

Leveraging nut-containing plant-based dietary patterns for cardiometabolic health: Moving from evidence to guidelines to clinical practice

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Nutrition Research Seminar

INC World Forum for Nutrition Research and Dissemination

Vancouver, BC, Canada

May 08, 2024



St. Michael's
Inspired Care.
Inspiring Science.

Disclosures (past 24 months)

Board Member/Advisory Panel

- Diabetes Canada 2018 Clinical Practice Guidelines Expert Committee for Nutrition therapy
- Canadian Cardiovascular Society (CCS) 2016 Dyslipidemia Guidelines Update
- European Association for the Study of Diabetes (EASD) Clinical Practice Guidelines Expert Committee for Nutrition therapy
- Obesity Canada Clinical Practice Guidelines Expert Committee
- Institute for the Advancement of Food and Nutrition Sciences (IAFNS)

Research Support

- Canadian Institutes of Health Research (CIHR)
- Canadian Foundation for Innovation/Ontario Research Fund
- Diabetes Canada
- American Society for Nutrition (ASN)
- National Honey Board (USDA “check off” program)
- Institute for the Advancement of Food and Nutrition Sciences (IAFNS)
- Glycemic Control and Cardiovascular Disease in Type 2 Diabetes Fund at the University of Toronto (a fund established by the Alberta Pulse Growers)
- Nutrition Trialists Fund at the University of Toronto (a fund established by the Calorie Control Council and Physician’s Committee for Responsible Medicine)
- United Soybean Board (USDA “check off” program)
- Protein Industries Canada (a Government of Canada Global Innovation Cluster)

- The Plant Milk Fund at the University of Toronto (a fund established by the Karuna Foundation)
- The Plant Protein Fund at the University of Toronto (a fund which has received contributions from IFF among other donors)

“In-kind” food product donations for trials

Almond Board of California, California Walnut Commission, Danone, Nutrartis, Soylent, Dairy Farmers of Canada

Ad Hoc Consulting Arrangements

- Tate & Lyle

Honoraria or Speaker Fees

- Nestle
- IFIC
- General Mills
- Danone
- International Sweeteners Association
- Calorie Control Council
- Abbott
- Ingredion

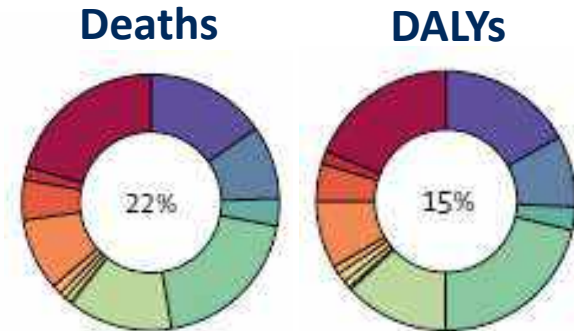
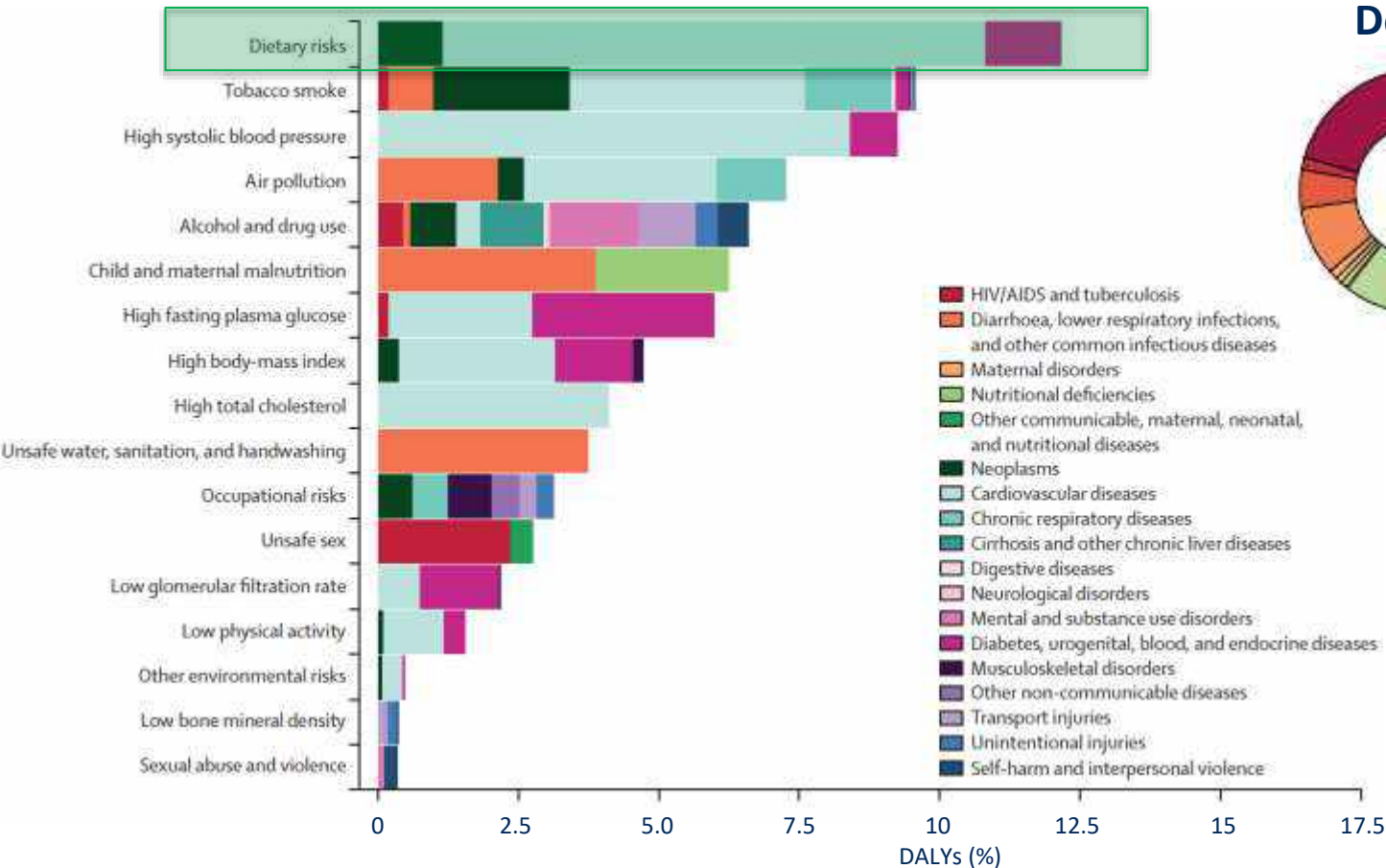
Other

- Spouse is an employee of AB InBev
- Director, Toronto 3D Knowledge Synthesis and Clinical Trials foundation

Does diet matter?

Poor diet is greatest contributor to premature morbidity and mortality worldwide:

Global burden of disease attributable to 79 risk factors in



91% CV deaths
95% CV DALYs

- Low fruit
- Low vegetables
- Low legumes
- High processed meat
- High sugar-sweetened beverages
- Low calcium
- Low omega-3
- Low PUFA
- High sodium
- High trans fats
- Low whole grains
- Low nuts and seeds
- High red meat

GBD 2015 Risk Factors Collaborators. *Lancet* 2016; 388: 1659–724

GBD 2017 Diet Collaborators. *Lancet* 2019 Apr 3. pii: S0140-6736(19)30041-8 [Epub ahead of print]

Nutrition is the cornerstone of therapy: CPGs for Diabetes, Dyslipidemia, Hypertension



Sievenpiper et al. Can J Diabetes. 2018;42 (Suppl 1):S64-S79.



Anderson JT et al. Can J Cardiol. 2016;pii:S0828-282X(16)30732-2.



Wharton et al. CMAJ 2020;192:E875-E891



ESC/EASD Task Force. Eur Heart J 2020;41:255-323



Grundy SM. Circulation 2019;139:e1082-e1143



American Diabetes Association. Diabetes Care 2020;43(Suppl. 1):S48-S65

*the cornerstone of chronic
disease prevention, including*

Doctors 'know too little about nutrition and exercise'

Letter from medics and dieticians calls for improvement in training to reduce lifestyle-related deaths



Health & Science

The Need For Nutrition Education In Medical School Curriculum

Doctors not taught to discuss diet, nutrition with patients



Home · Lifestyle · Health and Fitness · Nutrition

Food is medicine – so why aren't our doctors trained in the science of nutrition?



Your doctor may not be the best source of nutrition advice



Canadian medical students want more nutrition instruction

We learn nothing about nutrition, claim medical students



Sign in



Most doctors lack adequate training to give informed diet advice

Medscape Friday, September 21, 2018

Lauren Vogel
CMAJ August 07, 2018;190(31):E945; DOI: https://doi.org/10.1503/cmaj.109-5639



Expectations > theheart.org on Medscape

Doctors Need to Learn About Nutrition

How do we translate nutrition related to nuts into clinical practice?

“Nutrient-based” to “food- and dietary pattern-based” recommendations

Canadian Journal of Diabetes / Canadian Diabetes Association

Food and Dietary Pattern-Based Recommendations: An Emerging Approach to Clinical Practice Guidelines for Nutrition Therapy in Diabetes

John L. Sievenpiper MD, PhD^{1,2,3,4}, Paul B. Dawson PhD, RD⁵

ABSTRACT

OBJECTIVE: Clinical practice guidelines (CPGs) for the management of individuals with diabetes mellitus have evolved over time to reflect the best available evidence. The most recent CPGs have focused on the management of blood glucose, blood pressure, and lipid control. However, recent evidence suggests that a diet-based approach to the management of diabetes may be more effective than a nutrient-based approach. This review discusses the emerging approach to clinical practice guidelines for nutrition therapy in diabetes, which focuses on food and dietary patterns rather than nutrients. The approach is based on the concept of a dietary pattern, which is a collection of foods and beverages that are consumed together. The approach is based on the concept of a dietary pattern, which is a collection of foods and beverages that are consumed together. The approach is based on the concept of a dietary pattern, which is a collection of foods and beverages that are consumed together.

KEYWORDS: Diabetes, Nutrition, Dietary patterns, Food and dietary patterns, Clinical practice guidelines, Nutrition therapy, Diabetes management, Food and dietary patterns, Clinical practice guidelines, Nutrition therapy, Diabetes management, Food and dietary patterns, Clinical practice guidelines, Nutrition therapy, Diabetes management.

INTRODUCTION

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Canadian Journal of Diabetes / Canadian Diabetes Association

Obesity in adults: a clinical practice guideline

John L. Sievenpiper MD, PhD^{1,2,3,4}, Paul B. Dawson PhD, RD⁵

ABSTRACT

OBJECTIVE: The purpose of this guideline is to provide clinical practice guidelines for the management of obesity in adults. The guideline is based on the concept of a dietary pattern, which is a collection of foods and beverages that are consumed together. The approach is based on the concept of a dietary pattern, which is a collection of foods and beverages that are consumed together. The approach is based on the concept of a dietary pattern, which is a collection of foods and beverages that are consumed together.

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Canadian Journal of Diabetes / Canadian Diabetes Association

2016 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia in the Prevention of Cardiovascular Disease in the Adult

Trudi J. Anderson MD, PhD^{1,2,3,4}, David G. Jay MD, PhD^{5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93,94,95,96,97,98,99,100,101,102,103,104,105,106,107,108,109,110,111,112,113,114,115,116,117,118,119,120,121,122,123,124,125,126,127,128,129,130,131,132,133,134,135,136,137,138,139,140,141,142,143,144,145,146,147,148,149,150,151,152,153,154,155,156,157,158,159,160,161,162,163,164,165,166,167,168,169,170,171,172,173,174,175,176,177,178,179,180,181,182,183,184,185,186,187,188,189,190,191,192,193,194,195,196,197,198,199,200,201,202,203,204,205,206,207,208,209,210,211,212,213,214,215,216,217,218,219,220,221,222,223,224,225,226,227,228,229,230,231,232,233,234,235,236,237,238,239,240,241,242,243,244,245,246,247,248,249,250,251,252,253,254,255,256,257,258,259,260,261,262,263,264,265,266,267,268,269,270,271,272,273,274,275,276,277,278,279,280,281,282,283,284,285,286,287,288,289,290,291,292,293,294,295,296,297,298,299,300,301,302,303,304,305,306,307,308,309,310,311,312,313,314,315,316,317,318,319,320,321,322,323,324,325,326,327,328,329,330,331,332,333,334,335,336,337,338,339,340,341,342,343,344,345,346,347,348,349,350,351,352,353,354,355,356,357,358,359,360,361,362,363,364,365,366,367,368,369,370,371,372,373,374,375,376,377,378,379,380,381,382,383,384,385,386,387,388,389,390,391,392,393,394,395,396,397,398,399,400,401,402,403,404,405,406,407,408,409,410,411,412,413,414,415,416,417,418,419,420,421,422,423,424,425,426,427,428,429,430,431,432,433,434,435,436,437,438,439,440,441,442,443,444,445,446,447,448,449,450,451,452,453,454,455,456,457,458,459,460,461,462,463,464,465,466,467,468,469,470,471,472,473,474,475,476,477,478,479,480,481,482,483,484,485,486,487,488,489,490,491,492,493,494,495,496,497,498,499,500,501,502,503,504,505,506,507,508,509,510,511,512,513,514,515,516,517,518,519,520,521,522,523,524,525,526,527,528,529,530,531,532,533,534,535,536,537,538,539,540,541,542,543,544,545,546,547,548,549,550,551,552,553,554,555,556,557,558,559,560,561,562,563,564,565,566,567,568,569,570,571,572,573,574,575,576,577,578,579,580,581,582,583,584,585,586,587,588,589,590,591,592,593,594,595,596,597,598,599,600,601,602,603,604,605,606,607,608,609,610,611,612,613,614,615,616,617,618,619,620,621,622,623,624,625,626,627,628,629,630,631,632,633,634,635,636,637,638,639,640,641,642,643,644,645,646,647,648,649,650,651,652,653,654,655,656,657,658,659,660,661,662,663,664,665,666,667,668,669,670,671,672,673,674,675,676,677,678,679,680,681,682,683,684,685,686,687,688,689,690,691,692,693,694,695,696,697,698,699,700,701,702,703,704,705,706,707,708,709,710,711,712,713,714,715,716,717,718,719,720,721,722,723,724,725,726,727,728,729,730,731,732,733,734,735,736,737,738,739,740,741,742,743,744,745,746,747,748,749,750,751,752,753,754,755,756,757,758,759,760,761,762,763,764,765,766,767,768,769,770,771,772,773,774,775,776,777,778,779,780,781,782,783,784,785,786,787,788,789,790,791,792,793,794,795,796,797,798,799,800,801,802,803,804,805,806,807,808,809,810,811,812,813,814,815,816,817,818,819,820,821,822,823,824,825,826,827,828,829,830,831,832,833,834,835,836,837,838,839,840,841,842,843,844,845,846,847,848,849,850,851,852,853,854,855,856,857,858,859,860,861,862,863,864,865,866,867,868,869,870,871,872,873,874,875,876,877,878,879,880,881,882,883,884,885,886,887,888,889,890,891,892,893,894,895,896,897,898,899,900,901,902,903,904,905,906,907,908,909,910,911,912,913,914,915,916,917,918,919,920,921,922,923,924,925,926,927,928,929,930,931,932,933,934,935,936,937,938,939,940,941,942,943,944,945,946,947,948,949,950,951,952,953,954,955,956,957,958,959,960,961,962,963,964,965,966,967,968,969,970,971,972,973,974,975,976,977,978,979,980,981,982,983,984,985,986,987,988,989,990,991,992,993,994,995,996,997,998,999,1000.}

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Sievenpiper, Dworatzek. Can J Diabetes 2013;37:S1-S7

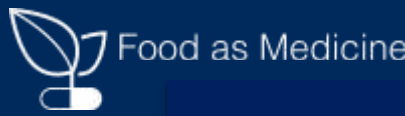
Dworatzek et al. Can J Diabetes 2013;37:S45eS55

Anderson et al. Can J Cardiol 2016;32:1263e1282

Sievenpiper et al. Can J Diabetes 2018;42:s64-s79

Wharton et al. CMAJ 2020;192:E875-E891

DNSG-EASD Guideline Development Group. Diabetologia 2023;66:965-98



New EASD clinical practice guidelines: Evidence syntheses commissioned to address the discordance in LNCS research



Evidence-based European recommendations for the dietary management of diabetes: An EASD Clinical Practice Guideline

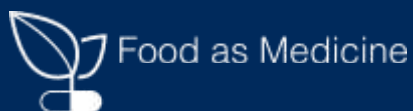
1. Prevention of type 2 diabetes
2. Energy-balance and weight management in diabetes
3. Carbohydrate intakes in diabetes management
4. Dietary fat intakes in diabetes management
5. Protein intakes in diabetes management
6. Food-based approaches in diabetes management
7. Traditional dietary patterns and therapeutic diets in diabetes management
8. Environmental sustainability and diabetes management
9. Food processing and diabetes management
10. Patient support and diabetes management



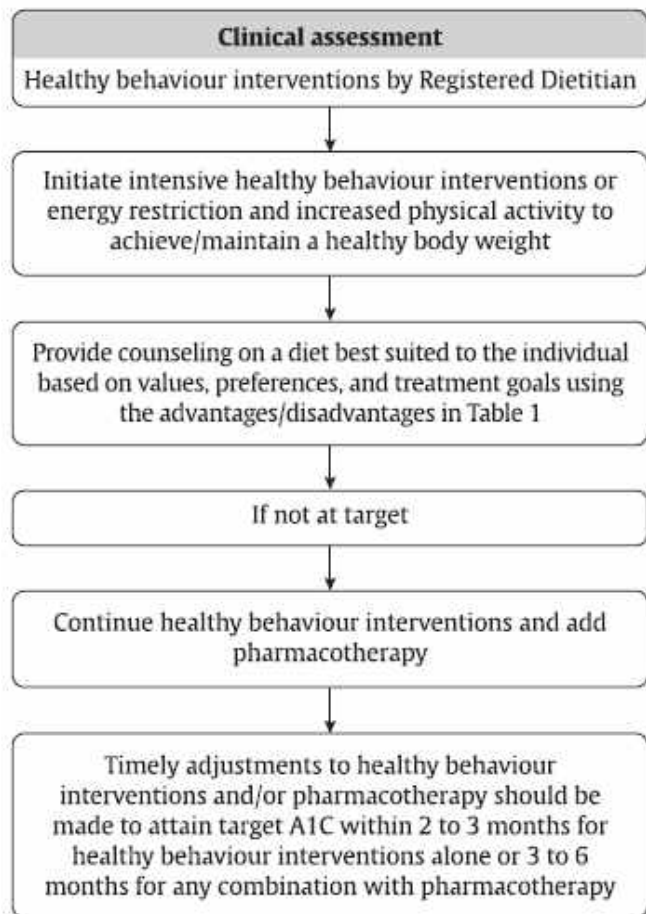
The DNSG-EASD Guideline Development Group.
Diabetologia 2023 Jun;66(6):965-98



European Association
for the Study of Diabetes



No “one-size-fits-all”: Importance of values, preferences, and treatment goals



*“Values and preferences. Adherence is one of the most important determinants for attaining the benefits of any diet. High food costs (e.g. fresh fruits and vegetables), allergies (e.g. peanut and tree nut allergies), intolerances (e.g. lactose intolerance), and gastrointestinal (GI) side effects (e.g. flatulence and bloating from fibre) may present as important barriers to adherence. Other barriers may include culinary (e.g. ability and time to prepare foods), cultural (e.g. culturally specific foods), and ecological/environmental (e.g. sustainability of diets) considerations. **Individuals should choose the dietary pattern that best fits with their values and preferences, allowing them to achieve the greatest adherence over the long term.**”*

Are there similar transcultural approaches beyond Mediterranean diet?

Recommended nut-containing, plant-based dietary patterns

Mediterranean Diet



(⊕⊕⊕⊕ Low to
⊕⊕⊕⊕ Moderate)

<https://oldwayspt.org/traditional-diets/mediterranean-diet>

Nordic Diet



(⊕⊕⊕⊕ Low to
⊕⊕⊕⊕ Moderate)

Kanerva et al. Public Health Nutr. 2014;17:1697-705

Vegetarian Diet



(⊕⊕⊕⊕ Very low to
⊕⊕⊕⊕ Moderate)

<https://oldwayspt.org/resources/oldways-vegetarianvegan-diet-pyramid>

Portfolio Diet

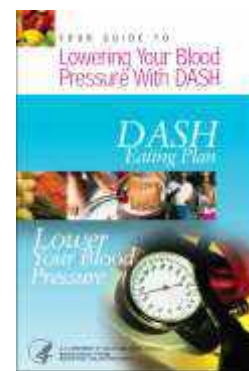


(⊕⊕⊕⊕ Very low to
⊕⊕⊕⊕ High)



<https://ccs.ca/app/uploads/2023/08/Portfolio-Infographic-EN-FINAL.pdf>

DASH Diet



https://www.nhlbi.nih.gov/files/docs/public/heart/new_dash.pdf

DASH Eating Plan	
Eat This	Avoid This
Vegetables	Fatty meats
Fruits	High-fat dairy
Whole grains	Salt
Low-fat or fat-free dairy	Sugar-sweetened beverages
Fish	Red meat
Healthy fats	Highly processed meats
Nuts	Sweets
Beans	High-sodium foods
Fruits & nuts	Alcohol
Vegetable oils	Trans fats

(⊕⊕⊕⊕ Low to
⊕⊕⊕⊕ Moderate)



What is the nut-containing *Portfolio Diet*?

A plant-based, dietary portfolio of cholesterol-lowering foods

1 Nuts
45g/day
Peanuts, tree nuts

2 Viscous Fiber
20g/day
Oats, barley,
psyllium, pulses,
eggplant, okra,
temperate climate
fruit

5 MUFA oils
Extra virgin olive oil, canola oil, soybean oil

3 Plant protein
50g/day
Soy products,
pulses

4 Plant Sterols
2g/day
Plant sterol
margarine/oil/
supplements



Health
Canada

Santé
Canada



U.S. FOOD & DRUG
ADMINISTRATION



European Food Safety Authority

Current approved health claims: Cholesterol and CHD risk reduction

NCEP Step II diet (low-SFA, low-chol diet)	↓10%*
1. Nuts (peanuts, 9 tree nuts)	↓5%
2. Soy (soy, pulses)	↓5%
3. Viscous Fibres (oat, barley, psyllium, PGX)	↓5%
4. Phytosterols (plant sterols and stanols)	↓5%
5. MUFA/PUFA oils (Olive, Canola, Soy)	(↓10%)*

*Replacement of SFA with MUFA/PUFA oils

↓30%



Health
Canada

Santé
Canada



U.S. FOOD & DRUG
ADMINISTRATION



European Food Safety Authority

Portfolio Diet: From efficacy to effectiveness

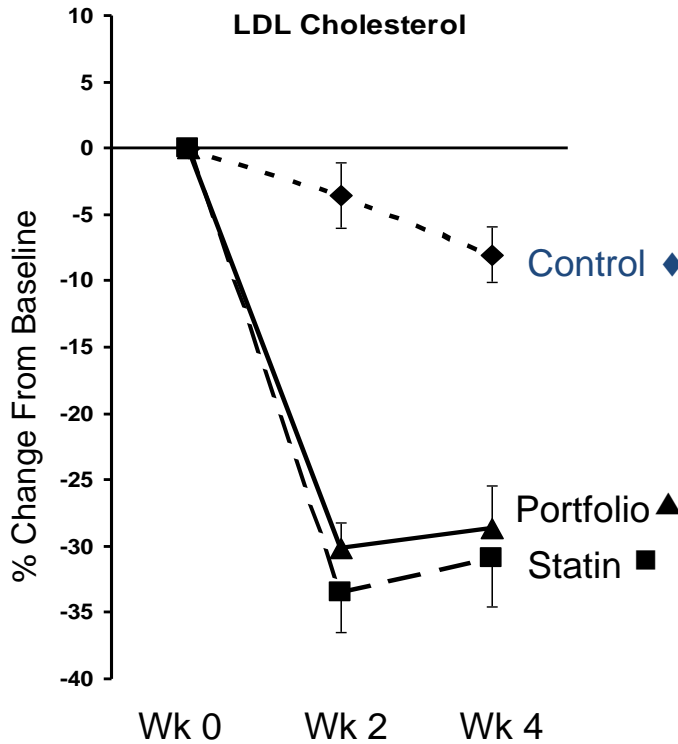


David Jenkins,
OC, MD, PhD, DSc,
FRCP, FRCPC, FRSC



Cyril Kendall, PhD

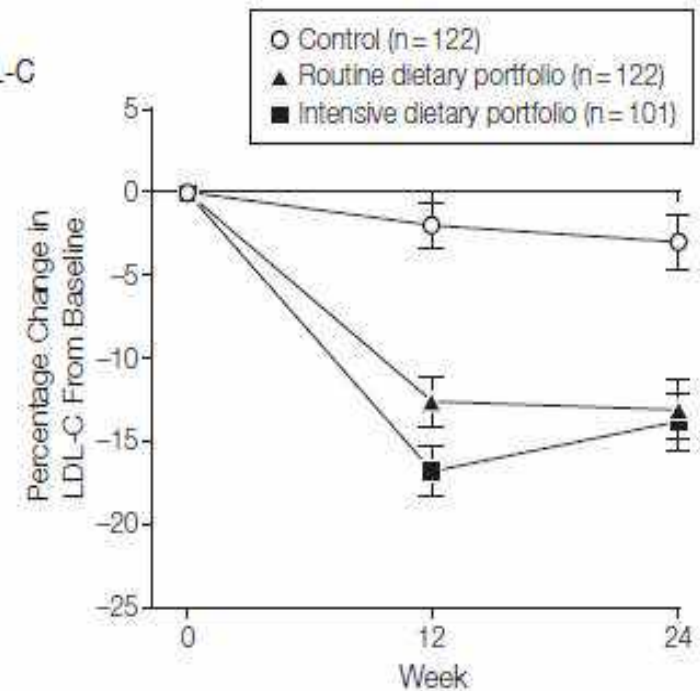
**Single centre RCT:
N=46, FU=1 month (food provided)**



LDL-C



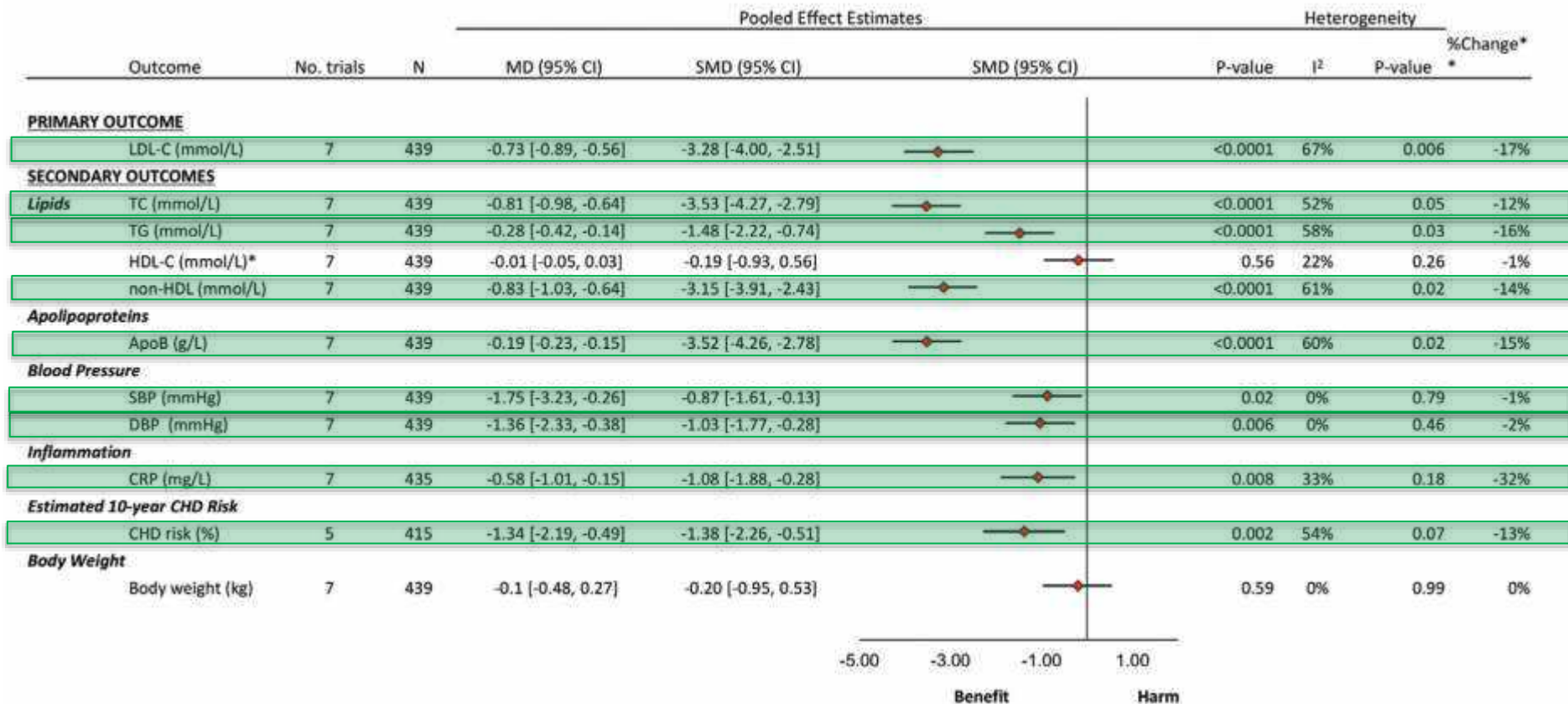
**Multicentre Canadian RCT:
N=345, FU=6 months (*ad libitum*)**



Jenkins DJ et al. JAMA 2003; 290(4):502-10

Jenkins DJ et al. JAMA 2011;306(8):831-9

Portfolio Diet and cardiometabolic risk: SRMA 7 controlled trial, N=439, FU=1-6mo



combination of a Portfolio dietary pattern and NCEP Step II diet significantly lowered the primary outcome LDL-C by intended combination

result in LDL-C reductions of **~27% (32% in efficacy and 15% in effectiveness trials)** in clinical practice

Chiavaroli et al. Prog Cardiovasc Dis 2018;61:43-55

Anti-hyperlipidemic drugs have large lipid-lowering effects

Drug Class	LDL-C (% Δ)
PCSK9-inhibitors Evolocumab Alirocumab	↓50-70%
Statins Lovastatin Pravastatin Simvastatin Fluvastatin Atorvastatin Rouvastatin	↓20-60%
Ezetimibe	↓15-22%
Resins Cholestyramine Colesevelam	↓15-30%



Li et al; Writing Group of 2017 Taiwan Lipid Guidelines for High Risk Patients. J Formos Med Assoc. 2017 Apr;116(4):217-248.
 Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. JAMA. 2001 May 16;285(19):2486-97

Portfolio dietary pattern is associated with lower lipids and decreased incidence of CVD outcomes: 3 Harvard Cohorts (NHS, N=73,924; NHS II, N=92,364; HPFS, N=43,970), FU=26-32-y (NHS, 1984-2016; NHS II, 1991-2017; HPFS, 1986-2016)

Circulation

ORIGINAL RESEARCH ARTICLE

Portfolio Diet Score and Risk of Cardiovascular Disease: Findings From 3 Prospective Cohort Studies

Andrea J. Glenn, PhD, RD, Maria Elena Ferrer, PhD, Vincent B. Malik, ScD, Cyril WC. Kwan, PhD, Andrew E. Werners, MD, DPH, Eric W. Rimm, MD, ScD, Walter C. Willett, MD, DPH, G. Scudiero, MD, ScD, Dawn A. Jenkins, MD, PhD, Paige B. Hain, MD, PhD, John L. Serrano, MD, PhD

BACKGROUND: The plant-based Portfolio dietary pattern includes restricted cholesterol lowering foods (ie, plant protein, nuts, viscous fiber, phytosterols), and plant monounsaturated fat shown to improve general cardiovascular disease (CVD) risk factors in randomized controlled trials. However, there is limited evidence on the role of long-term adherence to the diet and CVD risk. The primary objective was to evaluate the relationship between the Portfolio Diet Score (PDS) and the risk of total CVD, coronary heart disease (CHD), and stroke.

METHODS: We prospectively followed 72924 women in the Nurses' Health Study (1984-2016), 92346 women in the Nurses' Health Study II (1991-2017), and 43970 men in the Health Professionals Follow-up Study (1986-2016) without CVD or cancer at baseline. Diet was assessed using validated food frequency questionnaires at baseline and every 4 years using a PDS that positively ranks plant protein (legumes), nuts, seed oils, viscous fiber sources, phytosterols (nights), and plant monounsaturated fat sources, and negatively rates foods high in saturated fat and cholesterol.

RESULTS: During up to 32 years of follow-up, 16917 incident CVD cases, including 10666 CHD cases and 6473 strokes, were documented. After multivariate adjustment for lifestyle factors and a modified Alternate Healthy Eating Index (including overlapping components), comparing the highest with the lowest quartile, participants with a higher PDS had a lower risk of total CVD (adjusted hazard ratio [HR], 0.86 [95% CI, 0.81-0.92], $P < .0001$), CHD (adjusted HR, 0.86 [95% CI, 0.80-0.92], $P < .0001$), and stroke (adjusted HR, 0.86 [95% CI, 0.78-0.95], $P < .0001$). In addition, a 20-percentage higher PDS was associated with a lower risk of total CVD (adjusted HR, 0.92 [95% CI, 0.89-0.95]), CHD (adjusted HR, 0.92 [95% CI, 0.88-0.96]), and stroke (adjusted HR, 0.92 [95% CI, 0.87-0.97]). Results remained consistent across sensitivity and multivariable analyses, and there was no evidence of departure from linearity for CVD, CHD, or stroke in a subset of participants. A higher PDS was associated with a more favorable blood lipid and inflammatory profile in 3 large prospective cohorts.

CONCLUSIONS: The PDS was associated with a lower risk of CVD, including CHD and stroke, and a more favorable blood lipid and inflammatory profile, in 3 large prospective cohorts.

Key Words: cardiovascular disease, nuts, plant-based

Cardiovascular disease (CVD) continues to be a leading cause of death in the United States and globally.¹ Multiple lines of evidence, including randomized controlled trials (RCTs) and Mendelian randomization studies, have consistently established the causal

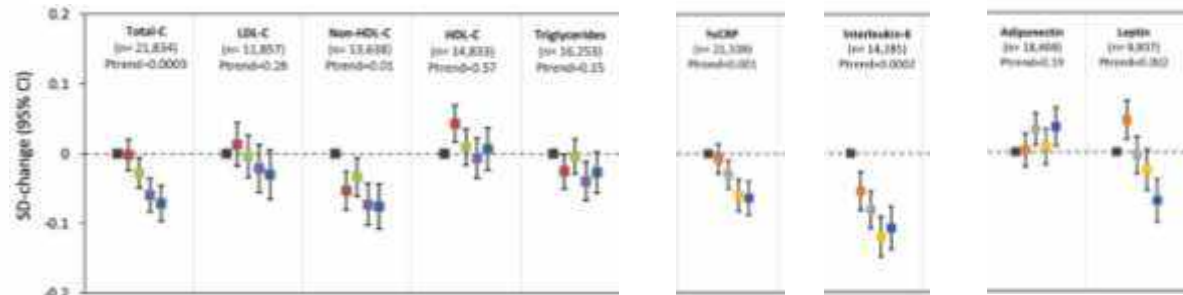
role of atherogenic blood lipids, low-density lipoprotein cholesterol (LDL-C), non-high-density lipoprotein cholesterol (HDL-C), and ApoB lipoprotein III in the pathogenesis of atherosclerotic CVD.²⁻⁴ In the prevention and management of CVD, diet is a critical modifiable



Andrea Glenn, MSc, RD



Frank Hu MD, MPH, PhD



OUTCOME	CASES	HR (95% CI)				
		Q1	Q2	Q3	Q4	Q5
Total CVD	16,917	1.0 (Ref)	0.97 (0.92, 1.01)	0.90 (0.86, 0.95)	0.90 (0.86, 0.95)	0.86 (0.81, 0.92)
CHD	10,666	1.0 (Ref)	0.96 (0.90, 1.02)	0.88 (0.83, 0.94)	0.93 (0.87, 0.99)	0.86 (0.80, 0.93)
Stroke	6,473	1.0 (Ref)	0.97 (0.90, 1.05)	0.92 (0.85, 1.00)	0.85 (0.78, 0.93)	0.86 (0.7, -0.95)

Glenn AJ et al. Circulation. 2023 Nov 28;148(22):1750-1763

How can we get physicians to prescribe diet?

St. Michael's

Inspired Care.
Inspiring Science.

30 Bond Street
Toronto, Ontario
M5B 1W8
tel: (416) 360-4000

Date 26 NOV 2015

Name MR SO AND SO

Address 15 SOMEWHERE AVE, TORONTO, ON

R PORTFOLIO DIET

1. NUTS - HANDFUL DAILY
(ANY NUTS = PEANUTS, TREE NUTS)
2. PLANT PROTEIN - 1 SERV. DAILY
(SOY PRODUCTS, BEANS, PEAS, CHICKPEAS, LENTILS)
3. VISCOS, SOLUBLE FIBRE - 20g DAILY
(OATS/BARLEY/PSYLLIUM - CERELS, BREADS, MEDICATION)
(PECTIN - EGGPLANT, OKRA, SPIRIT, BEAN, BEANS, ETC)
4. PLANT STEROLS - 1-2g DAILY

Do not refill
 Refill 0 1 2 3 4 times at 4000mg YOGURT CAPSULES day intervals

Physician's name - please print
[Signature]
Physician's signature M.D.

Form No. 64001 Rev. 12/2007

2021 INC Promotion and Dissemination Project Grant

2021 Call for Promotion and Dissemination Projects

APPLICATION FORM

Deadline: May 7, 2021, at 12:00 (noon) CEST

Please send your application as one complete PDF e-mail attachment by May 7, 2021, 12:00 (noon) CEST, to irone.gomes@truffaut.org

We need an electronic copy only. Please do not send paper copies.

Identification	
Project name:	An innovative technology-based approach to translating clinical practice guidelines for nuts: The tree nut-containing PortfolioDiet.app
Applicant name:	Toronto 3D Knowledge Synthesis and Clinical Trials foundation

General information:

- For any current project supported by INC, applicants may apply for new funding six months prior to the termination of any grant project currently funded by INC.
- All project proposals must be submitted using the Application Form, which must be written in English.
- Please read the associated Guidelines on eligibility and requirements before applying.
- For further information, please contact Ms. Irone Gomes, Statistics and Technical Projects Manager, irone.gomes@truffaut.org

Disclaimer: There shall be no expectation of grant unless and until a grant agreement is signed by both parties. All applicant's costs and charges incurred as a result of making this application shall be for the applicant's account and cannot be claimed as part of the project.

An innovative technology-based approach to translating clinical practice guidelines for nuts: The tree nut-containing PortfolioDiet.app



Page 1 of 27

Toronto 3D Knowledge Synthesis & Clinical Trials foundation

THE PORTFOLIO DIET

An evidence-based eating plan for lower cholesterol.

WHAT IS THE PORTFOLIO DIET?

The portfolio diet is a way of eating that evidence has shown can help lower cholesterol and your risk of heart disease. Instead of focusing on what you can't eat, the Portfolio diet is about what you can add to your menu!

The diet includes a "portfolio" of plant foods that you can choose from.

Research shows that medications and diet both work to lower your cholesterol. Medications can be more effective and easier, but some people don't want to take medications, cannot tolerate the side effects, or want to combine a nutritious diet with medications.

HOW DOES IT WORK?

The Portfolio diet is exactly as it sounds. It takes a few dietary patterns that have been shown to lower cholesterol and puts them together. To lower your cholesterol, you can "invest" in any one pattern, or some of them, or all of them.

NUTS, SEEDS, OLIVE OILS | **PLANT PROTEIN** | **PLANT STEROLS** | **STICKY FIBRE**

WHAT DOES THE PORTFOLIO DIET LOOK LIKE?

<p>1 NUTS & SEEDS, 45 g DAILY</p> <p>All nuts & seeds are good for your heart and cholesterol and contrary to concerns, do not contribute to weight gain. Try having nuts or seeds as a snack between meals, or by adding them to salads, cereals, or yogurt. Try not butter on your toast as another option. 45 g is about a handful of nuts. If you are allergic to peanuts, or tree nuts, try seeds.</p>		
<p>2 PLANT PROTEIN, 50 g DAILY</p> <p>Plant protein is becoming the easy option. It's a way to take action for your heart and the planet! Start by trying to get 10 g daily when you could look like 1 1/2 cup soy milk, 1/2 cup chickpeas, 1/4 cup ground soy, or 1/4 cup veggie burger. You could also try 1/2 cup edamame. Try replacing cow's milk with soy milk, ground beef with hearty ground soy or lentils, or meat with easy tofu strips in a stir-fry.</p>		
<p>3 VISCIOUS (STICKY) FIBRE, 20 g DAILY</p> <p>Cheese bread and cereals high in oats, barley, and/or psyllium to get your viscous fibre (2-4 g per slice of bread or 4-6 g per cup of dry cereal). Emphasize specific fruits (apples, oranges, berries, pomegranates) and vegetables (eggplant, okra) (1-2 g per serving). The easiest way to add viscous fibre is a supplement (psyllium, PGL, psylla). Try adding 1-2 tsp of a psyllium product to water or pure psyllium husk to smoothies, soy yogurt, or apple sauce (2-4 g per tsp).</p>		
<p>4 PLANT STEROLS, 2 g DAILY</p> <p>These occur naturally in plant foods (eg. oat, soybeans, peas, carrots etc) but to get the amount will require a supplement or fortified foods like spreads, juices, or yogurt.</p>		
<p>5 OILS (MUFAS), 45 g DAILY</p> <p>Try heart-healthy oils rich in monounsaturated fatty acids (MUFAs). Extra-virgin olive oil should be the first choice. Other choices include canola, soybean, pine, carotid oil) but to get the amount will require a supplement or fortified foods like spreads, juices, or yogurt.</p>		
<p>TOTAL: -30%</p>		

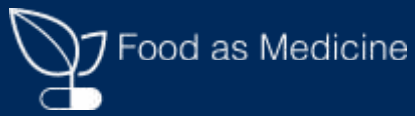
IT'S NOT ABOUT ONE BIG CHANGE. IT'S NOT ALL OR NOTHING. JUST START BY INTRODUCING ONE COMPONENT TO YOUR DIET AND BUILD FROM THERE.

ST. MICHAEL'S HOSPITAL, UNIVERSITY OF TORONTO



St. Michael's
Inspired Care.
Inspiring Science.

http://www.stmichaelshospital.com/media/hospital_news/2018/0706.php
<http://childnutrition.utoronto.ca/news/quick-visual-portfolio-diet-and-cholesterol>
https://ccs.ca/wp-content/uploads/2023/11/Portfolio-Infographic-EN_7Nov2023.pdf



CCS nut-containing Portfolio Diet Infographic: Physician education tools

The screenshot shows the CCS Companion Resources website. The browser address bar displays ccs.ca/companion-resources/. The page features the Canadian Cardiovascular Society logo and a navigation menu with links for About, Membership, Guidelines, Education, Advisory, Journals, Trainees/Early Career, Affiliates, and CCS Academy. A search bar and a 'MYCCS.ca' button are also visible. The main content area is titled 'Companion Resources' and includes a description of these resources. A section titled 'Infographics and Summary Cards' displays a grid of eight infographics. The 'Portfolio Diet' infographic is highlighted with a red border. A right-hand sidebar lists various guideline-related resources.

Companion Resources

Companion resources provide additional information that is complementary to selected CCS guidelines and statements. These resources include useful algorithms, links to supplementary material and offer a practical approach to patient care.

Infographics and Summary Cards

Our guideline-related infographics are a quick and easy way to access material from our recently published statements. Available as printable PDFs.

Guidelines

- Guidelines and Tools (LWT)
- About Guidelines
- Guideline Development
- Guidelines and CPU Library
- Guideline Resources
 - Subspecialty Side Panels
 - Companion Resources
 - Guidelines and CPU Library
 - Quick Guides
 - Podcasts and Ebooks
 - Guidelines TV
 - On-Demand Guideline Workshops

Infographics and Summary Cards

- MRI Safety in Patients With CIEDs
- Contract Agent MRI Decision Tool
- Portfolio Diet**
- Cardiorenal Risk Reduction
- Heart Failure with Preserved Ejection Fraction
- Heart Failure with Reduced Ejection Fraction
- Myocardial Infarction
- Stroke

<https://ccs.ca/companion-resources/>

- THE - PORTFOLIO DIET

An evidence-based eating plan for lower cholesterol

A GUIDE FOR HEALTH CARE PROVIDERS

WHAT IS THE PORTFOLIO DIET?

A plant-based portfolio of cholesterol-lowering foods

The Portfolio Diet consists of five pillars, each of which have a health claim* for cholesterol or coronary heart disease risk reduction and have an additive effect when combined^{1,2}

Pillar	Amount	Example Foods	Health Claim
1	NUTS & SEEDS, 45 g DAILY	e.g., almonds, walnuts, nut butters, flax seeds	-5-10%
2	PLANT PROTEIN, 50 g DAILY	e.g., soy beverage, tofu, meat alternatives, chickpeas, beans	-5-10%
3	VISCOUS FIBRE, 20 g DAILY	e.g., oatmeal, psyllium, apples, oranges, berries	-5-10%
4	PLANT STEROLS, 2 g DAILY	e.g., plant sterols supplement (powder, liquid, capsule)	-5-10%
5	HEART HEALTHY OILS (MUFAs), 45 g DAILY	e.g., extra virgin olive oil, canola oil, avocado	-5-10% ¹

TOTAL: -30%

*Health claim: LDL-C levels lower
1. Health Canada's Health Claims Approval for the Portfolio Diet
2019, 2020, 2021, 2022, 2023, 2024
2. American Heart Association, 2020, 2021, 2022, 2023, 2024

WHAT IS THE EVIDENCE BEHIND THE PORTFOLIO DIET?

A meaningful reduction in LDL-C and other cardiometabolic risk factors

1) Drug-like LDL-C Lowering Efficacy¹

A "head-to-head" trial with 20 mg atorvastatin showed similar 1-30% LDL-C making the Portfolio Diet an excellent option for patients hesitant to start pharmacotherapy.

2) Clinically Meaningful Reductions Even With Partial Adoption²

A multi-centre trial demonstrated ~50% adherence resulted in a clinically significant 1-15% LDL-C ↓ LDL-C directly relates to adherence. Even partial adoption of the Portfolio Diet alone or as an add-on therapy to statins can ↓ LDL-C making it realistic and feasible for patients.

3) Cardiovascular Benefits Beyond LDL-C³

Meta-analysis shows the Portfolio Diet ↓ cardiovascular risk factors beyond LDL-C.

CVD Risk Factors* 7 trial comparisons (n=439)

- LDL-C ↓27%
- Non-HDL-C ↓24%
- ApoB ↓22%
- TO ↓16%
- SBP ↓4.75 mmHg
- CRP ↓26%
- Framingham Risk ↓19%

*Numbers estimate the overall effect of the Portfolio Diet with its intended combination with a low saturated fat/cholesterol diet in patients with high cholesterol

WHAT RESOURCES CAN I USE TO SUPPORT MY PATIENTS?

1 PRINTABLE PATIENT INFOGRAPHIC*

Available in

English

French

*Reviewed and updated by 2023

2 PORTFOLIODIET.APP

An education and engagement tool

<https://portfoliodiet.app/>

Download on the App Store. Get it on Google Play.

DIET & HEALTH TRACKING

CALCULATOR

TOP SHEETS

TAILORED RESOURCES

LEARN MORE

VIDEOS

PERSONALIZED GOALS

COMMUNITY SUPPORT

RECIPIES

Behaviour Change Map*

- Knowledge
- Skills
- Social/professional reinforcement
- Beliefs about capabilities
- Optimism
- Beliefs about consequences
- Reinforcement
- Norms
- Goals
- Metacognitive/decision processes
- Environmental context/resources
- Social influences
- Emotion
- Behavioral regulation

*Reviewed and updated by 2023

HOW DOES THE PORTFOLIODIET.APP SUPPORT THE PATIENT-PROVIDER RELATIONSHIP?

Patient

- Track their adherence
- Learn about the diet
- Explore recipes
- Have collaborative discussions with their healthcare provider

The Portfolio Diet App helps:

Improve patient-provider relationships

Provider

- Find resources for patients
- Learn about the evidence
- Find supporting guidelines
- Provide a framework for behaviour change counselling with little added time

The Portfolio Diet is recommended by:



Nut-containing [PortfolioDiet.app](https://www.portfoliodiet.app): Scoring/tracking

Nuts & Seeds  **5 points**

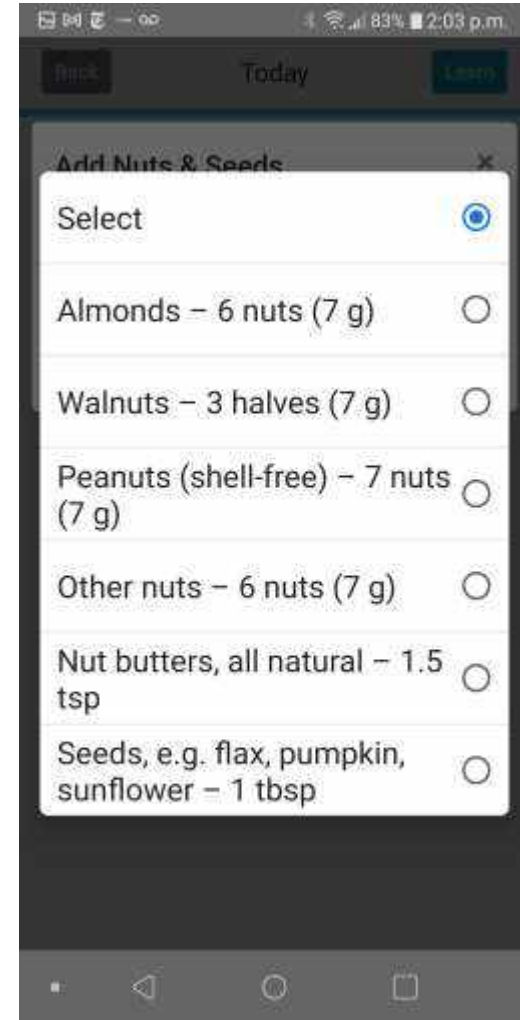
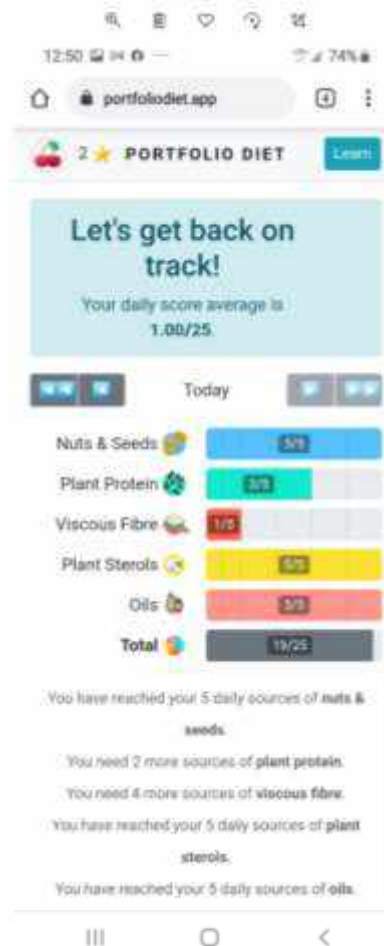
Plant Protein  **5 points**

Viscous Fibre  **5 points**

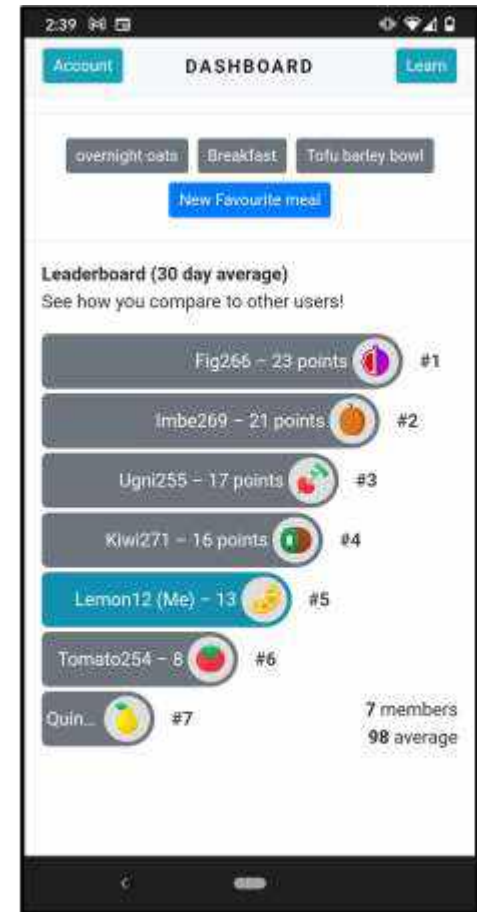
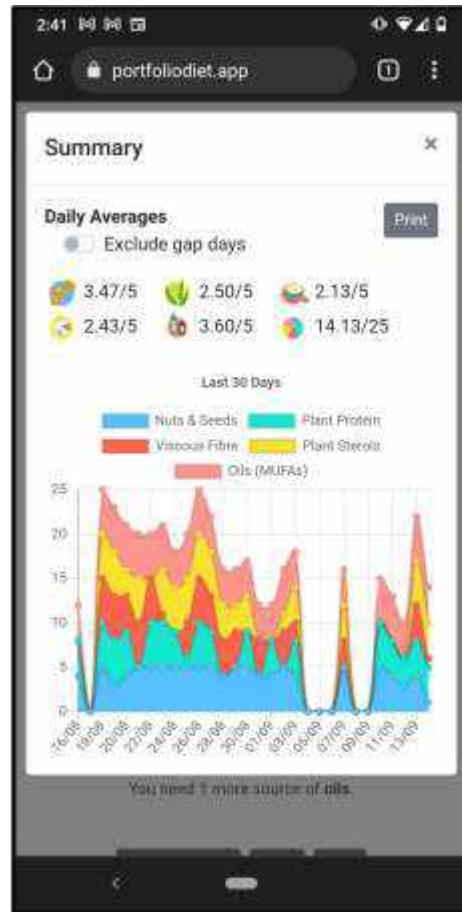
Plant Sterols  **5 points**

Oils  **5 points**

Total  **25 points**

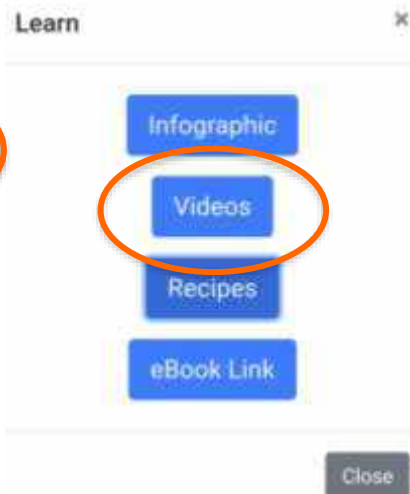
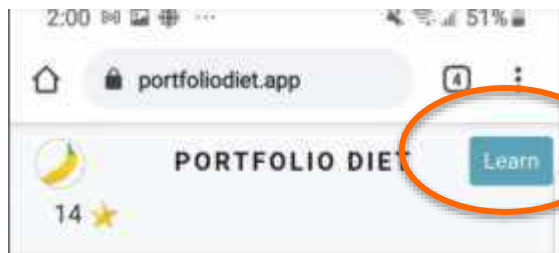


Nut-containing PortfolioDiet.app: Dashboard/Gamification



Dashboard summary statistics on adherence (A, total score; B, individual component score; C, trend; D, Leaderboard)

Nut-containing PortfolioDiet.app: Recipes, Tip Sheets, Videos



All about Nuts and Seeds

Nuts and seeds are rich sources of **heart-healthy fats**, protein, vitamins & minerals. They can help **lower LDL-cholesterol**.

Adding nuts to your diet can be quick and simple!

- Take them to go as a snack
- Top your salad or oatmeal with nuts
- Pair 2 tsp of any nut butter with fruits, vegetables or on oat bran bread as a snack

Choosing types of nuts

- Choose a variety of nuts and seeds to benefit from the range of nutrients they provide
- Choose "all natural" or "just the nuts" versions of nut butters
- Choose plain, unsalted nuts
- Choose coated or flavoured nuts less often
- If choosing Brazil nuts, limit to 2 - 4 nuts/day among a mix of other nuts as they are very high in selenium

Aim for 5 servings of nuts each day (45g/d = 1/3 cup)

	9 almonds, peanuts & other small nuts (9 g)
	5 walnut halves (9 g)
	2 tsp nut butter
	1 Tbsp seeds (flax, sunflower, chia, pumpkin, hemp)

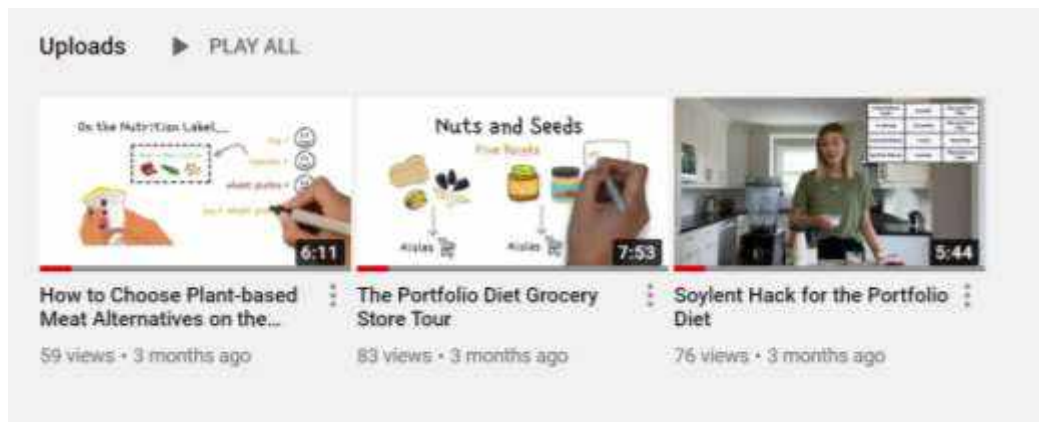
Limit to 5 Portfolio servings to make room for other Portfolio foods in your diet

Tailoring to your tastes

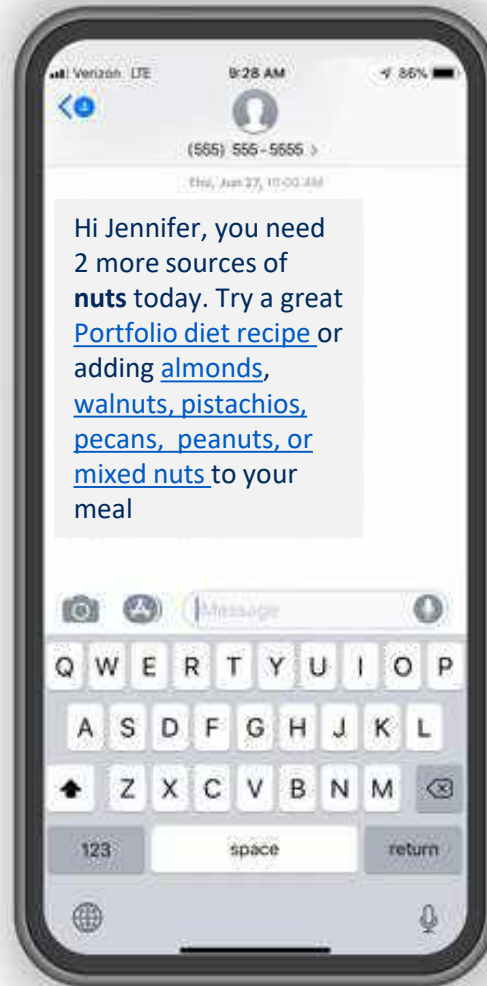
- Flavour your own nuts with cumin, garlic or chili powder
- Try different nuts- buy small amounts at a bulk food store

For ideas on including nuts and seeds in your diet, check out our recipe ideas under the recipe tab.

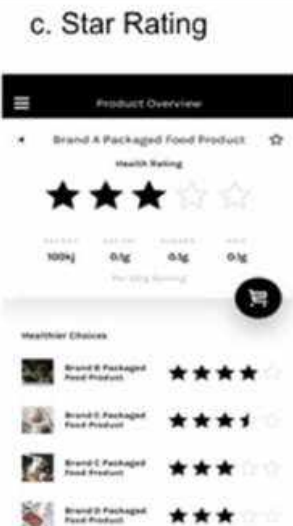
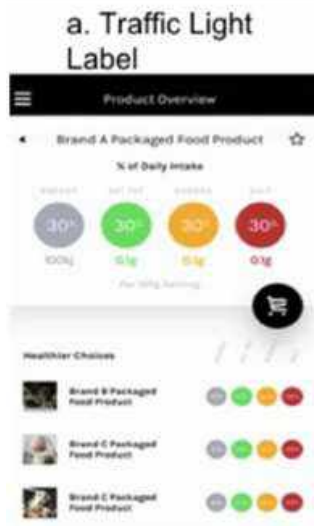
See the [Peanut or Tree Nut Allergy Tip Sheet](#) for more information if you are allergic to nuts and/or tree nuts.



Nut-containing [PortfolioDiet.app](#): Nudges/coaching!



Nut-containing PortfolioDiet.app: Collaboration with FoodFlip for AI driven dietary assessment – coming soon!

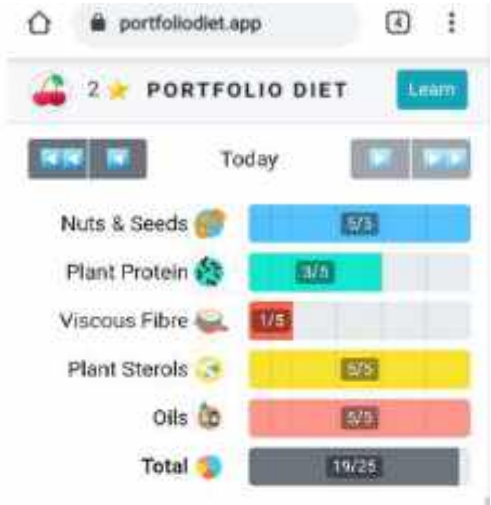


d. No FOP (Nutrition Facts table)- control

Nutrition Facts
Valeur nutritive

Per 1/2 cup (50 g) / pour 1/2 tasse (50 g)

Amount Teneur	% Daily Value % valeur quotidienne
Calories / Calories 170	
Fat / Lipides 0.1 g	1 %
Saturated / saturés 0,1 g + Trans / trans 0 g	1 %
Cholesterol / Cholestérol 0 mg	
Sodium / Sodium 5 mg	1 %
Carbohydrate / Glucides 41 g	14 %
Fibre / Fibres 1 g	4 %
Sugars / Sucres 33 g	
Protein / Protéines 2 g	
Vitamin A / Vitamine A	10 %
Vitamin C / Vitamine C	0 %
Calcium / Calcium	2 %
Iron / Fer	10 %



Nut-containing PortfolioDiet.app: Collaboration with *RxFood* for AI driven dietary assessment – coming soon!



Nut-containing [PortfolioDiet.app](#): Environmental impact scoring – coming soon!

Nuts & Seeds  5 points

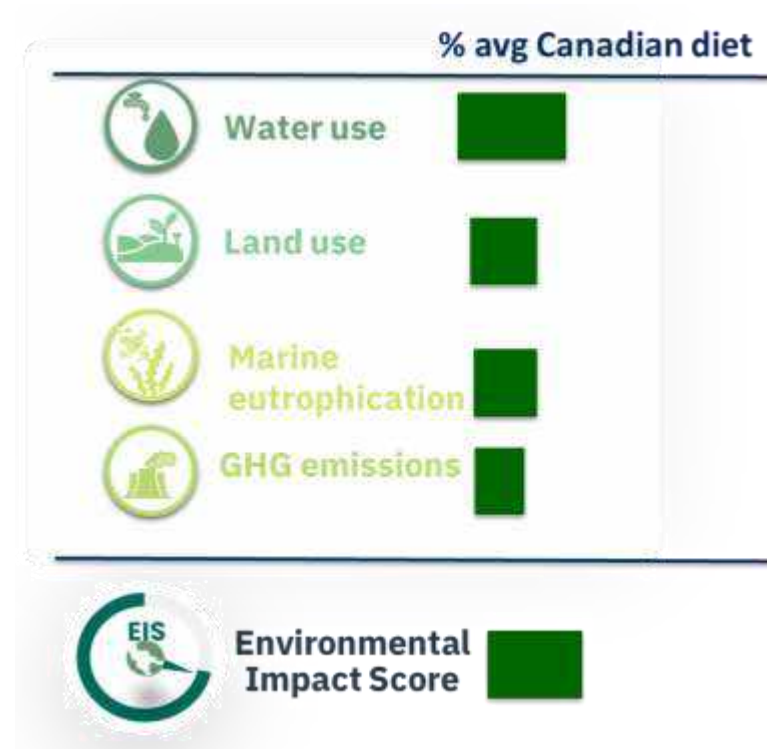
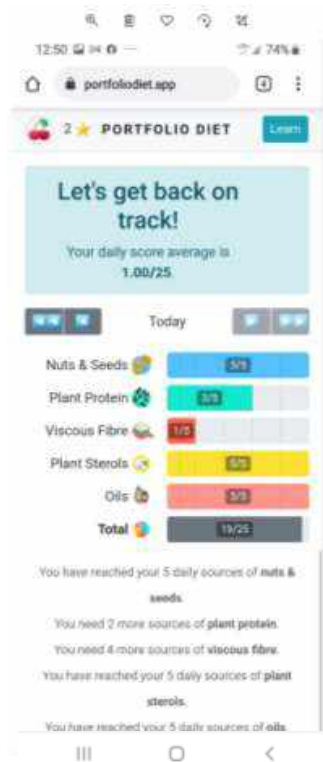
Plant Protein  5 points

Viscous Fibre  5 points

Plant Sterols  5 points

Oils  5 points

Total  25 points



What does it mean for patients?

Case of a 74-year old man with Obesity, mixed dyslipidemia, T2DM, HTN, & MetS

ID: 74 year old, male, Caucasian

RFR: Hypolipidemia w/ inability to meet targets

PMH: T2DM, HTN, Colon CA (remission), hypothyroidism

Meds: Atorva 80mg¹, Eze 10mg¹,
Amlodipine 5mg¹, Synthroid 0.025mg¹

HPI: Dx 2010 on routine work-up
No 2^o causes identified
No CHD, stroke, PVD
-tve stress test, -tve 24h-holter

CV risk factors: Visceral obesity
Ex-15 pack year smoker
HTN
T2DM
No FHx of premature CVD

Diet & Lifestyle: High red meat
High refined starch, low fibre
Low fruit & veg

O/E: No stigmata

BMI 29.8, WC >102cm

BP 154/91 mmHg

Thyroid, CVS, resp, GI, neuro - unremarkable

Labs:	Nov 2014 ("off")		Jan 2015 ("on")
Total-C	8.81	→	5.45
TGs	2.56	→	2.29
HDL-C	1.40	→	1.23
LDL-C	6.25	→	3.18
Non-HDL-C	7.41	→	4.22
Apo B	1.79		

HbA1c: 6.1%

Normal thyroid, liver, renal tests

FRS: >30%

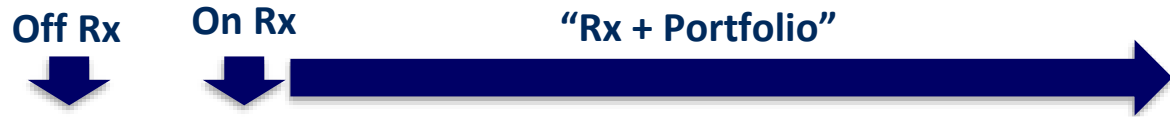
A/P: Obesity, mixed dyslipidemia with T2DM, HTN, and MetS
4/5 criteria
(↑ WC, ↑ TG, ↑ BP, ↑ FPG), FRS>30%, on **max dual therapy**
Lipids not at target of LDL-C/non-HDL-C <2.5/3.2mmol/L
or ≥50% ↓
BP not at target (SBP <130/80 mmHg)
GC at target (<7%)
? approach

Case of a 74-year old man with obesity, mixed dyslipidemia, T2DM, HTN, & MetS

4 years of follow-up on *Portfolio diet* + exercise & dual max therapy



www.PortfolioDiet.app



Lipids	Baseline	1-y	1.5-y	2-y	2.5-y	3-y	3-5-y	4-y	Delta %
Total-C	8.81	5.45	3.74	3.24	3.15	3.03	3.52	3.85	-57%
TAGs	2.56	2.29	1.11	1.36	0.97	0.61	0.94	1.19	-54%*
HDL-C	1.40	1.23	1.36	1.22	1.26	1.08	1.38	1.54	+10%
LDL-C	6.25	3.18	1.88	1.40	1.45	1.67	1.71	1.77	-72%**
Non-HDL-C	7.41	4.22	2.38	2.02	1.89	1.95	2.14	2.31	-69%***

* -48%
 ** -44%
 *** -45%

additional lowering beyond dual max therapy "at target"

Weight: -4.1kg (from 96.3kg to 92.2kg) "at target"
 BP: -25/15 mmHg (from 154/91 mmHg to 129/76 mmHg) "at target"
 HbA1c: -0.5% (from 6.1% to 5.6%) "normal"

What does it mean for research?

Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016

Research

JAMA Internal Medicine | Original Investigation

Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016

Thomas J Moore, MD, Hanfeng Zhong, BA, David A. Asch, MD, PhD, S. Gopinathan, MD, MSc

IMPORTANCE: A crucial question in health care is the extent of scientific evidence that should be generated to establish that a new therapeutic agent has benefits that outweigh its risks. Estimating the costs of these studies of efficacy provides an important perspective.

OBJECTIVE: Determine the estimated costs of pivotal clinical trials for novel therapeutic agents approved by the US Food and Drug Administration (FDA) from 2015 to 2016.

DESIGN: Retrospective analysis of FDA-approved pivotal clinical trials for novel therapeutic agents from 2015 to 2016.

SETTING: Pivotal clinical trials for novel therapeutic agents approved by the FDA from 2015 to 2016.

MEASUREMENTS AND MAIN RESULTS: The mean (95% CI) cost of pivotal clinical trials for novel therapeutic agents approved by the FDA from 2015 to 2016 was \$52.7 million (range, \$1.4-\$200.9 million). The mean (95% CI) cost per patient was \$6,100 (range, \$1,400-\$200,900). The mean (95% CI) cost per patient-year was \$6,100 (range, \$1,400-\$200,900).

CONCLUSIONS: The estimated costs of pivotal clinical trials for novel therapeutic agents approved by the FDA from 2015 to 2016 were \$52.7 million (range, \$1.4-\$200.9 million). The mean (95% CI) cost per patient was \$6,100 (range, \$1,400-\$200,900). The mean (95% CI) cost per patient-year was \$6,100 (range, \$1,400-\$200,900).

JAMA Intern Med. 2018;178(11):1451-1457. doi:10.1001/jamaintern.2018.2000

Published November 24, 2018

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Clinical outcome trials with n>1,000, FU>6 mo = \$52-77 million!

Table 2. Estimated Costs of Pivotal Clinical Trials for Therapeutic Agents Approved From 2015 to 2016

Trial Characteristic	Agents, No. ^a	Trials, No. (%) (n = 138) ^b	Mean (95% CI), US\$ in millions ^c
Therapeutic area			
Cardiovascular	5	5 (3.6)	157.2 (112.5-200.9)
Central nervous system disorders	8	21 (15.2)	25.7 (18.4-33.1)



Look AHEAD trial (n=5,145, FU=9.6y) = \$300 million
 $\$300 \text{ million} / 5,145 / 9.6\text{y} = \$6,100/\text{participant}/\text{year}$

Patient enrollment, No.

1-100	6	8 (5.8)	5.9 (4.8-7.0)
101-250	25	32 (23.2)	16.2 (12.2-20.3)
251-500	14	33 (23.9)	18.6 (14.1-23.2)
501-1000	27	44 (31.9)	33.6 (23.6-43.6)
>1000	16	21 (15.2)	77.2 (55.8-98.6)

Treatment duration, wk

≤25	39	89 (64.5)	19.7 (14.6-24.7)
>26	32	49 (35.5)	51.7 (36.9-66.4)

Moore TJ, et al. JAMA Intern Med. 2018 Nov 1;178(11):1451-1457



Coronary Heart Effectiveness Assessment of the Portfolio diet in primary Care (CHEAP) trial

PI: Dr. JL Sievenpiper, MD, PhD, FRCPC

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Dr. DJA Jenkins, OC, MD, PhD, DSc, FRCP, FRCPC, FRSC

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Dr. G. Booth, MD, FRCPC

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CHEAP trial power and design:

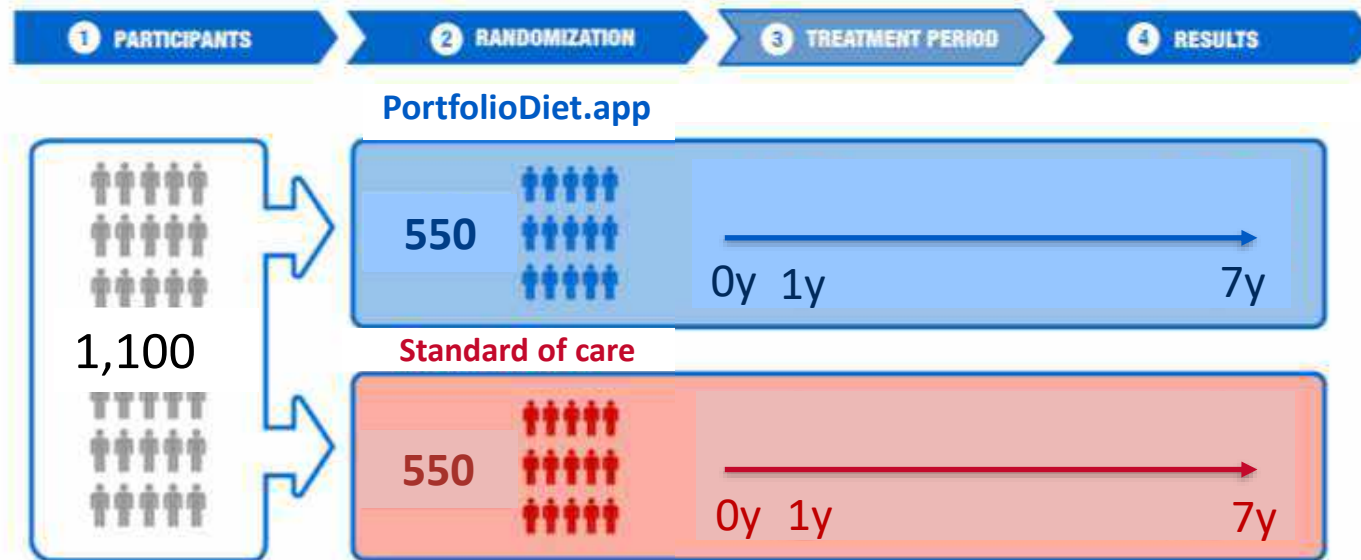
Parallel, 2 group RCT of the effect of standard of care + Portfolio diet ([PortfolioDiet.app](#)) versus standard of care alone on achieving lipid targets at 1y and reducing major CV events at 7y in 1,100 high risk mixed 2° and 1° prevention participants on background statin therapy in primary care

Power

Primary outcomes with stepwise gatekeeper procedure:

1. Proportion achieving $\geq 8\%$ reduction in LDL-C or non-HDL-C at 1y
2. 5-point MACE (MI, revascularization, CV hospitalization, CV mortality, stroke) at 7y

Design



CHEAP trial Intervention

Portfolio diet program

Portfolio diet program

1.



PortfolioDiet.app

www.PortfolioDiet.app

2.



16 session “DPP-like” virtual program

3.



Provision of food to drive adherence

Conclusions

1. Although diet remains the **cornerstone of therapy** for the prevention and management of NCDs, **most physicians** cite a **lack of education/tools/time to counsel on nutrition** with supporting **dietitian services** often **inadequate**.
2. **Dietary guidelines** have moved away from a focus on **nutrients** (e.g. “low fat”) to a focus on **foods and dietary patterns** with the recognition there is **no one-size-fits-all**.
3. Various **nut-containing dietary patterns** that combine the advantages of different foods (e.g. **Med diet, Nordic, Vegetarian, DASH, and Portfolio Diets**) result in **clinically meaningful improvements** in risk factors and are associated with **reductions in cardiometabolic diseases**, comparable to and beyond that seen with **medications alone**.
4. To **implement nut-containing dietary patterns** in practice, **innovative digital tools** (infographics and mobile health apps with tracking, gamification, nudging/health coaching, educational resources, AI) are being developed and tested with the potential to revolutionize healthcare delivery and improve outcomes
5. The INC-funded **PortfolioDiet.app** as a **digital translation of clinical practice guidelines** for the **Portfolio diet** will provide a **tool** for greater **physician and patient engagement, personalization**, and mounting of ambitious **clinical outcome trials** at a **low cost**

**Please keep supporting
research!**

Acknowledgements



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