed study characteristics are provided in Table 2.

One evidence-based guideline¹⁷ was identified regarding dietary choices for achieving weight loss in obese adults with type 2 diabetes. This guideline recommends diets which restrict caloric intake, reduce fat intake, promote consumption of carbohydrates with low rather than high glycemic index, or restrict the total amount of dietary carbohydrate.¹⁷

Table 2: Summary of Included Studies on Low Carbohydrate Diets for Obese Adults with Diabetes

First Author, Year	Study Characteristics	Intervention	Comparator	Outcomes	Conclusions
Systematic Reviews and Meta-Analyses					
Snorgaard, 2017¹	<ul style="list-style-type: none"> SR & MA 10 included RCTs N = 1376 	<ul style="list-style-type: none"> Low-carb diet 	<ul style="list-style-type: none"> High-carb diet 	<ul style="list-style-type: none"> HbA1c (glycemic control) Weight BMI LDL cholesterol QoL 	<ul style="list-style-type: none"> Low-carb diets had greater effect on glycemic control Increasing carbohydrate restriction led to greater glucose lowering No additional advantages of low-carbohydrate diets with regards to glycemic control, weight, or LDL cholesterol
Ajala, 2013²	<ul style="list-style-type: none"> SR & MA 20 included RCTs N = 3073 	<ul style="list-style-type: none"> Low-carb, vegetarian, vegan, low-glycemic index, high-fiber, 	<ul style="list-style-type: none"> Low-fat, high-GI, American Diabetes Association, European 	<ul style="list-style-type: none"> Glycemic control HDL levels Weight loss 	<ul style="list-style-type: none"> The low-carb diet led to a greater improvement in glycemic control Low-carb diet led to greater weight

Table 2: Summary of Included Studies on Low Carbohydrate Diets for Obese Adults with Diabetes

First Author, Year	Study Characteristics	Intervention	Comparator	Outcomes	Conclusions
		Mediterranean, and high-protein diets	Association for the Study of Diabetes, and low-protein diets		<ul style="list-style-type: none"> loss HDL cholesterol levels were higher after low-carb diet Low-carb diets were effective in improving risk factors of cardiovascular disease
Randomized Controlled Trials					
Brinkworth, 2016³	<ul style="list-style-type: none"> RCT N = 115 	<ul style="list-style-type: none"> Very low-carb, high-fat diets 	<ul style="list-style-type: none"> High-carb, low-fat diet 	<ul style="list-style-type: none"> Body weight Psychological mood state and well-being Diabetes-specific emotional distress QoL 	<ul style="list-style-type: none"> Both diets resulted in similar weight loss and improvements in QoL and mood state There were no significant advantages of the very low-carb, high-fat diet over the high-carb, low-fat diet
Goday, 2016⁴	<ul style="list-style-type: none"> RCT N = 89 	<ul style="list-style-type: none"> Very low-calorie-ketogenic diet 	<ul style="list-style-type: none"> Standard low-calorie diet 	<ul style="list-style-type: none"> Body weight HbA1c (glycemic control) Adverse events 	<ul style="list-style-type: none"> Very low-calorie-ketogenic diet was effective in reducing body weight and improved glycemic control The very low-calorie-ketogenic diet was well tolerated with no serious adverse events
Sato, 2016⁵	<ul style="list-style-type: none"> RCT N = 66 	<ul style="list-style-type: none"> Low-carb diet 	<ul style="list-style-type: none"> Calorie restricted diet 	<ul style="list-style-type: none"> HbA1c (glycemic control) BMI 	<ul style="list-style-type: none"> Low-carb diet was effective in reducing HbA1c and BMI
Tay, 2016⁶	<ul style="list-style-type: none"> RCT N = 115 	<ul style="list-style-type: none"> Very low-carb, high-fat diet 	<ul style="list-style-type: none"> High-carb, low-fat diet 	<ul style="list-style-type: none"> Cognitive performance 	<ul style="list-style-type: none"> Both diets had similar effects on cognitive performance

Table 2: Summary of Included Studies on Low Carbohydrate Diets for Obese Adults with Diabetes

First Author, Year	Study Characteristics	Intervention	Comparator	Outcomes	Conclusions
Wycherley, 2016 ⁷	<ul style="list-style-type: none"> RCT N = 115 	<ul style="list-style-type: none"> Hypocaloric very low-carb, low saturated fat diet 	<ul style="list-style-type: none"> Isocaloric higher carb, low fat diet. 	<ul style="list-style-type: none"> Body weight HbA1c Endothelial function 	<ul style="list-style-type: none"> Both groups experienced similar reductions in weight and HbA1c levels Both diets had similar effect on endothelial function
Tay, 2015 ⁸	<ul style="list-style-type: none"> RCT N = 115 	<ul style="list-style-type: none"> Very-low-carb, high-unsaturated fat, low-saturated fat diet 	<ul style="list-style-type: none"> High-carb, low-fat diet 	<ul style="list-style-type: none"> HbA1c (glycemic control) Body weight Cardiovascular disease risk factors 	<ul style="list-style-type: none"> Weight loss, HbA1c, and fasting glucose were similarly reduced in either diet The low-carb diet achieved greater improvements in the lipid profile, blood glucose stability, and further reduced the amount of diabetes medication required
Tay, 2015 ⁹	<ul style="list-style-type: none"> RCT N = 115 	<ul style="list-style-type: none"> Very low-carb, high-protein, low saturated fat diet 	<ul style="list-style-type: none"> High unrefined carb, low-fat diet 	<ul style="list-style-type: none"> Body weight Blood pressure Renal function 	<ul style="list-style-type: none"> Both group experienced similar weight loss and decrease in blood pressure The low-carb diet had similar effects on clinical markers of renal function
Esposito, 2014 ¹⁰	<ul style="list-style-type: none"> RCT N = 215 	<ul style="list-style-type: none"> Low-carb Mediterranean diet 	<ul style="list-style-type: none"> Low-fat diet 	<ul style="list-style-type: none"> HbA1c Need for diabetes medications Remission of type 2 diabetes Cardiovascular risk factors 	<ul style="list-style-type: none"> The low-carb Mediterranean diet group had greater reduction of HbA1c levels, higher rate of diabetes remission, and delayed need for diabetes medication compared with the low-fat diet group

Table 2: Summary of Included Studies on Low Carbohydrate Diets for Obese Adults with Diabetes

First Author, Year	Study Characteristics	Intervention	Comparator	Outcomes	Conclusions
Jonasson, 2014 ¹¹	<ul style="list-style-type: none"> RCT N = 59 	<ul style="list-style-type: none"> Low-carb diet 	<ul style="list-style-type: none"> Low-fat diet 	<ul style="list-style-type: none"> Effects of diet on inflammation in type 2 diabetes Body weight 	<ul style="list-style-type: none"> Both diets had similar effect on body weight, but only the low-carb diet significantly improved the subclinical inflammatory state of patients
Saslow, 2014 ¹²	<ul style="list-style-type: none"> RCT N = 34 	<ul style="list-style-type: none"> Very low-carb, high fat, non-calorie-restricted diet 	<ul style="list-style-type: none"> Medium-carb, low fat, calorie-restricted, carbohydrate counting diet 	<ul style="list-style-type: none"> Body weight HbA1c 	<ul style="list-style-type: none"> The very low-carb, high fat, non-calorie-restricted diet was more effective in reducing body weight, and HbA1c levels
Tay, 2014 ¹³	<ul style="list-style-type: none"> RCT N = 115 	<ul style="list-style-type: none"> Very low-carb, high-unsaturated/low-saturated fat diet 	<ul style="list-style-type: none"> High-unrefined carb, low-fat diet 	<ul style="list-style-type: none"> HbA1c Glycemic variability Antiglycemic medication Blood lipids Blood pressure 	<ul style="list-style-type: none"> Both diets were effective in reducing HbA1c levels and cardiovascular disease risk markers The low-carb diet was more effective in improving glycemic variability and antiglycemic medication requirements
Yamada, 2014 ¹⁴	<ul style="list-style-type: none"> RCT N = NR 	<ul style="list-style-type: none"> Low-carb diet 	<ul style="list-style-type: none"> Calorie-restricted diet 	<ul style="list-style-type: none"> Glycemic control Metabolic profiles 	<ul style="list-style-type: none"> The low-carb diet was more effective in reducing HbA1c and triglyceride levels
Guldbrand, 2012 ¹⁵	<ul style="list-style-type: none"> RCT N = 61 	<ul style="list-style-type: none"> Low-carb diet 	<ul style="list-style-type: none"> Low-fat diet 	<ul style="list-style-type: none"> Body Weight HbA1c 	<ul style="list-style-type: none"> Weight loss did not significantly differ between the two groups HbA1c levels only decreased in the low-carb diet group

Table 2: Summary of Included Studies on Low Carbohydrate Diets for Obese Adults with Diabetes

First Author, Year	Study Characteristics	Intervention	Comparator	Outcomes	Conclusions
Non-Randomized Studies					
Masharani, 2015¹⁶	<ul style="list-style-type: none"> NRS N = 24 	<ul style="list-style-type: none"> Paleo diet (lean meat, fruits, vegetables and nuts) 	<ul style="list-style-type: none"> Diet based on recommendations by the American Diabetes Association containing moderate salt intake, low-fat dairy, whole grains and legumes 	<ul style="list-style-type: none"> Blood pressure 24-h urine electrolytes HbA1c Fructosamine levels Insulin resistance Lipid levels 	<ul style="list-style-type: none"> The Paleo diet resulted in improved glucose control and lipid profiles

Abbreviations: BMI = body mass index; GI = glycemic index; LDL = low-density lipoprotein; MA = meta-analysis; NR = not reported; NRS = non-randomized study; QoL = quality of life; RCT = randomized controlled trials; SR = systematic review.

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-Analyses

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[PubMed: PM28316796](#)
2. Ajala O, English P, Pinkney J. Systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes. *Am J Clin Nutr*. 2013 Mar;97(3):505-16.
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Randomized Controlled Trials

3. Brinkworth GD, Luscombe-Marsh ND, Thompson CH, Noakes M, Buckley JD, Wittert G, et al. Long-term effects of very low-carbohydrate and high-carbohydrate weight-loss diets on psychological health in obese adults with type 2 diabetes: randomized controlled trial. *J Intern Med*. 2016 Oct;280(4):388-97.
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<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5059023>
[PubMed: PM26632754](#)
10. Esposito K, Maiorino MI, Petrizzo M, Bellastella G, Giugliano D. The effects of a Mediterranean diet on the need for diabetes drugs and remission of newly diagnosed type 2 diabetes: follow-up of a randomized trial. *Diabetes Care*. 2014 Jul;37(7):1824-30.
[PubMed: PM24722497](#)
11. Jonasson L, Guldbrand H, Lundberg AK, Nystrom FH. Advice to follow a low-carbohydrate diet has a favourable impact on low-grade inflammation in type 2 diabetes compared with advice to follow a low-fat diet. *Ann Med* [Internet]. 2014 May [cited 2017 Apr 19];46(3):182-7. Available from:
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12. Saslow LR, Kim S, Daubenmier JJ, Moskowitz JT, Phinney SD, Goldman V, et al. A randomized pilot trial of a moderate carbohydrate diet compared to a very low carbohydrate diet in overweight or obese individuals with type 2 diabetes mellitus or prediabetes. PLoS ONE [Internet]. 2014 [cited 2017 Apr 19];9(4):e91027. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3981696>
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[PubMed: PM22562179](#)

Non-Randomized Studies

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Guidelines and Recommendations

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Appendix — Further Information

Previous CADTH Reports

18. Diabetic Diets for Frail Elderly Long-Term Care Residents with Type II Diabetes Mellitus: A Review of Guidelines [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2015 Jun 15 [cited 2017 Apr 19]. (CADTH Rapid Response Reports: Summary with Critical Appraisal). Available from: https://www.cadth.ca/sites/default/files/pdf/htis/june-2015/RC0668_Diabetic%20diets%20for%20FE%20LTR Final.pdf

Systematic Reviews and Meta-Analyses

Alternate Intervention

19. Wang Q, Xia W, Zhao Z, Zhang H. Effects comparison between low glycemic index diets and high glycemic index diets on HbA1c and fructosamine for patients with diabetes: A systematic review and meta-analysis. *Prim Care Diabetes*. 2015 Oct;9(5):362-9.
[PubMed: PM25524422](#)

Randomized Control Trials

Alternate Comparator

20. Otten J, Stomby A, Waling M, Isaksson A, Tellstrom A, Lundin-Olsson L, et al. Benefits of a Paleolithic diet with and without supervised exercise on fat mass, insulin sensitivity, and glycemic control: a randomized controlled trial in individuals with type 2 diabetes. *Diabetes Metab Res Rev*. 2017 Jan;33(1).
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Alternate Outcomes

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Mixed Population

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Evidence-Based Guidelines

Alternate Interventions

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Review Articles

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[PubMed: PM26413954](http://pubmed.ncbi.nlm.nih.gov/26413954/)

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[PubMed: PM26446553](#)