An innovative digital approach to translating clinical practice guidelines of nutrition therapy in primary care: Coronary Heart Effectiveness Assessment of the Portfolio diet in primary Care (CHEAP) trial

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Updated May 19, 2022

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What is the *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

MUFA oils

Extra virgin olive oil, canola oil, soybean oil

3 Vegetable Protein

45g/day
Soy products, pulses

4 Plant Sterols

2g/day
Plant sterol margarine/oil/ supplements

Health Canada / Santé Canada

FDA U.S. FOOD & DRUG ADMINISTRATION

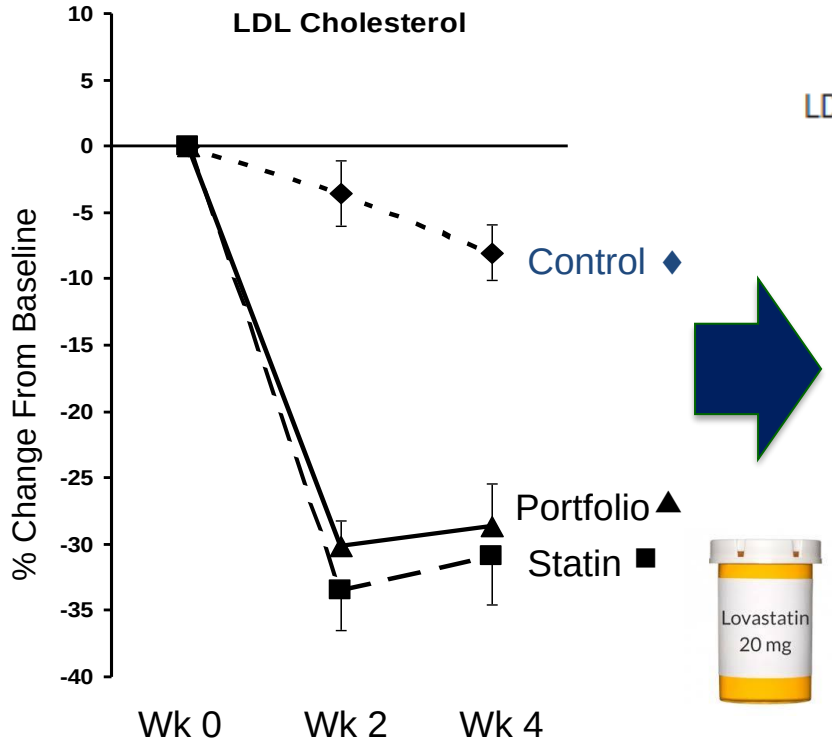
efsa European Food Safety Authority

Portfolio Diet:
From efficacy to effectiveness

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

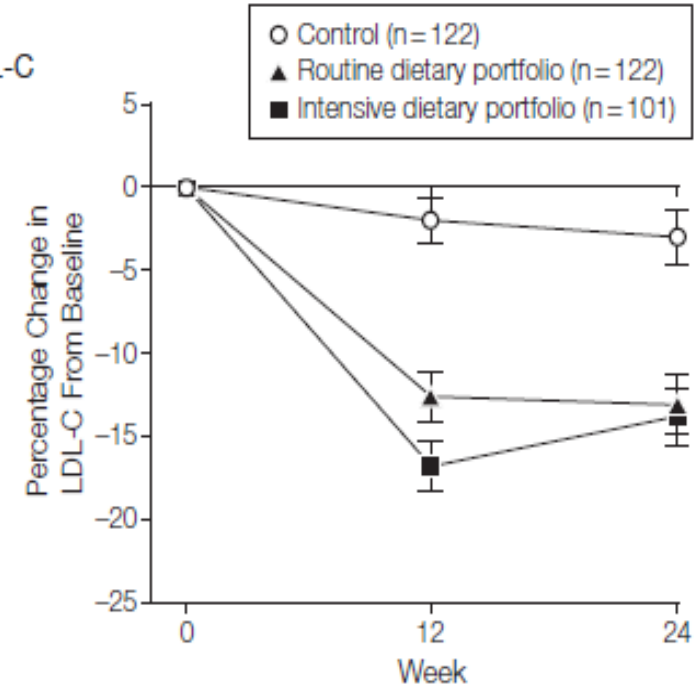
Cyril Kendall, PhD

Single centre trial: N=46, FU=1 mo



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

Multicentre Canadian trial: N=345, FU=6 mo



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

Portfolio Diet and Cardiometabolic risk:

SRMA 7 controlled trial, N=439, FU=1-6mo

Contents lists available at ScienceDirect

Progress in Cardiovascular Diseases

journal homepage: www.onlinepcd.com

Portfolio Dietary Pattern and Cardiovascular Disease: A Systematic Review and Meta-analysis of Controlled Trials☆,☆☆

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Systematic review and meta-analysis

ABSTRACT

Background: The evidence for the Portfolio dietary pattern, a plant-based dietary pattern that combines recognized cholesterol-lowering foods (nuts, plant protein, viscous fibre, plant sterols), has not been summarized.
Objective: To update the European Association for the Study of Diabetes clinical practice guidelines for nutrition therapy, we conducted a systematic review and meta-analysis of controlled trials using GRADE of the effect of the Portfolio dietary pattern on the primary therapeutic lipid target for cardiovascular disease prevention, low-density lipoprotein cholesterol (LDL-C), and other established cardiometabolic risk factors.
Methods: We searched MEDLINE, EMBASE, and The Cochrane Library through April 19, 2018. We included controlled trials ≥ 3-weeks assessing the effect of the Portfolio dietary pattern on cardiometabolic risk factors compared with an energy-matched control diet free of Portfolio dietary pattern components. Two independent reviewers extracted data and assessed risk of bias. The primary outcome was LDL-C. Data were pooled using the generic inverse-variance method and expressed as mean differences (MDs) with 95% confidence intervals (CIs). Heterogeneity was assessed (Cochran Q statistic) and quantified (I^2-statistic). GRADE assessed the certainty of the evidence.
Results: Eligibility criteria were met by 7 trial comparisons in 439 participants with hyperlipidemia, in which the Portfolio dietary pattern was given on a background of a National Cholesterol Education Program (NCEP) Step II diet. The combination of a portfolio dietary pattern and NCEP Step II diet significantly reduced the primary outcome LDL-C by −17% (MD, −0.73 mmol/L, [95% CI, −0.89 to −0.56 mmol/L]) as well as non-high-density lipoprotein cholesterol, apolipoprotein B, total cholesterol, triglycerides, systolic and diastolic blood pressure, C-reactive protein, and estimated 10-year coronary heart disease (CHD) risk, compared with an NCEP Step 2 diet alone ($p < 0.05$). There was no effect on high-density lipoprotein cholesterol or body weight. The certainty of the evidence was high for LDL-cholesterol and most lipid outcomes and moderate for all others outcomes.

Abbreviations and Acronyms: ApoB, Apolipoprotein B; BMI, Body mass index; CRP, C-reactive protein; CCS, Canadian Cardiovascular Society; CV, Cardiovascular; CVD, Cardiovascular disease; CTT Collaboration, Cholesterol Treatment Trialists'; CIs, Confidence intervals; CHD, Coronary heart disease; DNSG, Diabetes and Nutrition Study Group; DBP, Diastolic blood pressure; DASH, Dietary Approaches to Stop Hypertension; EAS, European Atherosclerosis Society; EFSA, European Food Safety Authority; ESC, European Society of Cardiology; EASD, European Association for the Study of Diabetes; FDA, Food and Drug Administration; GRADE, Grading of Recommendations Assessment, Development, and Evaluation; non-HDL-C, High-density lipoprotein cholesterol; LDL-C, Low-density lipoprotein; MID, Minimally important difference; MUFAs, Monounsaturated fatty acids; NCEP, National Cholesterol Education Program; non-HDL-C, Non-high density lipoprotein cholesterol; PREDIMED, Prevención con Dieta Mediterránea; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RevMan, Review Manager; SBP, Systolic blood pressure; TC, Total cholesterol; TG, Triglycerides.

☆ Statement of Conflict of Interest: see page 51.

☆☆ Protocol registration: Clinicaltrials.gov identifier, NCT03534414.

* Address reprint requests to Dr. Cyril WC Kendall, PhD and Dr. John L Sievenpiper, MD, PhD, FRCPC, Department of Nutritional Sciences, Faculty of Medicine, University of Toronto, The Fitzgerald Building, 150 College Street East, Room 432, Toronto, ON M5S 3E2, Canada.
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https://doi.org/10.1016/j.pcad.2018.05.004
0033-0620/

Laura Chiavaroli, PhD

Diabetes and Nutrition Study Group

EASD European Association for the Study of Diabetes

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

CHEAP (Coronary Heart Effectiveness Assessment of the Portfolio Diet in Primary Care)

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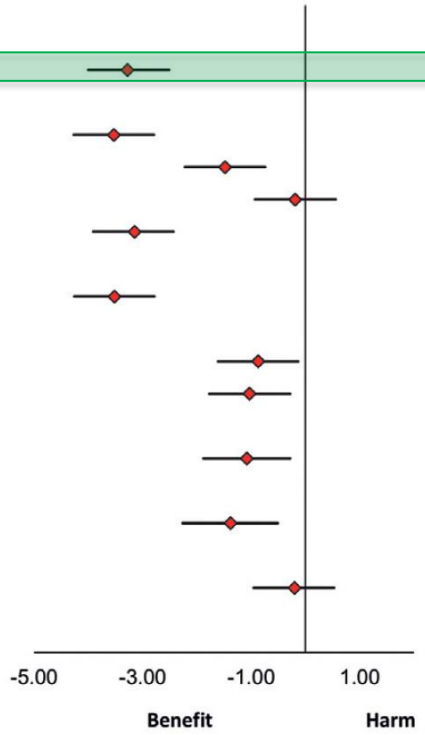
Portfolio Diet and cardiometabolic risk:
SRMA 7 controlled trial, N=439, FU=1-6mo

	Outcome	No. trials	N	Pooled Effect Estimates MD (95% CI)	Pooled Effect Estimates SMD (95% CI)	Heterogeneity P-value	Heterogeneity I^2	Heterogeneity P-value	%Change**
PRIMARY OUTCOME									
	LDL-C (mmol/L)	7	439	-0.73 [-0.89, -0.56]	-3.28 [-4.00, -2.51]	<0.0001	67%	0.006	-17%
SECONDARY OUTCOMES									
Lipids	TC (mmol/L)	7	439	-0.81 [-0.98, -0.64]	-3.53 [-4.27, -2.79]	<0.0001	52%	0.05	-12%
	TG (mmol/L)	7	439	-0.28 [-0.42, -0.14]	-1.48 [-2.22, -0.74]	<0.0001	58%	0.03	-16%
	HDL-C (mmol/L)*	7	439	-0.01 [-0.05, 0.03]	-0.19 [-0.93, 0.56]	0.56	22%	0.26	-1%
	non-HDL (mmol/L)	7	439	-0.83 [-1.03, -0.64]	-3.15 [-3.91, -2.43]	<0.0001	61%	0.02	-14%
Apolipoproteins									
	ApoB (g/L)	7	439	-0.19 [-0.23, -0.15]	-3.52 [-4.26, -2.78]	<0.0001	60%	0.02	-15%
Blood Pressure									
	SBP (mmHg)	7	439	-1.75 [-3.23, -0.26]	-0.87 [-1.61, -0.13]	0.02	0%	0.79	-1%
	DBP (mmHg)	7	439	-1.36 [-2.33, -0.38]	-1.03 [-1.77, -0.28]	0.006	0%	0.46	-2%
Inflammation									
	CRP (mg/L)	7	435	-0.58 [-1.01, -0.15]	-1.08 [-1.88, -0.28]	0.008	33%	0.18	-32%
Estimated 10-year CHD Risk									
	CHD risk (%)	5	415	-1.34 [-2.19, -0.49]	-1.38 [-2.26, -0.51]	0.002	54%	0.07	-13%
Body Weight									
	Body weight (kg)	7	439	-0.1 [-0.48, 0.27]	-0.20 [-0.95, 0.53]	0.59	0%	0.99	0%



*"The **combination** of a **Portfolio dietary pattern and NCEP Step II diet** significantly lowered the primary outcome LDL-C by 17% (21% in efficacy and 12% in effectiveness trials)… suggesting that the benefit of the **intended combination**… would 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

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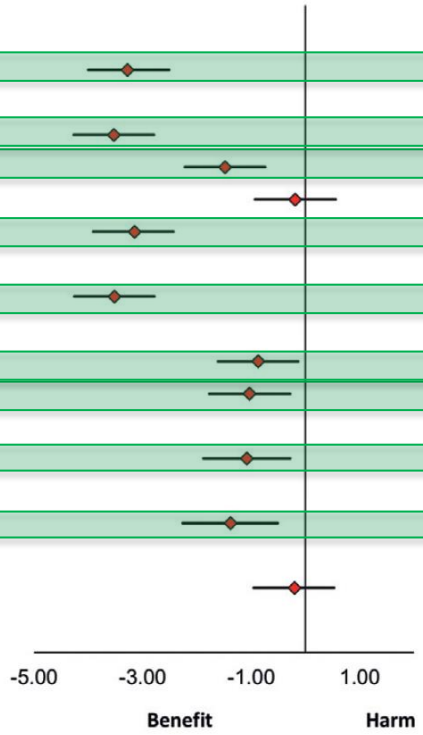

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Chiavaroli et al. Prog Cardiovasc Dis 2018;61:43-55

Portfolio diet Lipid-lowering is at the lower limit of efficacy of anti-hyperlipidemic drugs with evidence of cardiovascular risk reduction

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

By analogy with established antihyperlipidemic therapies, the Portfolio diet is associated with decreased CVD events: Women's Health Initiative (WHI), n=123,330 (postmenopausal women), mean FU=15.3y

Journal of the American Heart Association

ORIGINAL RESEARCH

Relationship Between a Plant-Based Dietary Portfolio and Risk of Cardiovascular Disease: Findings From the Women's Health Initiative Prospective Cohort Study

Andrea J. Glenn, MSc, RD;* Kenneth Lo, PhD;* David J. A. Jenkins, MD, PhD; Beatrice A. Boucher, MHSc; Anthony J. Hanley, PhD; Cyril W. C. Kendall, PhD; JoAnn E. Manson, MD, DrPH; Mara Z. Vitolins, DrPH, RDN; Linda G. Snetselaar, PhD; Simin Liu, MD, PhD; John L. Sievenpiper, MD, PhD

BACKGROUND: The plant-based Dietary Portfolio combines established cholesterol-lowering foods (plant protein, nuts, viscous fiber, and phytosterols), plus monounsaturated fat, and has been shown to improve low-density lipoprotein cholesterol and other cardiovascular disease (CVD) risk factors. No studies have evaluated the relation of the Dietary Portfolio with incident CVD events.

METHODS AND RESULTS: We followed 123 330 postmenopausal women initially free of CVD in the Women's Health Initiative from 1993 through 2017. We used Cox proportional-hazard models to estimate adjusted hazard ratios (HRs) and 95% CI of the association of adherence to a Portfolio Diet score with CVD outcomes. Primary outcomes were total CVD, coronary heart disease, and stroke. Secondary outcomes were heart failure and atrial fibrillation. Over a mean follow-up of 15.3 years, 13 365 total CVD, 5640 coronary heart disease, 4440 strokes, 1907 heart failure, and 929 atrial fibrillation events occurred. After multiple adjustments, adherence to the Portfolio Diet score was associated with lower risk of total CVD (HR, 0.89; 95% CI, 0.83–0.94), coronary heart disease (HR, 0.86; 95% CI, 0.78–0.95), and heart failure (HR, 0.83; 95% CI, 0.71–0.99), comparing the highest to lowest quartile of adherence. There was no association with stroke (HR, 0.97; 95% CI, 0.87–1.08) or atrial fibrillation (HR, 1.10; 95% CI, 0.87–1.38). These results remained statistically significant after several sensitivity analyses.

CONCLUSIONS: In this prospective cohort of postmenopausal women in the United States, higher adherence to the Portfolio Diet was associated with a reduction in incident cardiovascular and coronary events, as well as heart failure. These findings warrant further investigation in other populations.

Key Words: cardiovascular disease ■ dietary patterns ■ dietary portfolio ■ plant-based ■ prospective cohort study

The Dietary Portfolio, or Portfolio Diet, is a plant-based dietary pattern that was developed in the early 2000s to lower low-density lipoprotein cholesterol (LDL-C).[1–6] The underlying diet is low in saturated fat and cholesterol (National Cholesterol Education Program Step II diet[7]), with the addition of a "portfolio" of 4 cholesterol-lowering foods and nutrients: nuts, plant protein (soy and pulses), viscous fiber (oats, barley, psyllium, eggplant, okra, apples, oranges, and berries), and phytosterols (originally provided as

Correspondence to: Simin Liu, MD, PhD, Department of Epidemiology, Brown University, 121 South Main St, Providence, RI 02903; and John L. Sievenpiper, MD, PhD, St. Michael's Hospital, #6138-61 Queen Street East, Toronto, Ontario M5C 2T2, Canada. E-mails: simin_liu@brown.edu (S.L.);john.sievenpiper@utoronto.ca (J.L.S.)
*A. J. Glenn and K. Lo contributed equally.
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Supplementary Material for this article is available at https://www.ahajournals.org/doi/suppl/10.1161/JAHA.121.021515
For Sources of Funding and Disclosures, see page 11.

JAHA is available at: www.ahajournals.org/journal/jaha

Andrea Glenn, MSc, RD

Simin Liu, MD, ScD

OUTCOME	# CASES	Q1 HR [95% CIs]	Q2 HR [95% CIs]	Q3 HR [95% CIs]	Q4 HR [95% CIs]
Total CVD	13,365	1.0 (Ref)	0.97 [0.92-1.02]	**0.91 [0.86-0.96]**	**0.89 [0.83-0.94]**
CHD	5, 640	1.0 (Ref)	0.92 [0.85-0.99]	**0.85 [0.78-0.93]**	**0.86 [0.78-0.95]**
Stroke	4, 440	1.0 (Ref)	1.03 [0.95-1.13]	0.97 [0.88-1.07]	0.97 [0.87-1.08]
Heart Failure	1, 907	1.0 (Ref)	0.97 [0.85-1.11]	**0.86 [0.75-0.99]**	**0.83 [0.71-0.99]**

Glenn AJ et al. J Am Heart Assoc. 2021;10:e021515

CHEAP (Coronary Heart Effectiveness Assessment of the Portfolio Diet in Primary Care)

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International health organizations supporting the Portfolio diet for CV risk reduction

Canadian Cardiovascular Society
Leadership. Knowledge. Community.

"We suggest that all individuals be encouraged to…adopt a healthy dietary pattern to lower their CVD risk…ii. Portfolio dietary pattern (Conditional Recommendation; Moderate-Quality Evidence)"… We recommend the following dietary components for LDL-C lowering: i. Portfolio dietary pattern (Strong Recommendation; High-Quality Evidence)"
Anderson TJ, et al. Can J Cardiol. 2016;32:1263-1282.

DIABETES CANADA

"The Portfolio Diet under conditions where all foods were provided has been shown to reduce LDL-C (~30%), hs-CRP (~30%) and calculated 10-year CVD risk by the Framingham Risk Score (~25%) in participants with hypercholesterolemia over 4 weeks"
Sievenpiper JL, et al. Can j Diabetes 2018; 2018 Apr;42 Suppl 1:S64-S79.

HEART UK
THE CHOLESTEROL CHARITY

"The Portfolio Eating plan is a recognised dietary approach to lowering cholesterol."
https://www.heartuk.org.uk/downloads/healthprofessionals/factsheets/the-portfolio-diet.pdf

Heart Foundation

"For people with existing CVD, the Portfolio dietary pattern had the strongest evidence for the reduction in risk factors for CVD, followed by the DASH diet."
https://www.heartfoundation.org.au/images/uploads/main/Eating_for_Heart_Health_-_Position_Statement.pdf

American Heart Association. AMERICAN COLLEGE of CARDIOLOGY

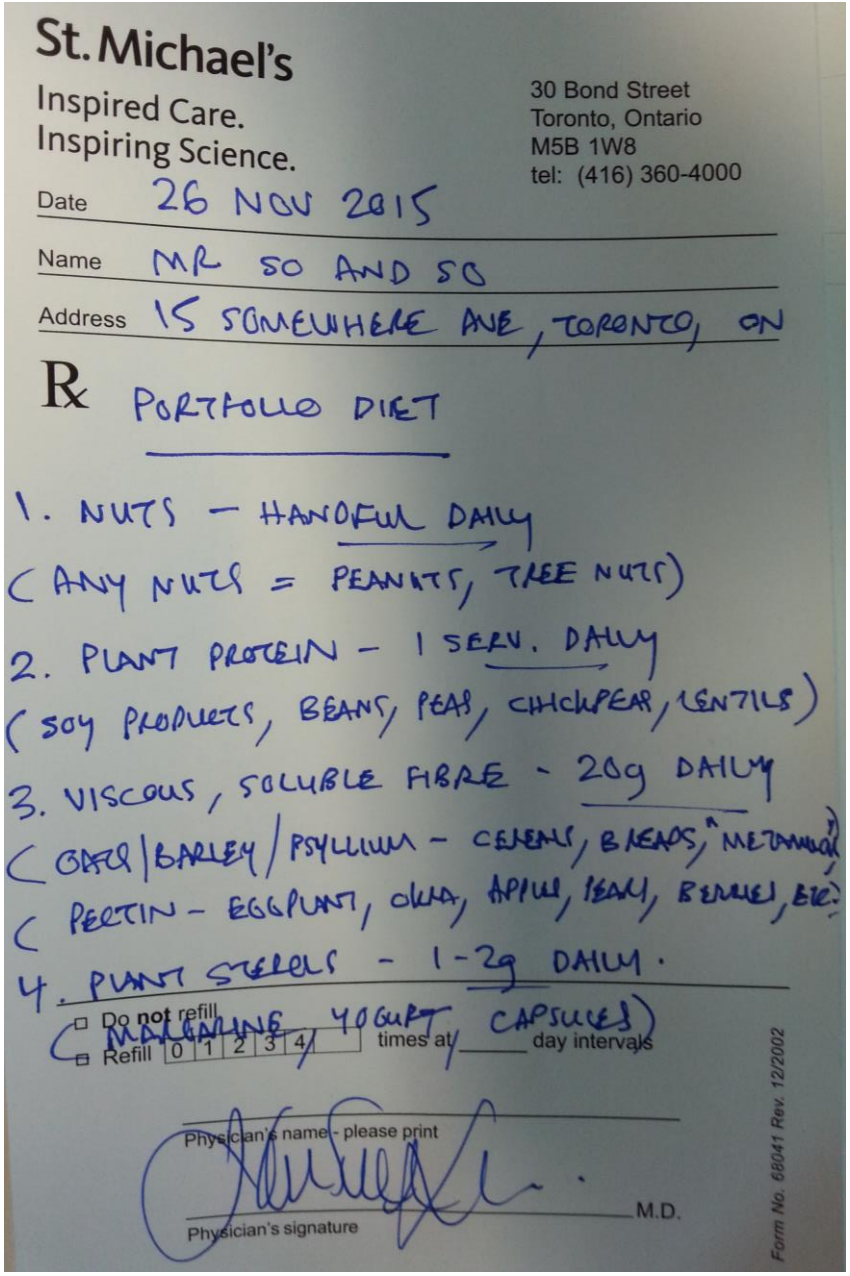
"Good adherence to various LDL lowering diets will reduce LDL-C levels by 10% to >15% (S4.4.3-3)

"S4.4.3-3. Chiavaroli L, Nishi SK, Khan TA, et al. Portfolio dietary pattern and cardiovascular disease: a systematic review and meta-analysis of controlled trials. Prog Cardiovasc Dis. 2018;61:43–53."
Grundy SM, et al. Circulation. 2019;139:e1082–e1143.

ESC European Society of Cardiology

"The Portfolio diet, incorporating plant sterols, soya protein, viscous fibres, and nuts, has the potential to reduce LDL-C levels by 20–25%.[54] This Panel believes that these approaches are appropriate either alone or in association with statin or non-statin drug regimens…"
Stroes ES, et al. Eur Heart J 2015;36:1012–1022

How do we translate the guidelines into clinical practice?



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M5B 1W8
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Date 26 NOV 2015

Name MR SO AND SO

Address 15 SOMEWHERE AVE, TORONTO, ON

℞ PORTFOLIO DIET

1. NUTS – HANDFUL DAILY
(ANY NUTS = PEANUTS, TREE NUTS)
2. PLANT PROTEIN – 1 SERV. DAILY
(SOY PRODUCTS, BEANS, PEAS, CHICKPEAS, LENTILS)
3. VISCOUS, SOLUBLE FIBRE – 20g DAILY
(OATS/BARLEY/PSYLLIUM – CEREALS, BREADS, MEDICATION)
(PECTIN – EGGPLANT, OKRA, APPLES, PEARS, BERRIES, ETC.)
4. PLANT STEROLS – 1-2g DAILY.
(MARGARINE, YOGURT, CAPSULES)

☐ Do not refill
☐ Refill 0 1 2 3 4 / times at / day intervals

Physician's name - please print

Physician's signature M.D.

Form No. 68041 Rev. 12/2002

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https://www.ccs.ca/images/Images_2017/Portfolio_Diet_Scroll_eng.pdf

http://childnutrition.utoronto.ca/news/quick-visual-portfolio-diet-and-cholesterol

http://www.stmichaelshospital.com/media/hospital_news/2018/0706.php

CHEAP (Coronary Heart Effectiveness Assessment of the Portfolio Diet in Primary Care)

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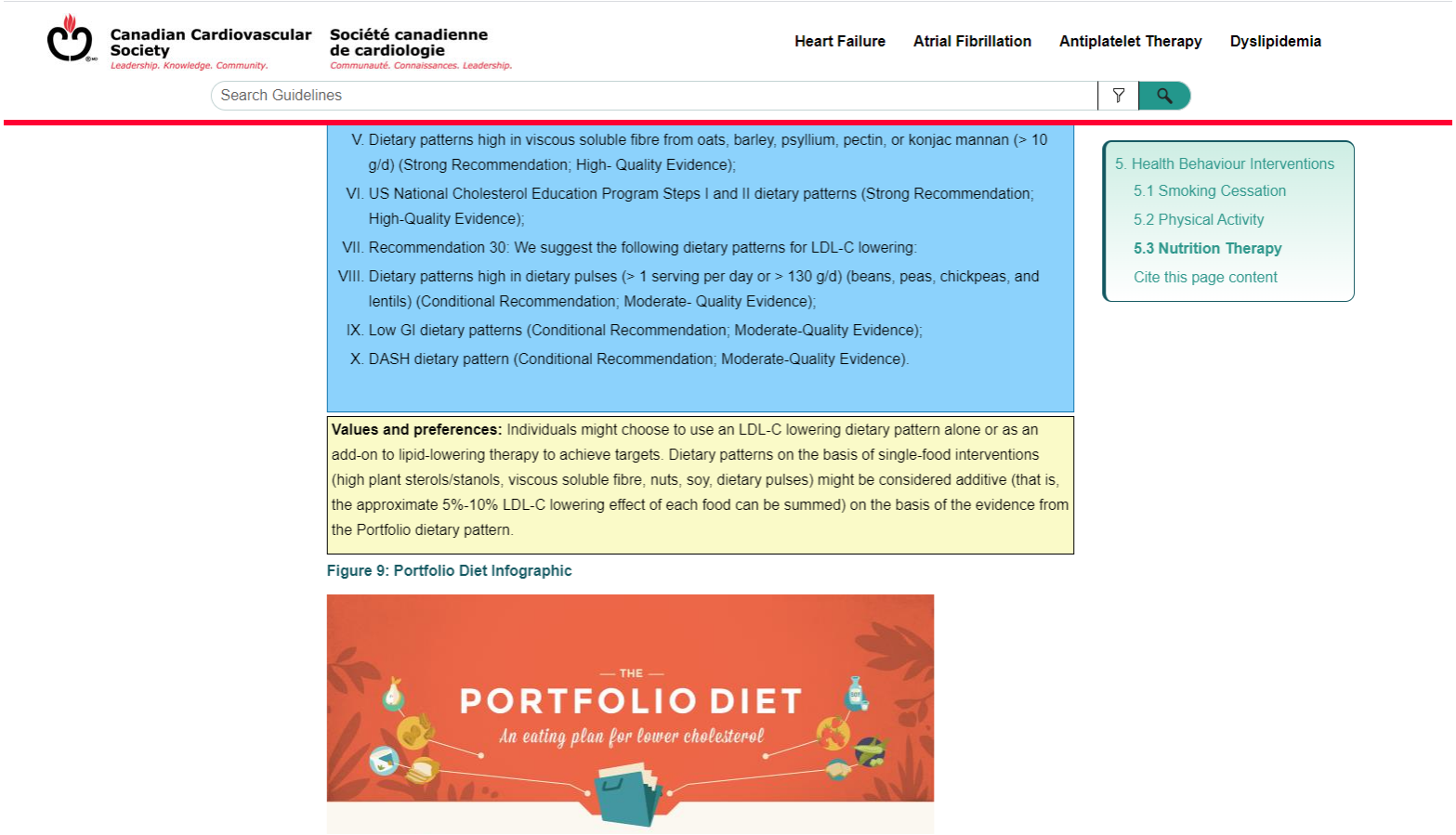
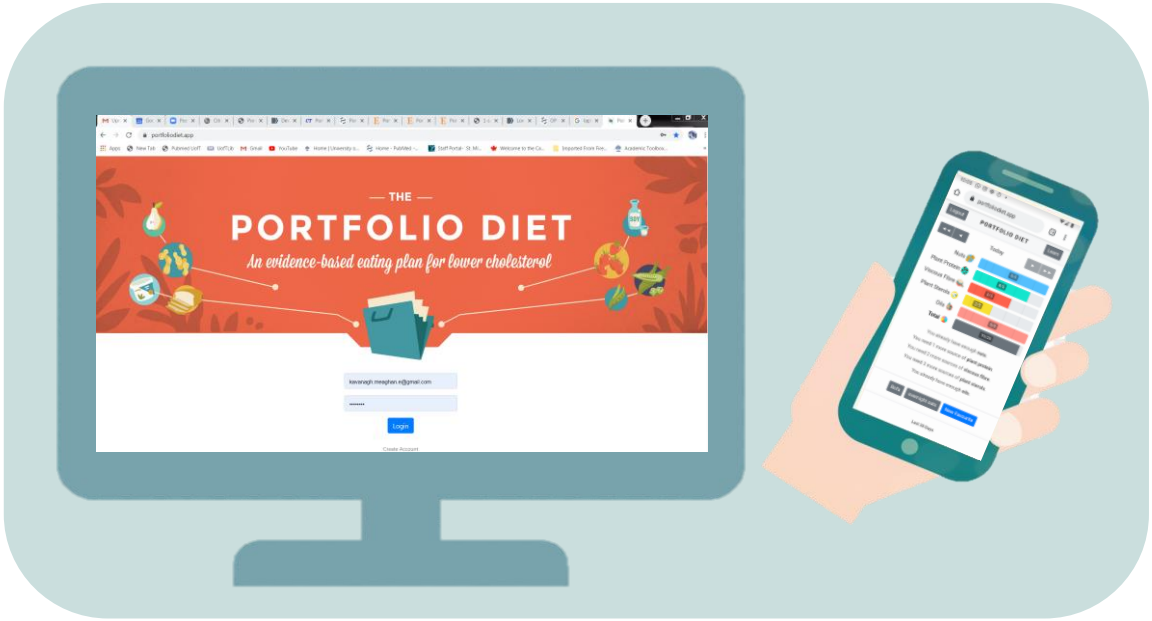
CCS Portfolio Diet Infographic: Physician education tools



http://www.ccs.ca/eguidelines/Content/Topics/Dyslipidemia/5.%20Health%20Behaviour%20Interventions.htm



www.PortfolioDiet.app

PortfolioDiet.app team

Chi-Ming Chow ,
MD, MSc, FRCPC,
FACC, FASE

USquareSoft

http://usquaresoft.com/

Antiplatelets | Atrial Fib. | Drive+Fly | Heart Failure | Lipids | Paediatrics

iCCS | CWC | EACVI | SVS iPG | iSVU

Canadian Diabetes Association CLINICAL PRACTICE GUIDELINES

Canadian Diabetes Association Clinical Practice Guidelines 2.0

iASE | Echo AUC | IScore | CMR | CDA CPG

Laura Chiavaroli, PhD, PDF

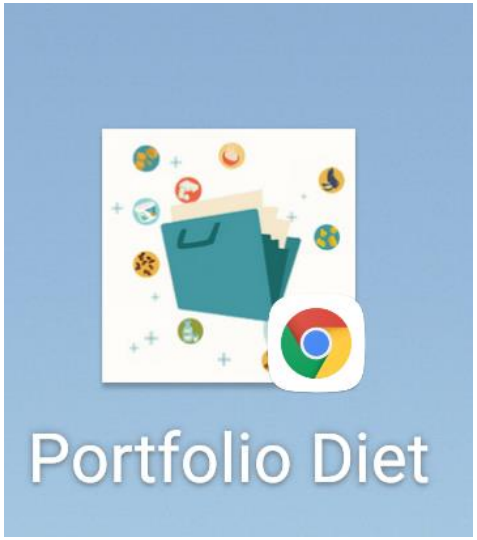
Meaghan Kavanagh, MSc, PhD candidate

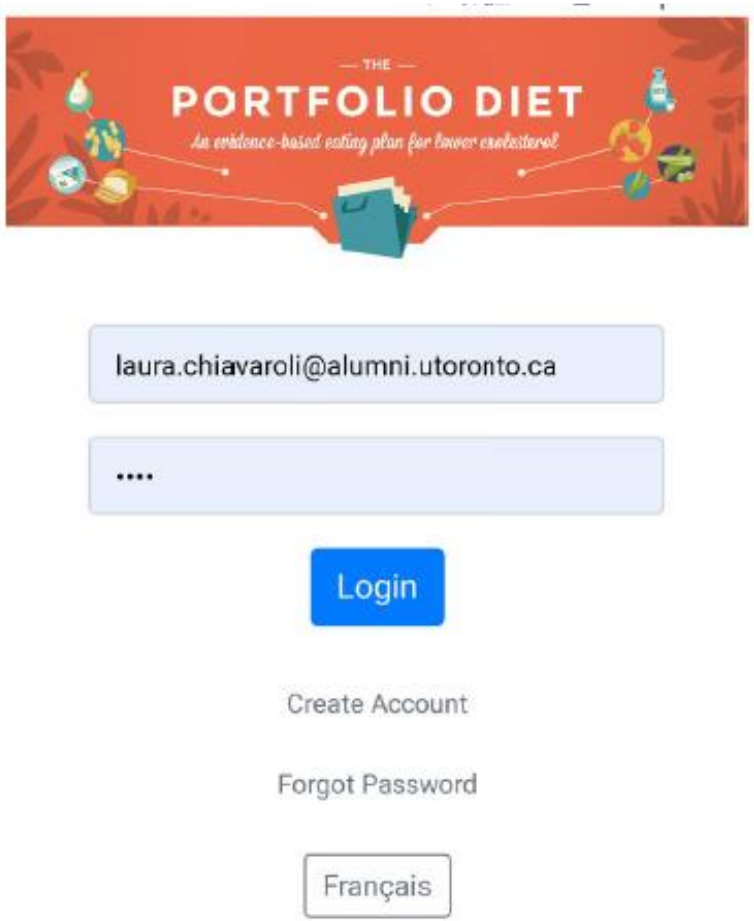
Andrea Glenn, MSc, RD, PhD candidate

Andreea Zurbau, PhD, RD, PDF

Stephanie Nishi, PhD, RD, PDF (Spain)

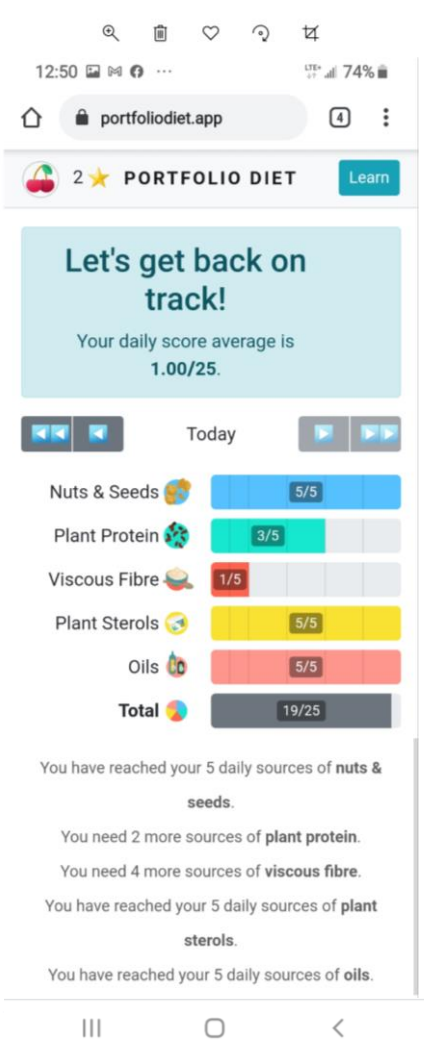
PortfolioDiet.app icon and login page

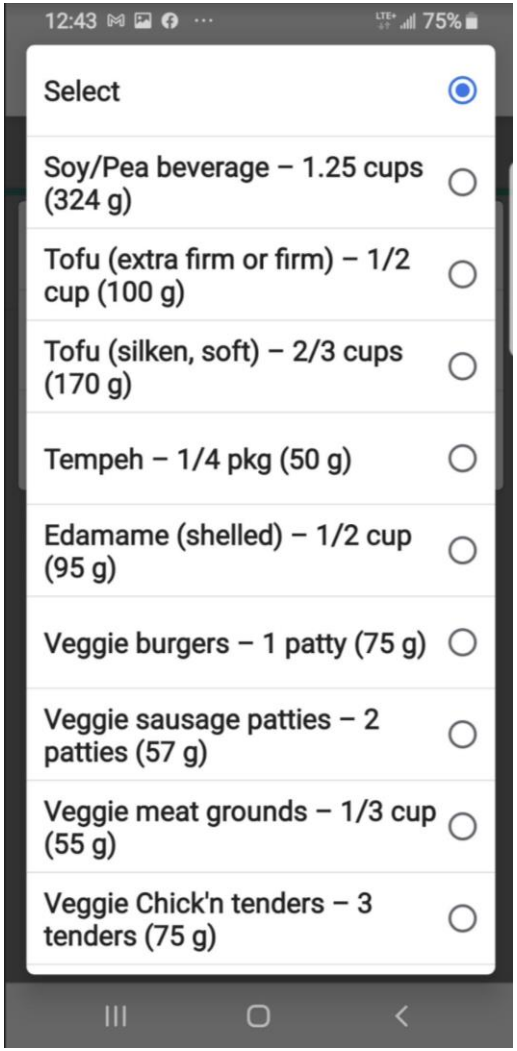




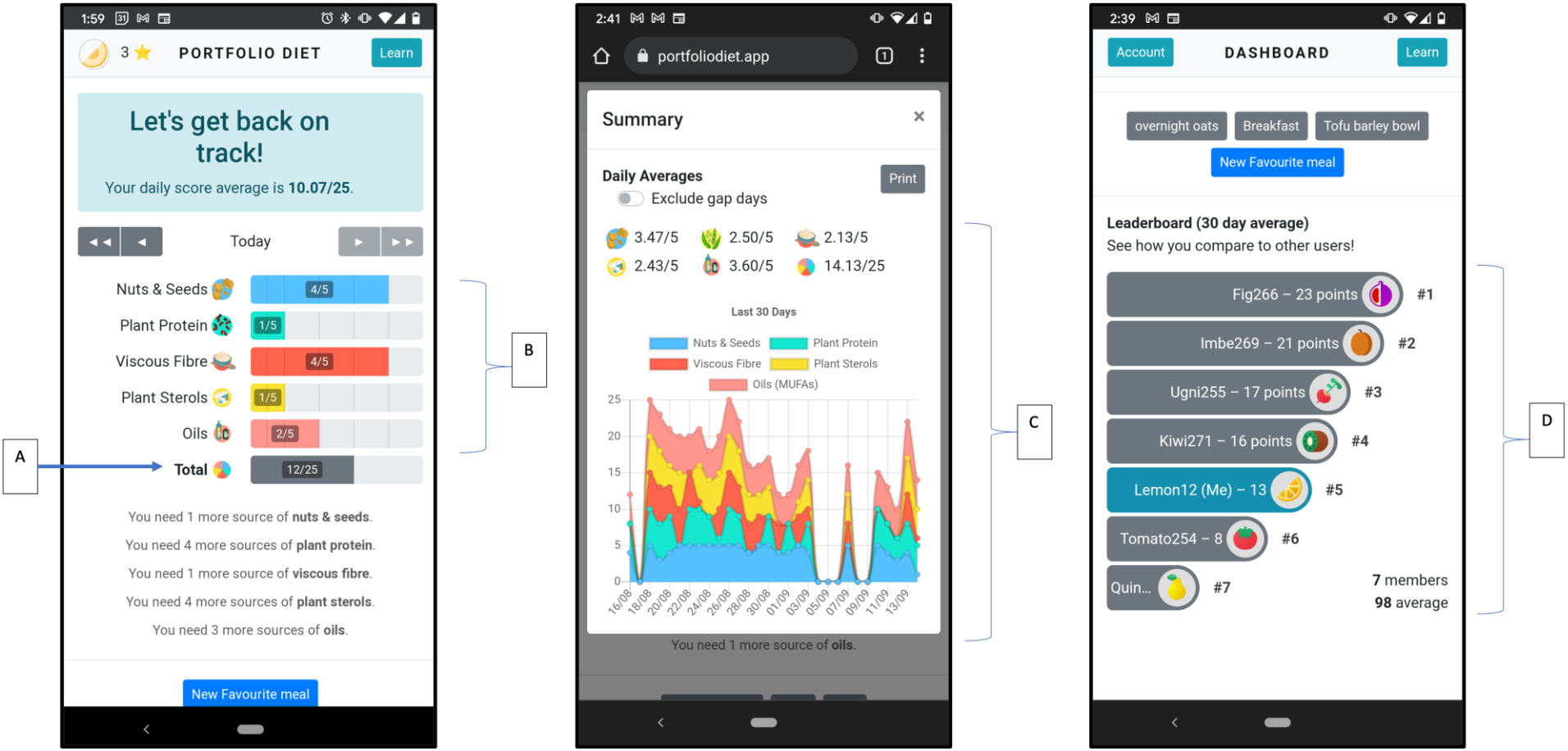
PortfolioDiet.app scoring

Nuts & Seeds	5 points
Plant Protein	5 points
Viscous Fibre	5 points
Plant Sterols	5 points
Oils	5 points
Total	**25 points**



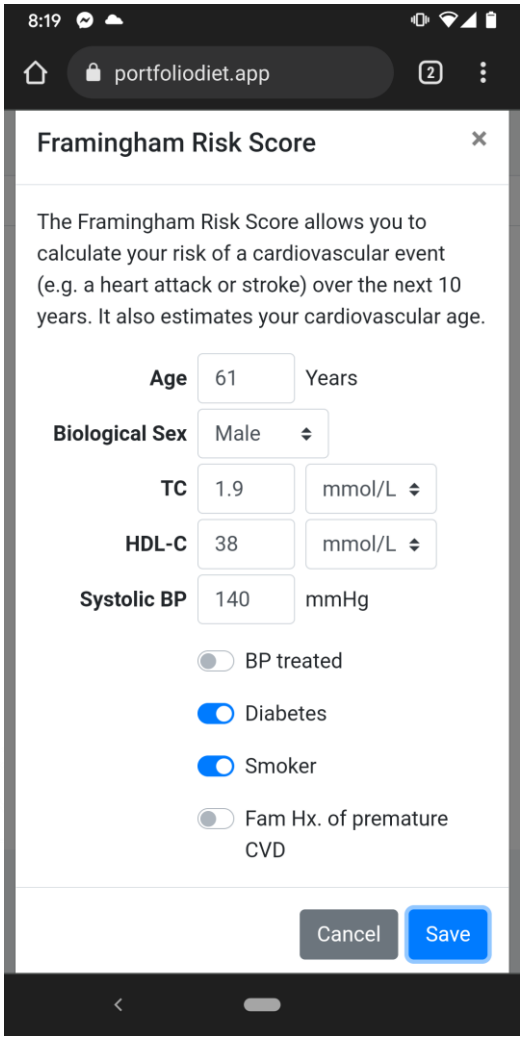


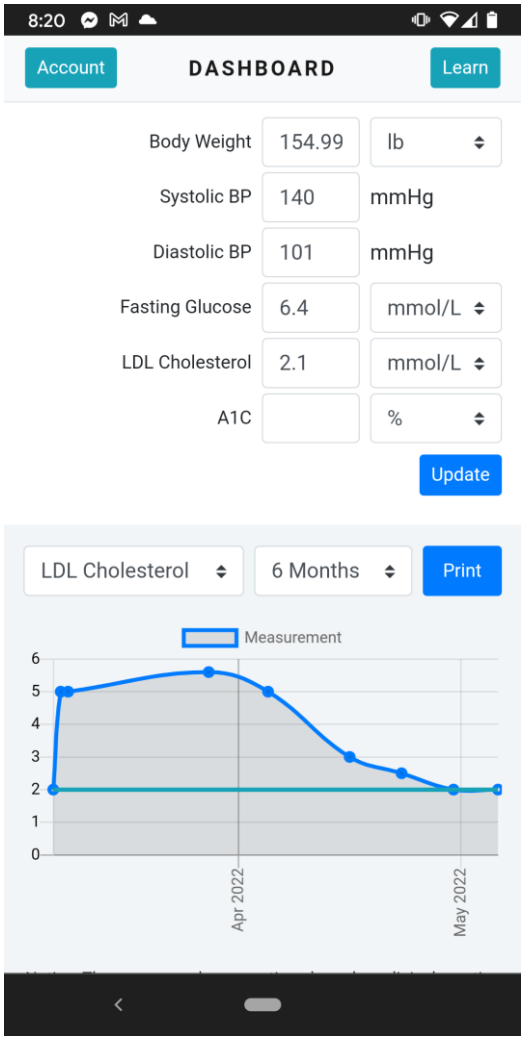
PortfolioDiet.app dashboard/gamification



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

PortfolioDiet.app Clinical measurements





PortfolioDiet.app cookbook, tip sheets/videos, and infographic development

You already have enough **nuts**.

You need 1 more source of **plant protein**.

You already have enough **viscous fibre**.

You need 3.5 more sources of **plant sterols**.

You need 2 more sources of **oils**.

Breakfast #1 | New Favourite

Blueberry-Orange Smoothie

Prep Time: 5 mins

Cook Time: 0 mins

Makes 750g = 1 serving

Ingredients

- 1 cup soy milk, unsweetened
- 1 cup frozen blueberries
- 1 cup frozen oranges
- 170g soft tofu
- 1 serving plant sterols*
- ¼ tsp ground cardamom

*400mg of plant sterols from supplemental packets, powder, or opened capsules

How To

1 Place all ingredients in a blender and blend until smooth.

Tip: Not a fan of cardamom? Then skip it completely or swap with fresh or ground ginger, cinnamon, orange zest or cocoa powder.

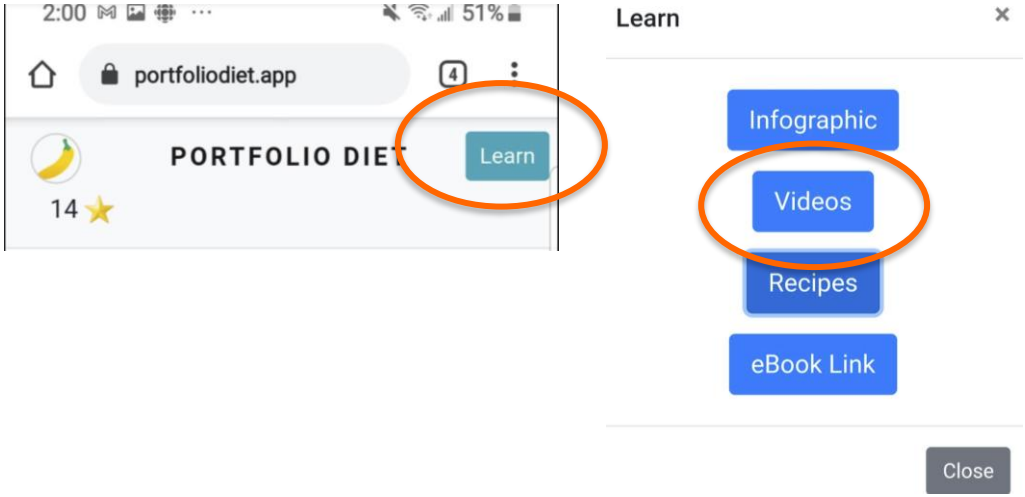
Mix in 1 tsp psyllium husk for an additional viscous fibre point!

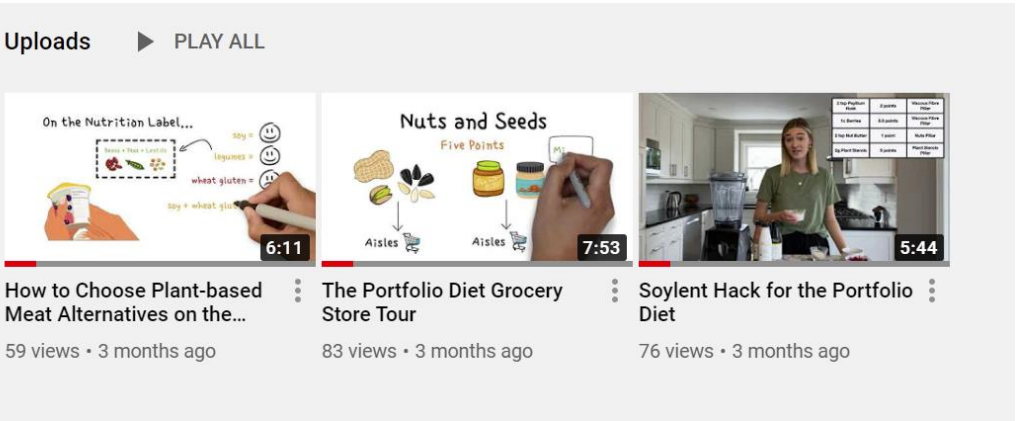
Nutrition Information
(1 serving – 750 g): Entire recipe

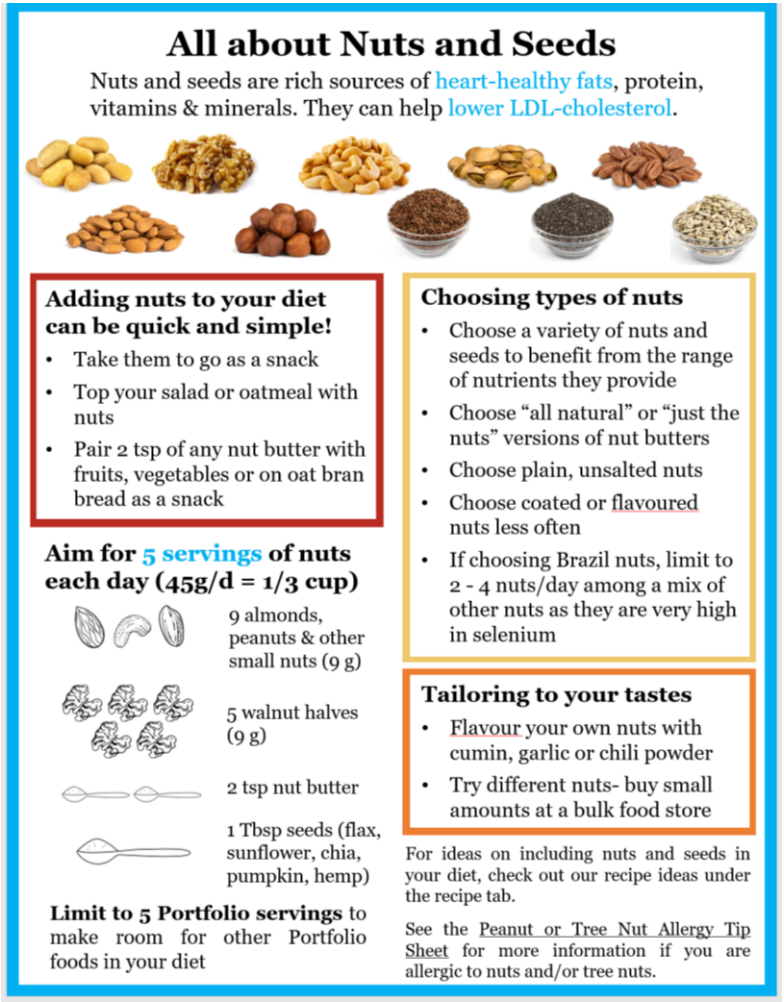
Calories	344 kcal	Monounsaturated Fat	1.1 g
Protein	19.3 g	Polyunsaturated Fat	2.9 g
Soy Protein	16.9 g	Total Carbohydrate	38.6 g
Fat	10.1 g	Dietary Fibre	9.7 g
Saturated Fat	0.6 g	Viscous Fibre	4.0 g

Portfolio Diet Score: 7.5 points per serving
Plant Protein: 1.5 points
Viscous Fibre: 1 point
Plant Sterols: 5 points

PortfolioDiet.app cookbook, tip sheets/videos, and infographic development







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

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

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

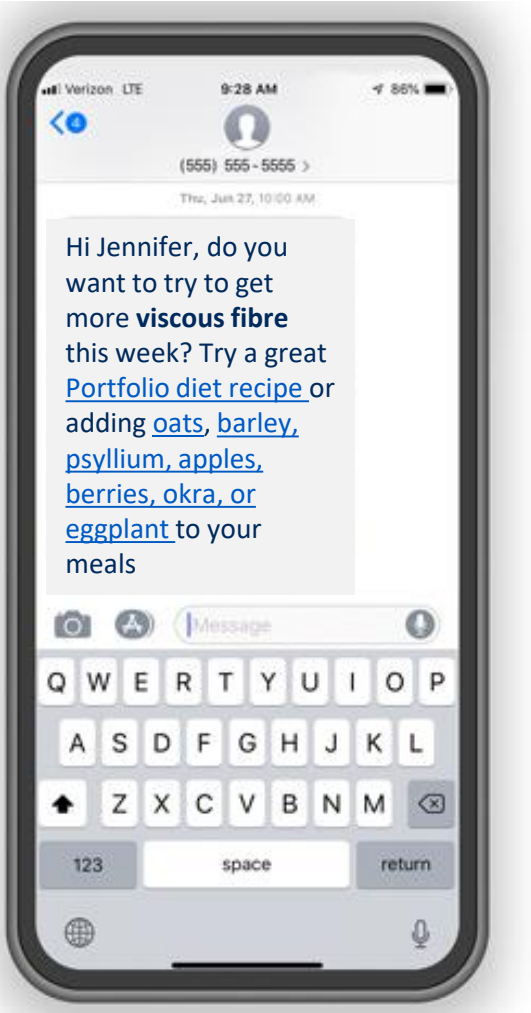
Tailoring to your tastes

- 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.

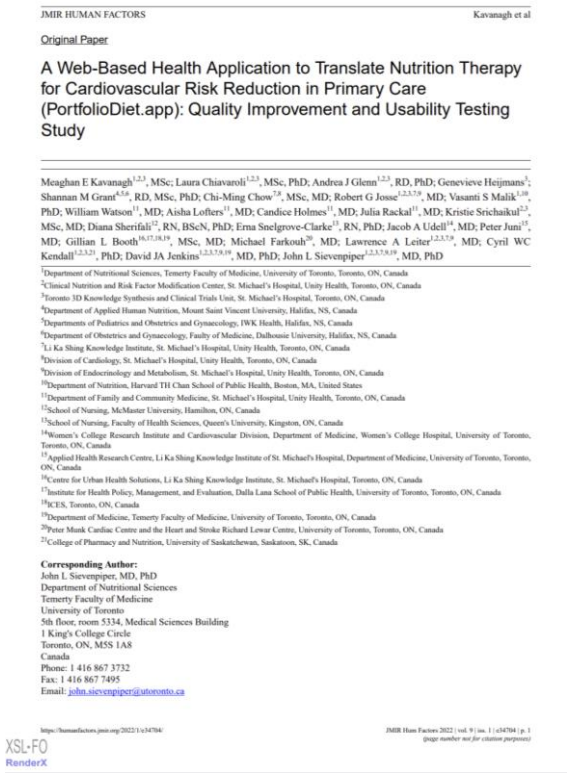
See the Peanut or Tree Nut Allergy Tip Sheet for more information if you are allergic to nuts and/or tree nuts.

PortfolioDiet.app: Nudges/coaching!



QI and usability testing of the PortfolioDiet.app

Meaghan Kavanagh, MSc



JMIR HUMAN FACTORS Kavanagh et al

Original Paper

A Web-Based Health Application to Translate Nutrition Therapy for Cardiovascular Risk Reduction in Primary Care (PortfolioDiet.app): Quality Improvement and Usability Testing Study

Meaghan E Kavanagh[1,2,3], MSc; Laura Chiavaroli[1,2,3], MSc, PhD; Andrea J Glenn[1,2,3], RD, PhD; Genevieve Heijmans[3]; Shannan M Grant[4,5,6], RD, MSc, PhD; Chi-Ming Chow[7,8], MSc, MD; Robert G Josse[1,2,3,7,9], MD; Vasanti S Malik[1,10], PhD; William Watson[11], MD; Aisha Lofters[11], MD; Candice Holmes[11], MD; Julia Rackal[11], MD; Kristie Srichaikul[2,3], MSc, MD; Diana Sherifali[12], RN, BScN, PhD; Erna Snelgrove-Clarke[13], RN, PhD; Jacob A Udell[14], MD; Peter Juni[15], MD; Gillian L Booth[16,17,18,19], MSc, MD; Michael Farkouh[20], MD; Lawrence A Leiter[1,2,3,7,9], MD; Cyril WC Kendall[1,2,3,21], PhD; David JA Jenkins[1,2,3,7,9,19], MD, PhD; John L Sievenpiper[1,2,3,7,9,19], MD, PhD

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https://humanfactors.jmir.org/2022/1/e34704/ JMIR Hum Factors 2022 | vol. 9 | iss. 1 | e34704 | p. 1
(page number not for citation purposes)

"The *PortfolioDiet.app* **educates** users on the Portfolio Diet and is considered **acceptable** by users. Although further refinements to the *PortfolioDiet.app* will continue to be made before its evaluation in a clinical trial, the result of this QI project is an **improved clinical tool**."

Kavanagh et al. JMIR Human Factors, in press

Is it effective in the real-world?

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. LA Leiter, MDCM, FRCPC, FACP, FACE, FAHA

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Dr. J. Udell, MD, MPH, FRCPC
Dr. M. Vallis, PhD
Dr. W. Watson, MD, cCFP

CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

CHEAP trial power and design:

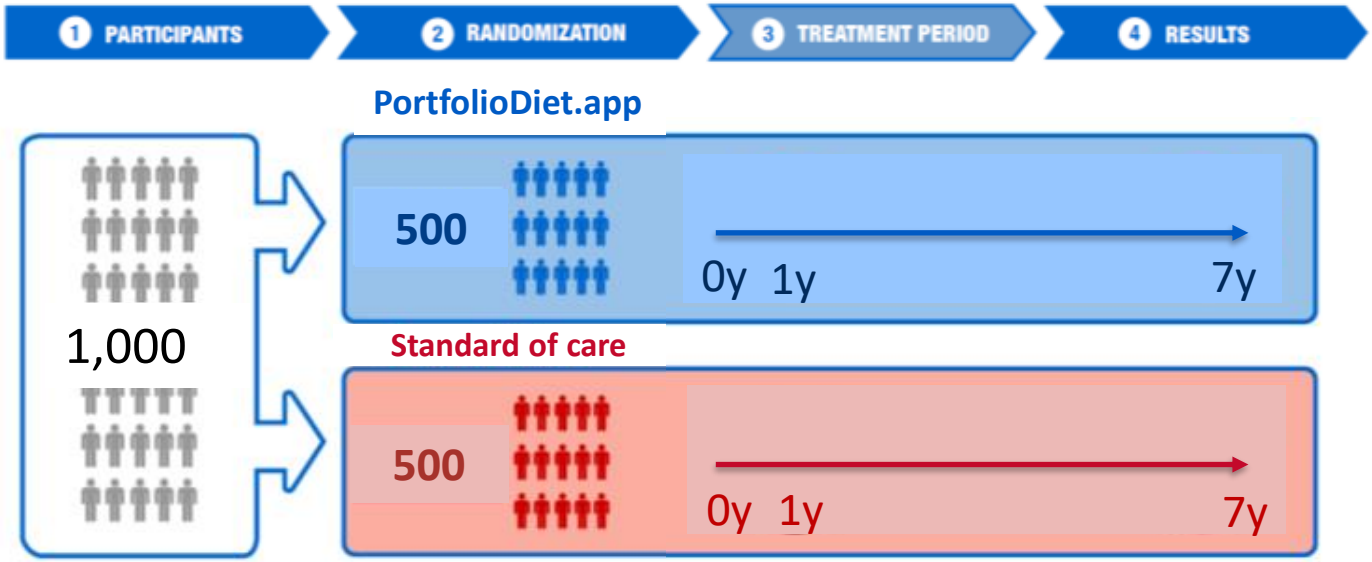
Parallel, 2 group RCT of the effect of standard of care + Portfolio diet (PortfolioDiet.app) versus standard of care alone on achieving lipid targets at 1y and reducing major CV events at 7y in 1,000 high risk mixed 2º and 1º prevention participants on background statin therapy in primary care

Power

Primary outcomes with stepwise gatekeeper procedure:

1. **Proportion achieving ≥10% reduction in LDL-C or non-HDL-C at 1y**
2. **MACE (MI, revascularization, CV hospitalization, CV mortality, stroke) at 7y**

Design



CHEAP trial participants:

1º and 2º prevention participants at high CV risk on background statin therapy

Inclusion

1. Statin therapy
2. M >55y, F>65y (postmenopausal)
3. At least one…
   a) **2º prevention (70%)** – prior ASCVD (MI, PCI, CABG)
   b) **1º prevention (30%)** – DM2 + 1 risk factor (HTN, smoking, eGFR >30 and <60, or ACR ≥ 3.0)

Exclusion

1. Major disease expected to result in death within 2 years (except CVD)
2. Active severe liver disease or ALT ≥ 3 x ULN
3. HyperCKemia CK > 5 x ULN
4. Malabsorption disorders
5. Drug or alcohol abuse disorders

CHEAP trial recruitment

10 sites
34 physicians
30±4 participants/physician over 2y
1.25 participants/physician/month

UTOPIAN
UNIVERSITY OF TORONTO
PRACTICE-BASED RESEARCH NETWORK

CHEAP trial randomization

- Stratified (site), block randomization (individual = unit of randomization)
- Allocation concealment (statistician blinded)
- Randomization by Applied Health Research Centre (AHRC)
- Delivery through Research Electronic Data Capture (REDCap)

AHRC
APPLIED HEALTH RESEARCH CENTRE

St. Michael's
Inspired Care.
Inspiring Science.

Research Electronic Data Capture (REDCap) program

REDCap™
Research Electronic Data Capture

CHEAP trial data/sample collections

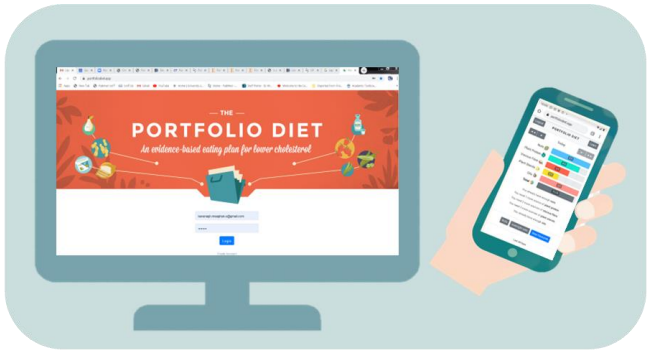
- Willett FFQ/questionnaires - REDCap
- Anthropometry/Blood pressure – LifeLabs
- Blood work (lipids, glucose, HbA1c, CRP) – LifeLabs
- Clinical events – IC/ES

LifeLabs®

IC/ES

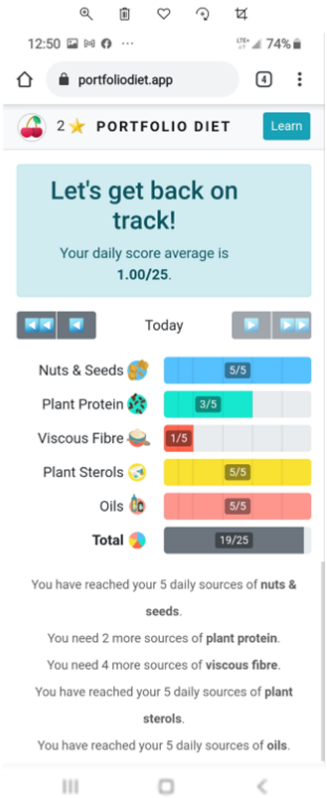
CHEAP trial intervention

PortfolioDiet.app



www.PortfolioDiet.app

Nuts & Seeds	**5 points**
Plant Protein	**5 points**
Viscous Fibre	**5 points**
Plant Sterols	**5 points**
Oils	**5 points**
Total	**25 points**



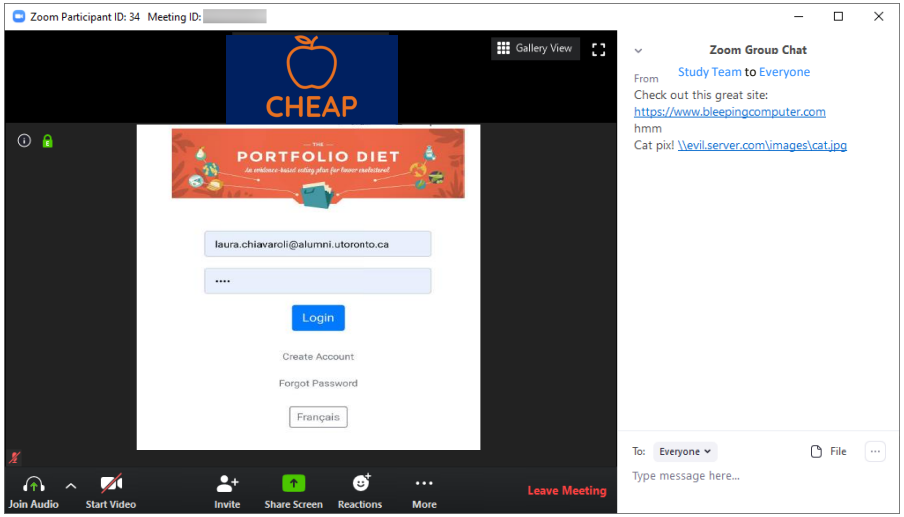
CHEAP trial Intervention
16 session "DPP-like" program on Zoom

Months 0-1 (weekly)
week 1 - session 1 - Intro to Portfolio diet and PortfolioDiet.app 1 (getting started and personal motivations)
week 2 - session 2 - The 5 pillars and PortfolioDiet.app 2 (a deeper dive into the 5 categories)
week 3 - session 3 – Portfolio Diet Tips and PortfolioDiet.app 3 (optimizing features, nudges)
week 4 - session 4 - Goal setting (based on ≥10% LDL-C/non-HDL-C, ≥ 12/25 PDS, individual portfolio food goals)

Months 1-3 (2-weekly)
Week 6 - session 5 - Problem solving 1 (5-step approach)
Week 8 - session 6 - Self-monitoring (leveraging PDS score and measurements)
Week 10 - session 7 - Problem solving 2 (managing stress and social cues)
Week 12 - session 8 - Taking charge of change

Months 4-6 (4-weekly)
Week 16- session 9 - Portfolio meal replacements for weight loss
Week 20 - session 10 - Talking Back to Negative Thoughts
Week 24 - session 11 - Cooking with nuts

Months 7-12 (6-weekly)
Week 28 - session 12 - Cooking with plant-protein
Week 34 - session 13 - Cooking with viscous fibre
Week 40 - session 14 - Cooking with plant sterols
Week 46 - session 15 - Favourite high-yield recipes
Week 52 - session 16- How to stay motivated



CHEAP trial intervention

Coupons/vouchers program to drive adherence

1 Nuts	2 Viscous fibre	3 Plant Protein	4 Plant sterols	Healthy oils
Almond Board of California 	Loblaw 	Danone 	Nutrartis 	Loblaw 
California Walnut Commission 	Kellogg  KIND 	Loblaw 		
Peanut Institute 	Shoppers Drug Mart 	Unico/Primo 		
KIND 				

CHEAP trial outcomes

Primary outcomeS:

≥10% reduction in LDL-C or non-HDL-C at 1y

MACE (MI, revascularization, CV hospitalization, CV mortality, stroke) at 7y

Secondary outcomes:

≥12/25 *Portfolio Diet Score at* 1y and 7y

CCS targets (LDL-C <1.8/<2.0, non-HDL-C <2.4/2.6 mmol/L) at 1y and 7y

Change in medications at 1y and 7y

Cost effectiveness at 1y and 7y

Participant satisfaction and quality of life (EQ5D) at 1y and 7y

Provider satisfaction at 1y and 7y

Other outcomes:

Changes in lipids, BP, FPG, HbA1c, CRP, body weight at 1y and 7y

Metabolic syndrome, diabetes at 1y and 7y

CHEAP trial analysis plan

- Unit of inference = the individual.
- Primary analysis by intention-to-treat (ITT) principle at 1y
- Inverse probability weighting (IPW) for missing data
- Logistic regression models for the proportion achieving the lipid targets and Portfolio diet score targets at 1y (ORs with 95% CI)
- Mixed models for continuous data at 1y (mean differences with 95% CI)
- Cox proportional-hazards models for clinical events at 7y (HR with 95% CI)
- Completers analyses, per protocol analyses and analyses adjusted for changes in background statin medication
- Subgroup analyses by age, sex/gender, prevention type, diabetes, statin intensity, baseline LDL-C, educational attainment, ethnicity, and site

Please join us!