

Nutrient intake and dietary quality changes within a personalized lifestyle intervention program for metabolic syndrome in primary care

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Abstract: A team-based 12-month lifestyle program for the treatment of metabolic syndrome (MetS) (involving physicians, registered dietitians (RDs), and kinesiologists) was previously shown to reverse MetS in 19% of patients (95% confidence interval, 14% to 24%). This work evaluates changes in nutrient intake and diet quality over 12 months ($n = 205$). Individualized diet counselling was provided by 14 RDs at 3 centres. Two 24-h recalls, the Canadian Healthy Eating Index (HEI-C), and the Mediterranean Diet Score (MDS) were completed at each time point. Total energy intake decreased by 145 ± 586 kcal (mean \pm SD) over 3 months with an additional 76 ± 452 kcal decrease over 3–12 months. HEI-C improved from 58 ± 15 to 69 ± 12 at 3 months and was maintained at 12 months. Similarly, MDS ($n = 144$) improved from 4.8 ± 1.2 to 6.2 ± 1.9 at 3 months and was maintained at 12 months. Changes were specific to certain food groups, with increased intake of fruits, vegetables, and nuts and decreased intake of “other foods” and “commercial baked goods” being the most prominent changes. There was limited change in intake of olive oil, fish, and legumes. Exploratory analysis suggested that poorer diet quality at baseline was associated with greater dietary changes as assessed by HEI-C.

Novelty

- Multiple dietary assessment tools provided rich information on food intake changes in an intervention for metabolic syndrome.
- Improvements in diet were achieved by 3 months and maintained to 12 months.
- The results provide a basis for further dietary change implementation studies in the Canadian context.

Key words: metabolic syndrome, dietary behaviour change, healthy eating index, HEI, Mediterranean Diet Score, MDS, nutrient intake, dietary analysis, dietary intake, diet therapy.

Résumé : Un programme en équipe de 12 mois sur le mode de vie pour le traitement du syndrome métabolique (« MetS ») (impliquant des médecins, des diététistes professionnels et des kinésiologues) a déjà démontré son efficacité pour inverser la maladie chez 19% des patients (intervalle de confiance 95% : 14 à 24%). Ce travail évalue les modifications de l'apport en nutriments et de la qualité de l'alimentation en 12 mois ($n = 205$). Des conseils diététiques individualisés sont donnés dans trois centres par 14 diététiciens professionnels. Deux rappels de 24 heures, l'indice canadien de saine alimentation (« HEI-C ») et le score du régime méditerranéen (« MDS ») sont remplis à chaque moment choisi. L'apport énergétique total diminue de 145 ± 586 kcal (moyenne \pm écart type) en 3 mois et une diminution supplémentaire de 76 ± 452 kcal est notée du 3 au 12 mois. HEI-C passe de 58 ± 15 à 69 ± 12 au 3 mois et est maintenu au 12 mois. De même, le MDS ($n = 144$) passe de $4,8 \pm 1,2$ à $6,2 \pm 1,9$ au 3 mois et est maintenu au 12 mois. Les changements sont spécifiques à certains groupes d'aliments; les changements les plus importants sont une consommation accrue de fruits, de légumes et de noix et une consommation réduite « d'autres aliments » et de « produits de boulangerie commerciaux ». La consommation d'huile d'olive, de poisson et de légumineuses varie peu. L'analyse exploratoire suggère que la piètre qualité de l'alimentation au départ est associée d'après HEI-C à des changements diététiques plus importants. [Traduit par la Rédaction]

Les nouveautés

- De multiples outils d'évaluation diététiques procurent des informations riches sur les modifications de l'apport alimentaire lors d'une intervention au sujet du syndrome métabolique.

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- Des améliorations du régime alimentaire sont réalisées en 3 mois et maintenues durant 12 mois.
- Les résultats fournissent une base pour d'autres études sur la mise en œuvre de changements alimentaires dans le contexte canadien.

Mots-clés : syndrome métabolique, changement du comportement alimentaire, indice de saine alimentation, HEI, score du régime méditerranéen, MDS, apport en nutriments, analyse du régime alimentaire, apport alimentaire, thérapie diététique.

Introduction

The potential of lifestyle modification programs to reverse metabolic syndrome in primary care settings is of major interest because of its high prevalence in developed countries and evidence from clinical trials of the potential for reversal. Metabolic syndrome (MetS) refers to a cluster of cardiometabolic risk factors, including elevated waist circumference, high blood pressure, high fasting plasma glucose, high triglycerides, and/or low high-density lipoprotein-cholesterol (Alberti et al. 2009). In Canada, the prevalence of MetS is 21% among adults (aged 18+ years) overall, and 39% among those aged 60 to 79 years (Statistics Canada 2015). The presence of MetS leads to a 1.5- to 2-fold increased relative risk of cardiovascular disease compared with those without the syndrome and those with MetS are reported to have double the annual health care costs and use health services more frequently than those without (Boudreau et al. 2009; Mottillo et al. 2010).

Our Canadian interdisciplinary research team reviewed the various studies and hypothesized that a team-based intensive program (Canadian Health Advanced by Nutrition and Graded Exercise; CHANGE) led by a family physician (FP) that involved registered dietitians (RDs) and kinesiologists would be feasible in the Canadian primary care system and would result in reversal or reduction in the number of the components of MetS at 12 months. The 12-month intervention was designed to be flexible for different types of primary care organizations, and intensive with extensive documentation of process and clinical indicators.

Prior to initiation of the study recruitment in October 2012, the relevant diet, health behaviour change, and implementation literature was reviewed for insights on emerging best practices for documenting the counselling process and the food and nutrient changes achieved by participants. The focus of the diet intervention in studies also varied widely. For example, 2 of the 3 largest clinical trials, the Diabetes Prevention Program (DPP) (Knowler et al. 2002) and the Look AHEAD study (Look AHEAD Research Group et al. 2013) focused on calorie reduction to promote weight loss. In contrast, the PREDIMED study in Spain promoted a Mediterranean diet and provided additional supplements of olive oil and nuts, without weight loss or additional physical activity promotion (Estruch et al. 2013). Review of a variety of shorter studies for reversal of MetS demonstrated a range of approaches, from a strong emphasis on weight loss, to Mediterranean or Dietary Approaches to Stop Hypertension (DASH) diet to individualized approaches (Dunkley et al. 2012; Yamaoka and Tango 2012). Thus, there is currently little agreement on what the key features of the diet intervention should be in MetS.

Irrespective of the particular diet being promoted, a key issue within the diet counselling field are the challenges of adherence to changes in food habits (Desroches et al. 2013), and the challenges of weight loss (Peirson et al. 2014). The main ways dietitians deal with these issues are to promote client-centred practice, joint goal setting, achievable, long-term food behaviour changes, self-monitoring, and relevant food skills (Royall et al. 2014). Given the variations observed in previous clinical trials, we adopted this approach, adding an assessment of a Mediterranean diet score to the protocol in May 2013 to compare our results with the PREDIMED study, which was first published in April 2013 (Estruch et al. 2013) with a subsequent correction and republication (Estruch et al. 2018).

The CHANGE study recruited 293 adult patients with MetS from 3 family medicine clinics, and at 12 months, 19% of patients (95% confidence interval (CI), 14% to 24%) showed reversal of MetS (Jeejeebhoy et al. 2017). Having demonstrated overall effectiveness of the program, in this paper we evaluate changes in nutrient intake and dietary quality achieved by the patients who completed the dietary assessments in the study to 12 months. Specifically, we report on energy and nutrient intake assessed by 24-h recall and diet quality (DQ) as assessed by the Canadian Healthy Eating Index (HEI-C) (Garriguet 2009), and the PREDIMED version of a Mediterranean Diet Score (MDS) (Martínez-González et al. 2012). An exploratory subgroup analysis was also undertaken to assess if achieved dietary changes differed by baseline DQ.

Materials and methods

Setting and design

Patients who met the criteria for MetS (Alberti et al. 2009) were enrolled from 3 participating clinics located in Edmonton, Alberta, Canada; Toronto, Ontario, Canada; and Quebec City, Quebec, Canada. Details on overall study methods are provided elsewhere (Jeejeebhoy et al. 2017; Klein et al. 2017). Briefly, each patient was assessed by their FP and referred to the RD and kinesiologist for individual assessment and intervention. All patients were followed by the RD and kinesiologist weekly for the first 3 months, then monthly for the next 9 months. The FP followed each patient at 3, 6, 9, and 12 months for blood work, assessment of progress, and ongoing encouragement to the patient in making lifestyle changes based on progress achieved in MetS components. Ethics approvals for the study were obtained from Health Research Ethics Board-Biomedical (University of Alberta), Comité d'éthique de la recherche des Centres de santé et de services sociaux de la Vieille-Capitale (Laval University), and Institutional Review Board Services, a Chesapeake IRB Company (Aurora, Ont., Canada).

Dietary intervention

Fourteen RDs employed by the clinics were involved in counselling over the course of the study. RDs were encouraged to continue their usual counselling routines, using joint goal-setting to focus on specific food behaviour changes, broadly based on the Integrated Behavioral Model (Montano and Kasprzyk 2008) and the generally accepted nutrition care process, which involves a comprehensive nutrition assessment, development of a nutrition care plan, implementation, and evaluation. A strong emphasis was placed on motivational interviewing, skill-building, and situating advice within personal lifestyle context. A previously published care map provided a visual summary with supporting evidence of the counselling strategy used in the intervention (Royall et al. 2014). In brief, the initial focus of the dietary intervention was on dietary strategies to promote weight loss (if feasible), followed by management of diabetes or impaired glucose tolerance, and finally consideration of dietary components that impacted hypertension and/or dyslipidemia. The rationale for this approach was that weight loss would improve all aspects of MetS, but if weight loss was not feasible (as determined by RD judgement based on the presence of barriers to reducing calorie intake, such as a history of weight cycling (Royall et al. 2014), then the next priority should be control of carbohydrates, since managing blood glucose levels in diabetes will also improve lipid levels.

Lipid levels and blood pressure are generally a secondary goal in dietetic practice if diabetes is present. Thus, weight loss was an expected focus of RD counselling, but changes to DQ were to be promoted in line with each client's metabolic profile. Dietary components associated with a Mediterranean diet (e.g., increased consumption of vegetables, fish, legumes, and olive oil, and decreased consumption of red or processed meats) was an added focus after publication of the PREDIMED study (Estruch et al. 2013).

Each RD received orientation to the diet intervention and the data collection methods either in person or via 60–90 min teleconference call, using a PowerPoint slide deck to anchor discussion. Dietitians also received several newly developed patient handouts on lifestyle treatment of MetS, a joint goal-setting guide (Brauer et al. 2016), and a 60-page counselling support document organized by the care map topics with links to diverse patient teaching resources, such as label reading, recipes, etc. This resource was developed by 2 MSc-trained practicing RDs. Several additional patient handouts were also developed over the course of the study based on RD feedback. Each RD also received a kit of commercial food models (Nasco, Fort Atkinson, Wis., USA) and generic cutlery and bowls and cups with different amounts and volumes shown to assist with portion estimations (supplementary Fig. S1¹). Ongoing support was provided by a listserv and periodic teleconferences held throughout the study to encourage sharing of experiences and resources.

Assessment of dietary intake

Dietary intake data were collected by RDs based on two 24-h recalls (on different days) using the multi-pass method (Blanton et al. 2006). Food intake data was entered into a dietary analysis program (ESHA Food Processor, Canadian version 10; ESHA Research, Salem, Ore., USA) to provide mean nutrient intake for the 2 days. Quality control was maintained by double data entry by 2 different research assistants at the University of Guelph followed by review by the study coordinator, use of a coding manual, and checking with the RDs collecting the data and food companies as needed. Both French and English food recalls were analyzed.

Food frequency questions were developed for the study to collect information on DQ. HEI-C was chosen because it had been used in multiple studies, provided an overall score, and a Canadian population estimate was available for comparison (Garriguet 2009). HEI-C scores (range 0 to 100) were determined using specific age and sex criteria based on Canada's Food Guide (CFG) recommendations and serving sizes (Health Canada 2007). Similarly, the criteria for the MDS (score range 0 to 14) (Martínez-González et al. 2012) were adjusted for CFG serving sizes, since "Spanish servings sizes" for vegetables and meat are larger than in Canada. Similarities and differences between the HEI-C and MDS scores are indicated in supplementary Tables S1–S3.¹

Overall data management

The majority of data were abstracted from the patients' medical charts and entered into a secure online data capture system (Research Electronic Data Capture; REDCap: <http://www.project-redcap.org/>) by locally designated clinic staff. The data capture system included data restrictions and real-time data integrity checks. Dietary intake data were analyzed at the University of Guelph and summary measures entered in the REDCap system. Detailed dietary data were merged with demographic and clinical data at each time point using SPSS Statistics (version 25.0; IBM Corp., Armonk, N.Y., USA).

Statistical analysis

Nutrient intake data were screened for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests, using *z* scores, with a *z* score over 3.29 as an indication of non-normal distribution for a medium-sized sample ($50 < N < 300$) (Kim 2013). Results of the normality tests for continuous variables showed that the majority of variables from this sample were not normally distributed. Parametric and nonparametric tests were conducted, and results of parametric tests are reported as both methods yielded similar results for statistical significance. Descriptive analyses were completed to determine mean \pm SD nutrient intake and HEI scores at baseline, 3 months, and 12 months. For baseline characteristics of participants, continuous variables were analyzed by using independent *t* test or 1-way ANOVA; categorical variables were analyzed by using the Pearson's χ^2 test and *z* test for comparison of proportions. Analysis was conducted on the original data with no imputation. Repeated-measures ANOVA was used to assess continuous variables (nutrients, HEI-C scores) and Cochran's *Q* test with McNemar tests post hoc for categorical variables (MDS scores).

Exploratory repeated-measures ANOVA was undertaken to assess whether change in total HEI-C score varied by baseline DQ, based on tertile of initial HEI-C. Differences were considered by sex, age, baseline percentile maximal oxygen uptake, body mass index (BMI), and PROCAM risk score (Assmann et al. 2002). Only sex was a significant covariate (supplementary Table S4¹).

Results

Of the 284 patients who attended baseline dietary, clinical, and laboratory assessment, 205 (72%) completed dietary assessment at 12 months. Baseline characteristics of those who completed baseline and 12 months ($n = 205$) were compared with those who did not ($n = 79$). Participants who did not complete the 12-month assessment were generally younger with a higher BMI and waist circumference, but otherwise had similar disease risk scores (Table 1 and supplementary Table S5¹). Baseline nutrient intake was comparable, with the exception of lower intake of vitamin C in participants who did not complete the 12-month assessment (supplementary Table S6¹). MDS results were available for 144 of the 205 participants (70%) in the study.

Nutrient intake and diet quality changes

The mean energy intake was reduced by 145 ± 586 kcal over 3 months and an additional 76 ± 452 kcal over 3–12 months. The mean change in nutrient intake showed decreased carbohydrate (notably sugar) and fat (saturated and trans fat), while protein intake as percent of energy intake increased (Table 2). Vitamins A and C, folate, magnesium, and potassium increased, while the intake of calcium and sodium decreased.

Total HEI-C score significantly improved at 3 months and was maintained at 12 months, representing a mean improvement of $\sim 10\%$ (9.8 out of 100 points) (Table 3). The improvements were observed in most HEI-C components except *milk and alternatives* and *unsaturated fats*. Some of the most promising changes over 12 months included *total vegetables and fruit* (overall mean improvement of 1.17 points, corresponding to 0.8–0.9 CFG serving), *saturated fat* (overall mean improvement of 1.72 points, corresponding to reduction of $\sim 1.1\%$ energy intake from saturated fats), *sodium* (overall mean improvement of 1.33 points, corresponding to reduction of ~ 384 mg of sodium), and *other foods* (overall mean improvement of 3.19, corresponding to reduction of $\sim 5.6\%$ energy intake from other foods; e.g., salty or sweet snack foods, sweetened beverages, and dessert items).

¹Supplementary data are available with the article through the journal Web site at <http://nrcresearchpress.com/doi/suppl/10.1139/apnm-2019-0070>.

Table 1. Baseline demographics of participants (N = 284) who completed baseline diet assessment.

Baseline demographics	Participants with 12 mo HEI-C assessment, N = 205	Participants without 12 mo HEI-C assessment, N = 79	Whole sample, N = 284	P*
Sex: female	107 (52%)	41 (52%)	148 (52%)	0.964
Age, y	60.2±8.8	56±11.3	59.1±9.7	0.01
Height, m	1.68±0.10	1.69±0.11	1.68±0.10	0.845
Weight, kg	89.0±14.3	94.2±13.6	90.3±13.8	0.006
BMI, kg/m ²	31.4±3.4	33.0±2.9	31.9±3.4	<0.001
Working status				0.618
Employed	115	50	165 (58%)	
Retired	75	22	97 (34%)	
Other	15	7	22 (8%)	
Charleston comorbidity index	0.85±0.87	0.78±0.81	0.83±0.86	0.544
PROCAM risk score [†]	8.61±6.4 (N = 205)	7.3±6.6 (N = 75)	8.26±6.49 (N = 280)	0.136
HEI-C score	58.2±14.5	56.7±13.5	57.8±14.2	0.419
MDS score [†]	4.73±1.60 (N = 144)	4.7±1.68 (N = 63)	4.73±1.62 (N = 207)	0.945
Age-sex percentile for $\dot{V}O_{2max}$ [†]	45.9±23.9 (N = 202)	48.8±24.8 (N = 77)	32.9±6.8 (N = 279)	0.377
Ethnicity				0.860
Europids, whites, sub-Saharan Africans, Mediterranean Middle East [Arab]	33	18	48 (17%)	
Asian and South Central American	12	3	15 (5%)	
United States and Canadian Whites	157	60	217 (76%)	
Ethnicity unclear	3	1	4 (1%)	

Note: Values are means ± SD or n (%). BMI, body mass index; HEI-C, Canadian Healthy Eating Index; MDS, Mediterranean Diet; $\dot{V}O_{2max}$, maximal oxygen uptake.

*Differences between subgroups were analyzed by independent t test for continuous variables and by Pearson χ^2 test for categorical variables and tested for equality of column proportions by z test.

[†]Values of these variables were based on participants with available data. Total number of participants used for calculation in each cell is specified in parentheses.

Table 2. Mean energy and nutrient intake at baseline, 3 months, and 12 months during the dietary intervention (N = 205).

Nutrients	Baseline	3 mo (N = 202)*	12 mo	P [†]
Energy (kcal)	1870±632	1733±526	1646±435	0.0001
Protein (g/d)	84±28	88±26	83±21	0.0780
Protein (% of energy)	18±4.0	20.7±4.3	20.6±4.0	0.0001
Carbohydrate (g/d)	224±86	208±69	198±61	0.0001
Carbohydrate (% of energy)	48±9.2	48±7.9	48±8.2	0.9500
Fibre (g/d)	22±9.8	26.3±11.2	25.2±10.9	0.0001
Fibre per 1000 kcal (g/d)	12.1±4.8	15.5±5.8	15.6±5.9	0.0001
Sugar (g/d)	86±47	81±33	74±29	0.0001
Sugar (% of energy)	18±6.7	19.1±6.2	18.3±5.9	0.1770
Fat (g/d)	70±30	62±25	60±23	0.0001
Fat (% of energy)	33±7.2	32±7.1	32±8	0.0790
SFA (g/d)	24±12	19±9	17±8	0.0001
SFA (%)	11.1±3.4	9.5±2.9	9.3±3.1	0.0001
MUFA (g/d)	23±11	22±10	22±10	0.2710
MUFA (% of energy)	11±4	11±4	12±4	0.3230
PUFA (g/d)	12±6	12±6	12±5	0.8790
PUFA (% of energy)	5.6±2.2	6.1±2.7	6.4±2.4	0.8790
Omega-3 PUFA (g/d)	1.2±0.9	1.6±1.5	1.6±1.1	0.0001
Omega-6 PUFA (g/d)	7.7±5.2	7.8±4.7	9.0±4.5	0.0001
Trans fat (g/d)	0.5±0.5	0.4±0.5	0.4±0.5	0.0250
Cholesterol (mg/d)	266±146	257±136	248±132	0.1710
Vitamin A (IU/d)	7017±6523	10 880±8796	10 874±7926	0.0001
Vitamin B12 (µg/d)	4.7±5.3	4.6±3.5	4.2±3.3	0.4990
Vitamin C (mg/d)	107±72	136±82	126±81	0.0001
Vitamin D (µg/d)	4.0±3.8	4.6±4.3	4.3±3.3	0.4060
Folate (µg/d)	313±126	331±127	334±121	0.0450
Calcium (mg/d)	839±396	858±370	777±321	0.0140
Iron (mg/d)	13.0±4.9	12.8±4.5	12.3±4.2	0.1900
Magnesium (mg/d)	293±118	328±114	325±115	0.0001
Potassium (mg/d)	2748±861	3091±969	2964±907	0.0001
Sodium (mg/d)	2663±1348	2118±890	2091±883	0.0001

Note: Values are means ± SD. MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids; SFA, saturated fatty acids.

*Number completing assessment at 3 months.

[†]By repeated-measures ANOVA over time.

Table 3. Mean change in total Canadian Healthy Eating Index (HEI-C) score and component scores at baseline, 3 months, and 12 months (N = 205).

HEI-C score (range)	Baseline (±SD)	3 mo (±SD)	12 mo (±SD)	Mean change over months (±SE)		
				0–3	3–12	0–12
Mean total HEI-C score (0–100)	58.4 (14.6)	69.4 (12.1)	68.2 (14.0)	10.9 (1.03)***	–1.2 (0.98)	9.8 (1.04)***
Total vegetables and fruit (0–10)	6.6 (2.6)	7.9 (2.2)	7.8 (2.5)	1.34 (0.18)***	–0.17 (0.19)	1.17 (0.21)***
Whole fruit (0–5)	3.6 (1.9)	4.3 (1.4)	4.2 (1.5)	0.70 (0.13)***	–0.07 (0.12)	0.62 (0.14)***
Dark green and orange vegetable (0–5)	2.7 (2.0)	3.7 (1.6)	3.6 (1.7)	1.00 (0.15)***	–0.05 (0.14)	0.95 (0.17)***
Total grains (0–5)	3.4 (1.3)	3.0 (1.3)	3.1 (1.2)	–0.35 (0.11)**	0.07 (0.10)	–0.28 (0.11)*
Whole grains (0–5)	2.7 (1.9)	3.3 (1.6)	3.2 (1.7)	0.59 (0.15)***	–0.06 (0.13)	0.53 (0.15)**
Milk and alternates (0–10)	4.8 (3.2)	5.6 (3.1)	5.0 (2.9)	0.77 (0.24)**	–0.58 (0.23)*	0.19 (0.22)
Meat and alternates (0–10)	8.0 (2.4)	8.5 (2.2)	8.9 (1.9)	0.47 (0.18)*	0.35 (0.20)	0.81 (0.20)***
Unsaturated fat (0–10)	3.3 (3.3)	3.1 (3.0)	2.8 (3.0)	–0.15 (0.26)	–0.29 (0.26)	–0.44 (0.30)
Saturated fat (0–10)	5.8 (3.5)	7.4 (2.9)	7.6 (3.0)	1.59 (0.28)***	0.14 (0.26)	1.72 (0.28)***
Sodium (0–10)	6.5 (3.2)	7.9 (2.2)	7.8 (2.3)	1.40 (0.23)***	–0.06 (0.17)	1.33 (0.22)***
Other foods (0–20)	11.0 (6.4)	14.6 (5.3)	14.2 (5.8)	3.60 (0.49)***	–0.41 (0.41)	3.19 (0.47)***

Note: Statistically significant changes (by repeated-measures ANOVA) over time are as follows: *, $P < 0.05$; **, $P < 0.01$; ***, $P < 0.001$.

MDS also significantly improved at 3 months and was maintained at 12 months, representing a mean improvement of 10% (1.4 out of 14 points) in total MDS at 12 months (Table 4). Half of the MDS components significantly improved and were maintained at 12 months: notably, *poultry more often than red meat* (23.6% increase in the number of participants achieving the criteria), followed by *nuts* (21.6% increase), decreased intake of *red or processed meats* (19.4% increase), and *commercial baked goods* (16% increase), and an increase intake of *vegetables* (16% increase). It should be noted that a large percentage of participants already achieved the criteria for some components at baseline, such as low intake of *butter or cream* and *sugar-sweetened beverages*. Some food behaviours did not change, such as *olive oil as main added fat*, *sofrito sauce (tomato-based sauce)*, and *wine*. Exploratory analysis of the number of people making substantive changes to meet the MDS criteria over 3 months ($n = 144$) showed that 20% made no changes extensive enough to change a score, 26% made 1 change, 22% made 2 changes, 17% made 3 changes, 10% made 4 changes, and 5% or 7 people made 5 or more changes. No combinations of changes emerged as dominant (data not shown).

Repeated-measures analysis

The HEI-C score varied over time by baseline HEI-C, with those in the lowest tertile of HEI-C at baseline making the most changes in food intake, while those in the upper tertile had no change in overall score (Fig. 1). The pattern was similar in males and females and interaction terms were not significant. Comparison of baseline nutrient intake by HEI-C category confirmed that the low HEI-C group differed on intake of multiple nutrients, especially fibre, saturated fat, and sodium (supplementary Table S7¹).

Discussion

There is a need to better understand the type and magnitude of food behaviour changes made by participants in community-based health behaviour studies to develop realistic and effective interventions over time. Use of 3 different dietary assessment tools in this study (i.e., 24-h recalls, HEI-C, and MDS) provided rich information on nutrient intake and DQ, which are needed when examining the potential benefits of diet counselling (Reedy et al. 2017). Results from all 3 dietary assessment methods showed improvements in DQ and nutrient intake that were largely achieved at 3 months and maintained to 12 months. Interpretation of the results must acknowledge the known limitations of dietary assessment tools for assessing individual intake and change over time. Twenty-four-hour recall methods (including multiple 24-h recalls) have had significant development in recent years with the development of online multi-pass methods (e.g., ASA-24-C); however, no self-report can provide an accurate estimate of absolute nutrient intake (Kirkpatrick et al. 2017). HEI-C was developed for epidemiological analysis to assess adequacy and moderation of the

North American diet in populations (Garriguet 2009), while MDS is a food frequency tool used to define specific goals of counselling on key aspects of the Mediterranean diet (Martínez-González et al. 2012). Its 0/1 scoring is simple to implement but does not detect smaller changes in food intake.

To provide context for our findings, we have compared our results (CHANGE study) with those reported in the Canadian Community Health Survey (CCHS) and the 3 other large dietary intervention trials that report incidence of cardiometabolic disease in patients at high cardiometabolic risk: DPP, Look AHEAD, and PREDIMED trials (Knowler et al. 2002; Look AHEAD Research Group et al. 2013; Estruch et al. 2018).

Baseline intake compared with other major studies

The average energy and macronutrient intake of participants at baseline (i.e., kcal intake and percentage of kcals from carbohydrate, protein, and fat) in our study was almost identical to the average intake of Canadian adults (aged 19+ years) as reported in the 2015 CCHS: 1900 kcal/day, 47.7% kcal from carbohydrate, 17.0% kcal from protein, and 32.2% kcal from fat (Statistics Canada 2017). Similar to our study, CCHS used 24-h recalls to assess nutrient intake. In contrast, DPP, Look Ahead, and PREDIMED studies used food frequency questionnaires (FFQs) to assess intake, which tend to overestimate energy intake (Subar et al. 2015). Recognizing the differences in the diet assessment methods, DPP and Look AHEAD, both from the United States, reported baseline mean energy intake (1943 and 1992 kcal, respectively) (Mayer-Davis et al. 2004; Raynor et al. 2015) similar to our study and lower than the average baseline energy intake reported by the PREDIMED study (2210–2320 kcal/day in the 3 groups) (Salas-Salvadó et al. 2008). Whether this higher estimated energy intake in PREDIMED reflects real differences in consumption or differences in diet assessment methods is currently unknown.

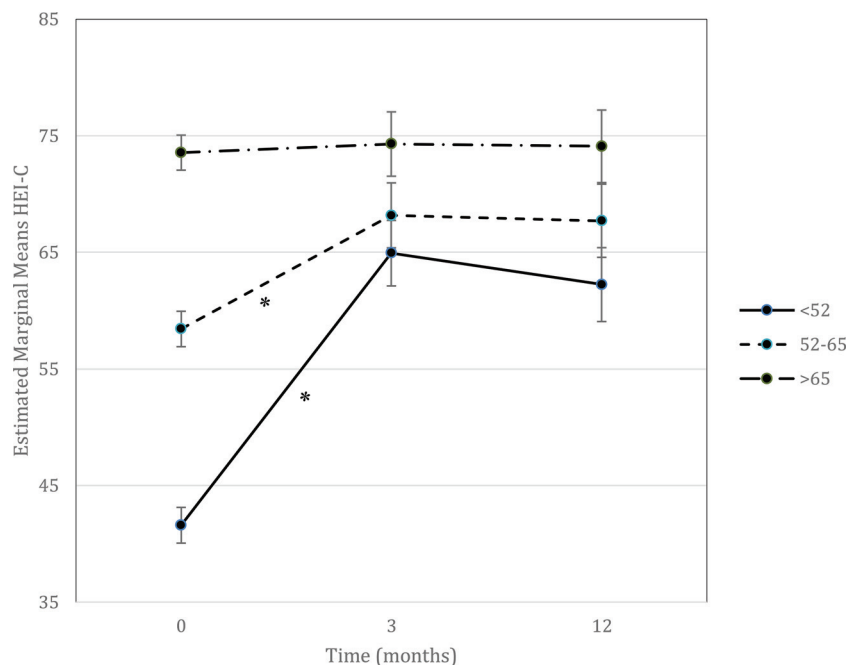
The differences in overall percent of energy as fat in the different studies are felt to reflect real differences, which is in contrast to differences that may be attributable to different diet assessment methodologies. Our results (33% total fat at baseline) were numerically similar to the DPP average (34%) and lower than either the Look AHEAD trial (40%) or the PREDIMED trial (39%) (Mayer-Davis et al. 2004; Salas-Salvadó et al. 2008; Raynor et al. 2015). Only PREDIMED reported intake of monounsaturated fatty acids, which was much higher at baseline than observed in our study (20% vs 11% of kcal) (Salas-Salvadó et al. 2008). In contrast omega-3 polyunsaturated fatty acid intake was modestly higher in our study compared with PREDIMED (1.1 vs 0.6 g/day).

None of the studies reported intake of total carbohydrates or added sugars, which would have been a useful analysis in this group of participants with mixed glucose tolerance levels. Fibre intake varied across studies: our results were 22 g/day, compared

Table 4. Mean Mediterranean Diet Score (MDS) and percentage of participants meeting scoring criteria for each MDS component at baseline, 3 months, and 12 months in participants with complete 12-month data (N = 144).

MDS component	Criteria to achieve a score of 1*	Baseline	3 mo	12 mo	Cochran's Q	P
Total MDS		4.75±1.62a	6.22±1.92b	6.14±1.83b		<0.001
Fruits	≥3 servings/d	28.5 (41)a	34.0 (49)a	36.1 (52)a	2.732	0.255
Vegetables	≥4 servings/d; at least 2 servings raw	14.6 (21)a	31.3 (45)b	30.6 (44)b	15.361	<0.001
Red or processed meats	<2 servings/d	68.8 (99)a	86.8 (125)b	88.2 (127)b	22.523	<0.001
Poultry more often than red meat	Yes	53.5 (77)a	74.3 (107)b	77.1 (111)b	29.6	<0.001
Legumes	≥3 servings/wk	6.9 (10)a	11.8 (17)ab	15.3 (22)b	5.892	0.053
Fish or seafood	≥4 servings/wk	13.2 (19)a	21.5 (31)a	21.5 (31)a	5.647	0.059
Nuts	≥3 servings/wk	34.0 (49)a	57.6 (83)b	55.6 (80)b	25.927	<0.001
Butter or cream	<1 tbspd	70.8 (102)a	85.4 (123)b	85.4 (123)b	15.207	<0.001
Olive oil	≥4 tbspd	4.9 (7)a	2.1 (3)ab	0 (0)b	8.222	0.016
Olive oil as main added fat	Yes	36.8 (53)a	45.1 (65)a	39.6 (57)a	2.909	0.234
Wine	≥7 servings/wk	7.6 (11)a	6.3 (9)a	2.8 (4)a	5.2	0.074
Commercial baked goods	≤2 times/wk	47.2 (68)a	68.8 (99)b	63.2 (91)b	22.853	<0.001
Sugar-sweetened beverages	<1 time/d	88.2 (127)a	95.1 (137)b	97.9 (141)b	17.333	<0.001
Sofrito sauce	≥2 times/wk	0 (0)a	1.4 (2)a	0.7 (1)a	3.0	0.223

Note: Values are means ± SD or % (n). Proportions in a row with same lowercase letter did not differ from each other at significance level of $P < 0.05$. 1 tbspd = 15 mL. *Criteria values were adjusted to match servings from Canada's Food Guide (Health Canada 2007; see supplementary Table S3').

Fig. 1. Mean total Canadian Healthy Eating Index (HEI-C) score of participants at baseline, 3 months, and 12 months, displayed by category of baseline HEI-C score, and adjusted for sex. Overall, group over time differences were highly significant ($P < 0.001$). *, $P < 0.05$ the statistical significance of change in HEI-C score in each group over time was estimated from the 95% confidence intervals. [Colour online.]

with a lower intake of 15 g/day in the DPP, 19 g/day in Look AHEAD, and 24 g/day in PREDIMED (Mayer-Davis et al. 2004; Salas-Salvadó et al. 2008; Raynor et al. 2015).

Baseline average DQ as assessed by total HEI-C was similar to the Canadian population as reported in the 2004 CCHS (total HEI-C = 58.8) (Garriguet 2009). Component scores showed a lower intake of unsaturated fats for CHANGE compared with CCHS (3.3 vs 8.3), which cannot be explained. HEI was not assessed in other major studies for comparison. We have a Canadian assessment of adherence to the Mediterranean diet, which showed that baseline MDS in CHANGE was much lower than in the Spanish PREDIMED trial (4.8 vs 8.6) (Estruch et al. 2018). This was largely accounted for by higher scores in the PREDIMED trial for a dietary pattern that included more fish and legumes, lower intake of red or processed meats, and regular inclusion of wine, olive oil, and sofrito sauce (a staple of Spanish cooking).

Dietary changes over time compared with other major studies

The average reduction in energy intake over 12 months was about 200 kcal in CHANGE, which was accompanied by a modest ~3% average weight loss (Jeejeebhoy et al. 2017). Reductions in energy intake were double this amount in the DPP and Look AHEAD trials and were confirmed by greater weight loss at 1 year (7.2% weight loss in DPP and 8.6% weight loss in Look AHEAD) (Mayer-Davis et al. 2004; Raynor et al. 2015). In contrast, PREDIMED reported no change in overall energy intake or weight (Salas-Salvadó et al. 2008). CHANGE results are more modest than the average of 283 kcal reported in a meta-analysis of lifestyle studies on metabolic syndrome (Yamaoka and Tango 2012).

In CHANGE, reduced energy intake was accompanied by modest reductions in total fat intake (33% to 32% of kcal). Total fat reductions reported in other trials are divergent. Both DPP

(Mayer-Davis et al. 2004) and Look AHEAD (Raynor et al. 2015) reported substantive reductions in mean percentage of energy from fat (DPP: 34.3% to 27.5%; Look AHEAD: 40% to 34.2%), whereas PREDIMED intervention groups reported a modest increase in fat intake (39%–40% to 40.7%–42.6%) from primarily polyunsaturated fat (Salas-Salvadó et al. 2008). Saturated fat declined from 11% to 9% in CHANGE and also declined in the other studies (DPP: 11.5% to 8.7%; Look AHEAD: 13.1% to 10.1%; PREDIMED control: 9.9% to 9.4%). The decreased carbohydrate intake (notably sugar intake, including mono- and disaccharides) that was evident in CHANGE cannot be compared with other studies, which failed to report this from FFQ analysis.

A consistent finding in CHANGE was that intake of vegetables and fruits can be increased by a mean of almost 1 serving/day, as seen by improvements in these components assessed by HEI-C and also improvements in MDS. This was confirmed by nutrient analysis that showed increased intake of vitamin A, vitamin C, folate, magnesium, and potassium. Sodium reduction (~400 mg/day) was another dietary improvement in CHANGE, which translated to improved scores on HEI-C.

Mediterranean diet changes

Although total score for MDS in CHANGE started much lower at baseline than PREDIMED, the overall increase in MDS observed in CHANGE (1.4/14 points) was of similar magnitude to the increase in PREDIMED intervention groups (1.9/14 points) (Estruch et al. 2018). In PREDIMED, the increase was primarily attributed to increasing intake of olive oil and nuts (products that were provided to participants in the PREDIMED trial), but also increased in the groups who did not receive the supplemental foods. For example, after 1 year, 58% of the control group and 78% of the nut group met the criteria of >4 tablespoons (60 mL) per day of olive oil. The contrast between CHANGE participants and PREDIMED on fish and legumes were especially marked. After 1 year, 19% of CHANGE participants met the criteria for fish compared with 63% in the PREDIMED control group (Estruch et al. 2018). Only 13% of CHANGE participants met the legume criterion after 1 year, while 29% of PREDIMED control subjects and over 40% of intervention subjects met this criterion. Thus, there are numerous differences in the cuisines of the 2 countries, and addition of 1 or 2 foods to the Canadian diet will not achieve a Mediterranean diet.

Exploratory subgroup analysis

Our exploratory analysis examined whether baseline diet as measured by HEI-C score impacted the ability to make improvements in DQ. Results suggest that RD counselling is most beneficial in those with poorer diets, while those with initially good diets make few changes, at least according to HEI-C score. The observation may help explain why some other studies of Mediterranean style diet in Canada have not seen much change in HEI-C with diet counselling (Asaad et al. 2016), since initial DQ was relatively good. This novel observation requires confirmation in other diverse patient samples.

Study strengths and limitations

This program for treating MetS had good retention, with 72% of participants enrolled completing dietary assessments at 12 months. We decided to focus results on those who completed all dietary assessments, since little has been published on the specifics of dietary change among participants with MetS. Participants who did not complete the study tended to be younger, with a higher BMI and waist circumference. Addressing specific issues of people who drop out of programs should be a focus of future studies. Another strength of the study was the analysis using different dietary assessment tools that allowed for comparison with other relevant large studies. Use of food frequency tools revealed the substantive difference in the cuisines of Spain and Canada and made it possible to determine which foods were most likely to

change over time, providing much needed intermediate data to inform future diet intervention studies for the Canadian context. The MDS data reveal substantive differences in baseline diets, as seen by using the same tool in both studies and suggest that many dietary changes would be needed to achieve a Mediterranean diet among most Canadians.

A significant limitation of this and other studies is the limited validity of dietary assessment tools in intervention studies. Additional focus on developing relevant diet assessment tools for the Canadian context is urgently needed. Another limitation of the study was the shift to Mediterranean diet principles 6 months into the study, and the subsequent reduction in the numbers with complete MDS data. This subset of subjects would have been exposed to Mediterranean principles, but it is possible that greater adoption of a Mediterranean style diet can be achieved in future work.

We chose a tailored individualized approach to the diet counselling intervention, which did not prescribe a particular “diet”, in an effort to better meet the needs of the range of patients with MetS in practice, many of whom have a history of dieting and are not good candidates for weight loss programs. Such patients could benefit from qualitative changes in the foods they eat to be consistent with the principles of more whole-foods dietary patterns, including Canada’s Food guide, DASH, and Mediterranean diets (Schulze et al. 2018). We believe we were relatively successful and contrast our overall retention rates of 70% with the 53% (6-month) and 37% (9-month) retention rate seen in a recent implementation study of the DPP, with its emphasis on weight loss (Hillmer et al. 2017).

Conclusions

This study used multiple dietary tools (i.e., 24-h recalls, HEI-C, MDS) to assess nutrient intake and dietary quality in individuals participating in a lifestyle intervention program for MetS. Participants with MetS in the CHANGE study had a range of baseline diets and mean nutrient intakes that were comparable to the general Canadian population. Changes in dietary intake occurred in the first 3 months of the intervention and were maintained to 12 months. Over 12 months of the diet intervention, energy intake modestly decreased, reflected in decreased sugar, saturated fat, and trans fat intake, with a proportionate increase in protein. The major changes to dietary patterns included: increased vegetables and fruits, increased nuts, decreased “other foods” (i.e., foods and beverages high in calories, fat, sugar, or salt), and decreased intake of red and processed meats. Increasing intake of fish and legumes to recommended levels was not common and will require specific strategies to support dietary change. Exploratory analysis suggested that poor DQ at baseline is associated with greater dietary changes as assessed by HEI-C. Additional work is needed to confirm this finding. Use of multiple tools provided complementary information on DQ and nutrient intake.

Conflict of interest statement

Paula Brauer, Dawna Royall, David Mutch, and Angelo Tremblay received grants for program development from Metabolic Syndrome Canada. Rupinder Dhaliwal was paid for their work on the study by Kingston General Hospital and Queen’s University from this grant. Rupinder Dhaliwal became an employee of Metabolic Syndrome Canada after the completion of study enrolment. Caroline Rhéame and Doug Klein received grants as participating sites for patient enrolment and data collection from Metabolic Syndrome Canada. Khursheed Jeejeebhoy is on the board of directors for Metabolic Syndrome Canada and was involved in discussions about fundraising for this nonprofit organization. The other authors have no conflicts of interest to report.

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