

Family physician–led, team-based, lifestyle intervention in patients with metabolic syndrome: results of a multicentre feasibility project

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Abstract

Background: Metabolic syndrome (MetS) is a medical condition with major complications and health care costs. Previous research has shown that diet and exercise can improve and reverse this condition. The goal of this study was to test the feasibility and effectiveness of implementing the Canadian Health Advanced by Nutrition and Graded Exercise (CHANGE) program into diverse family medicine practices to improve MetS.

Methods: In this longitudinal before–after study, 305 adult patients with MetS were recruited from 3 diverse family medicine team-based organizations to the CHANGE personalized diet and exercise program. Participants were followed for 12 months. Primary outcomes included feasibility and reversal of MetS. Secondary outcomes included improvement in MetS components, changes in diet quality, aerobic fitness and cardiovascular risk.

Results: Participants attended 76% and 90% of the kinesiologist and dietitian visits, respectively. At 12 months, 19% of patients (95% confidence interval [CI] 14%–24%) showed reversal of MetS, VO_{2max} increased by 16% (95% CI 13%–18%), and Healthy Eating Index and Mediterranean Diet Scores improved by 9.6% (95% CI 7.6%–11.6%) and 1.4% (1.1%–1.6%), respectively. In addition, the Prospective Cardiovascular Munster (PROCAM) 10-year risk of acute coronary event decreased by 1.4%, from a baseline of 8.6%.

Interpretation: A team-based program led by the family physician that educates patients about the risks of MetS, and with a dietitian and kinesiologist, empowers them to undertake an individualized supervised program of diet modification and exercise, is feasible, improves aerobic capacity and diet quality, reverses MetS and improves MetS components at 12 months.

Metabolic syndrome (MetS) refers to a cluster of 5 risk factors — hyperglycemia, hypertension, hypertriglyceridemia, low high-density lipoprotein cholesterol (HDL-C) and abdominal obesity¹ — that increase the risk for cardiovascular disease and type 2 diabetes.^{2–4} The basis of MetS is the insulin resistance associated with abdominal obesity, and this adiposity is a criterion for MetS, rather than weight.⁵ The concept of MetS has been criticized^{6,7} despite its wide acceptance by the World Health Organization,⁸ the National Cholesterol Education Program–Adult Treatment Panel III⁹ and the International Diabetes Federation.¹⁰ In addition to the features of MetS, other indices such as the Framingham and Prospective Cardiovascular Munster (PROCAM) scores¹¹ provide additional evidence for increased cardiovascular risk.⁵ In Canada, 20% of

the adult population has MetS,¹² with prevalence increasing with age,¹³ and patients with MetS are reported to have double the annual health care costs and use health services more frequently than those without.^{14,15} Lifestyle intervention trials have shown the potential to improve clinically relevant outcomes. The Diabetes Prevention Program for patients without diabetes but who have elevated fasting blood glucose

Competing interests: See end of article.

This article has been peer reviewed.

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CMAJ Open 2017. DOI:10.9778/cmajo.20160101

was the first large controlled trial of lifestyle intervention showing a much lower rate of clinical diabetes over 4 years (2%) compared with patients given metformin (8%) or a placebo (11%).¹⁶ A more recent large controlled trial from Spain showed that the Mediterranean diet alone (no physical activity component) reduced the risk of cardiovascular events by 30% over 4 years in patients who were already receiving pharmacological therapy.¹⁷ A recent meta-analysis of smaller clinical trials reported that diet and exercise are effective in resolving MetS and reducing the severity of its related abnormalities.¹⁸ Aerobic exercise training resulting in increased aerobic capacity has been shown to reduce insulin resistance, which is the basis of MetS.¹⁹

Despite these promising results, uptake of lifestyle-focused preventive care for cardiovascular risk into Canadian primary care settings remains limited.²⁰ Demonstration of the feasibility of efficacious interventions is needed. In patients without symptoms, the presence of MetS would be first detected by the family physician; in a recent primary care consensus statement, lifestyle modification has been emphasized as a key therapy.²¹ We hypothesized that a team-based program led by the family physician (called the Canadian Health Advanced by Nutrition and Graded Exercise [CHANGE] program) that educates the patient about the risks of MetS and empowers him or her to undertake an individualized supervised program of diet modification and exercise, would be feasible, sustainable over a year of observation, improve aerobic capacity and diet quality, reverse MetS and improve its components at 12 months.

Methods

Setting and design

This was a prospective, longitudinal before–after feasibility study conducted in 3 diverse primary care clinics across Canada (Edmonton Oliver Primary Care Network, Edmonton; Unité de médecine familiale Laval, Québec; Polyclinic Family & Specialty Medicine, Toronto), with recruitment from October 2012 to December 2014. Eligibility criteria were designed to enrol adult patients who met the criteria for MetS.¹ We excluded patients who, for medical, safety or logistic reasons, would be unable to participate in the longitudinal design of the study (refer to supplementary file for eligibility criteria [Appendix 1, available at www.cmajopen.ca/content/5/1/E229/suppl/DC1]). Eligible patients were approached for consent and placed in the CHANGE program by their family physician. Each patient was seen by the registered dietitian for individualized counselling, based on a care map that incorporated evidence from clinical trials and principles of health behaviour change from the integrated behavioural model,²² with an emphasis on the Mediterranean diet.²³ Each patient was also seen by the clinic kinesiologist for assessment of their fitness and physical activity habits and for an individualized fitness plan that included supervised and unsupervised aerobic activity, resistance training and flexibility exercises. Fitness, muscular endurance, vigour and flexibility were assessed using established assessment tests.²⁴ The

program prescribed follow-up visits with the family physician at 3, 6, 9 and 12 months for a review of blood pressure, glucose, lipids (triglycerides, high-density lipoprotein cholesterol [HDL-C]), medications and changes in waist circumference and body weight. Weekly visits with the dietitian and kinesiologist for the first 3 months were followed by monthly visits for 9 months (refer to supplementary program overview [Appendix 2, available at www.cmajopen.ca/content/5/1/E229/suppl/DC1]). Ongoing encouragement was provided by all staff to support the patient in making lifestyle changes based on progress achieved in MetS components.

Outcomes

The primary outcomes of the study were feasibility (defined by % diet and exercise visits attended over 12 mo) and the reversal of MetS, defined as less than 3 out of the 5 criteria, where the 5 criteria are defined in the legend to Table 1. Secondary outcomes included improvement in the individual components of MetS, diet quality as determined by two 24-hour recalls 1 week apart that were used to calculate the Canadian Health Eating Index (HEI-C)²⁵ and Mediterranean Diet Score (MDS),²⁶ aerobic capacity assessed by maximal oxygen consumption (VO_{2max}),²⁷ PROCAM score for assessing risk of myocardial infarction¹¹ (the PROCAM score was chosen owing to its simplicity and accuracy at predicting global risk of myocardial infarction in clinical practice and its relevance to MetS), and continuous metabolic syndrome (cMetS) score,²⁸ which is believed to be more sensitive than the common binary score.

Sample size

We aimed to enrol a total of 300 patients from 3 sites. This sample size would provide a 95% chance of estimating the true MetS reversal rate to within 5%, assuming the reversal rate was 25% or less. Conservatively assuming that the number of dietitian contacts and fitness visits were uniformly distributed between 0 and 21, this sample size would have a 99% chance of estimating the true proportion of prescribed visits and contacts attended at the participating sites to within 5%. For continuous outcomes, this sample size would provide 93% power at 2-sided α value of 0.05 to detect a within-patient change that is 1/5th of the standard deviation of the change values, which is considered a small effect size by Cohen convention.²⁹

Statistical analyses

The analyses included all patients with any follow-up data regardless of compliance with the program. Enrolled patients who did not meet the criteria for MetS at baseline or who had a baseline fasting blood glucose level of more than 11 mmol were excluded. Baseline characteristics were compared between patients who did and did not have the 12-month laboratory assessment using independent *t* test for continuous variables and the χ^2 test for categorical variables. For all continuous outcomes, data at each time point are presented as raw mean and standard deviation (SD). To reduce potential biases due to missing data, we estimated the expected mean

values and the expected change from baseline using the linear mixed effect model including all available assessments and allowing for an unstructured within-patient correlation. This model, estimated by restricted maximum likelihood, treated

time as a categorical variable and included age and sex as covariates. When some, but not all, laboratory variables were available at an assessment, we used the expectation maximization (EM) algorithm to impute the most likely missing values

Table 1: Baseline patient characteristics

| Characteristic | All eligible patients <i>n</i> = 293 | Patient with 12-month laboratory assessment <i>n</i> = 253 | Patient without 12-month laboratory assessment <i>n</i> = 40 | <i>p</i> values* |
|--|---|---|---|------------------|
| Age, yr, mean ± SD | 59.1 ± 9.7 | 60.3 ± 9.0 | 51.4 ± 11.1 | < 0.001 |
| Female sex, no. (%) | 152 (52) | 131 (52) | 21 (53) | 0.93 |
| Charlson comorbidity index | 0.8 ± 0.9 | 0.9 ± 0.9 | 0.6 ± 0.9 | 0.02 |
| Height, m, mean ± SD | 1.7 ± 0.1 | 1.7 ± 0.1 | 1.7 ± 0.1 | 0.02† |
| Weight, kg, mean ± SD | 90.8 ± 14.7 | 89.4 ± 13.4 | 99.5 ± 18.8 | < 0.001 |
| BMI, kg/m ² , mean ± SD | 31.9 ± 3.3 | 31.7 ± 3.4 | 33.4 ± 2.8 | 0.002 |
| Current smoker, no. (%) | 29 (10) | 27 (11) | 2 (5) | 0.55 |
| PROCAM risk, %, mean ± SD | 8.2 ± 6.4 | 8.6 ± 6.3 | 5.6 ± 6.8 | 0.006 |
| VO _{2max} , %, mean ± SD | 46.8 ± 24.0 | 46.2 ± 24.0 | 50.4 ± 24.6 | 0.31 |
| HEI-C, mean ± SD | 57.9 ± 14.2 | 58.6 ± 14.3 | 52.8 ± 12.8 | 0.03 |
| Mediterranean diet score, mean ± SD | 4.7 ± 1.6 | 4.8 ± 1.6 | 4.3 ± 1.7 | 0.12 |
| LDL-C, mmol/L, mean ± SD | 2.6 ± 1.1 | 2.6 ± 1.1 | 2.9 ± 1.0 | 0.06 |
| Metabolic syndrome criteria‡ | | | | |
| 1. Blood pressure or pharmacotherapy, no. (%) meeting criteria | 256 (87) | 227 (90) | 29 (73) | 0.002 |
| Systolic blood pressure, mm Hg, mean ± SD | 133.5 ± 14.5 | 133.5 ± 14.8 | 133.8 ± 12.9 | 0.88 |
| Diastolic blood pressure, mm Hg, mean ± SD | 80.6 ± 9.1 | 79.9 ± 9.0 | 84.9 ± 9.0 | 0.001 |
| Received pharmacotherapy for elevated blood pressure, no. (%) | 218 (74) | 196 (77) | 22 (55) | 0.002 |
| 2. Fasting blood glucose or pharmacotherapy, no. (%) meeting criteria | 240 (82) | 212 (84) | 28 (70) | 0.04 |
| Blood glucose, mmol/L, mean ± SD | 6.6 ± 1.4 | 6.6 ± 1.4 | 6.1 ± 1.1 | 0.04 |
| Received pharmacotherapy for elevated blood glucose levels, no. (%) | 129 (44) | 120 (47) | 9 (22) | 0.003 |
| 3. Triglyceride or pharmacotherapy, no. (%) meeting criteria | 187 (64) | 162 (64) | 25 (62) | 0.85 |
| Triglyceride level, mmol/L, mean ± SD | 2.2 ± 1.7 | 2.2 ± 1.8 | 2.2 ± 1.1 | 0.98 |
| Pharmacotherapy for cholesterol, no. (%) | 11 (4) | 10 (4) | 1 (2) | 0.65 |
| 4. HDL-C, no. (%) meeting criteria | 138 (47) | 119 (47) | 19 (47) | 0.99 |
| HDL-C, mmol/L, mean ± SD | 1.2 ± 0.3 | 1.2 ± 0.3 | 1.2 ± 0.3 | 0.33 |
| 5. Waist circumference, no. (%) meeting criteria | 277 (95) | 237 (94) | 40 (100) | 0.1 |
| Waist circumference, cm, mean ± SD | 108.1 ± 9.4 | 107.3 ± 8.9 | 113.4 ± 10.7 | < 0.001 |
| <p>Note: BMI = body mass index, HDL-C = high-density lipoprotein cholesterol, HEI-C = Canadian Healthy Eating Index, LDL-C = low-density lipoprotein cholesterol, PROCAM = (estimated risk of major cardiac event in next 10 years), SD = standard deviation.</p> <p>*Baseline characteristics were compared between patients who did and did not have the 12-month laboratory assessment using independent <i>t</i> test for continuous variables and the χ^2 test for categorical variables.</p> <p>†Although the height rounds to 1.7 m in both groups, the actual values are 1.72 and 1.68, which is a significant (<i>p</i> = 0.02) but not clinically important difference.</p> <p>‡Metabolic syndrome criteria defined as follows: blood pressure ≥ 130/85 mm Hg or receiving pharmacotherapy; fasting blood glucose ≥ 5.6 mmol/L or receiving pharmacotherapy; triglyceride level ≥ 1.7 mmol/L or receiving pharmacotherapy; male patients with an HDL-C level < 1.0 mmol/L or female patients with an HDL-C level < 1.3 mmol/L; waist circumference as determined by a prespecified technique (Europid, white, sub-Saharan African, Mediterranean, middle eastern [Arab] patients ≥ 94 cm for men, 80 cm for women; Asian and South Central American patients ≥ 90 cm for men and 80 cm for women; white American and Canadian patients ≥ 102 cm for men, 88 cm for women).</p> | | | | |

based on the available values. Nonparametric locally weighted regression smoothing (LOESS)³⁰ was used to display the association between the baseline PROCAM risk and the change in this risk by 12 months. All *p* values are 2-sided without adjustment for multiplicity of tests. To address the multiplicity of outcome testing, a false discovery rate was calculated for all outcome *p* values.³¹ We considered significance confirmed when the false discovery rate remained below 0.05. All analyses were performed using SAS version 9.4.

Ethics approval

Approvals 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 and Institutional Review Board Services, A Chesapeake IRB Company (Aurora, Ont.).

Results

Patient recruitment and feasibility

Recruitment into the CHANGE program over the 2-year period at the 3 participating sites met the target rate of a mean of 4 patients per site per month, for a total recruitment of 305 patients. Twelve patients were excluded. Figure 1 details the follow-up of the enrolled patients (*n* = 305). Baseline patient characteristics are presented in Table 1. Of the 293 included patients, 40 (14%) did not have 12-month laboratory data. Patients without a 12-month laboratory assessment tended to be younger, with fewer comorbidities, and with a lower baseline PROCAM risk of major cardiovascular events, but were heavier and had a worse HEI-C. The median (interquartile range [IQR]) diet contacts and fitness visits were 19 (14–21) and 16 (10–20), suggesting that the median patient had 90% of the 21 prescribed dietitian contacts and attended 76% of the 21 prescribed fitness visits.

Aerobic capacity and diet quality

The mean of the age–sex standard population-based percentiles of aerobic capacity as measured by estimated VO_{2max} increased significantly over 12 months (mean percentile increase 16%, 95% confidence interval [CI] 13%–18%). Both diet quality scores, HEI-C and MDS, improved significantly over time (95% CI 7.6%–11.6% and 1.1%–1.6%, respectively) (Table 2).

Metabolic reversal

At 12 months, 19% of patients (95% CI 14%–24%) showed reversal of MetS; the rate plateaued at 6 months, but remained stable for 12 months, showing no regression with time (Table 3). Compared with baseline, the percentage of patients who had a decrease in the number of MetS criteria was 33% at month 3 (*n* = 263), 41% at month 6 (*n* = 244), 43% at month 9 (*n* = 227) and 42% at month 12 (*n* = 253) (data not shown). Systolic and diastolic blood pressures, triglycerides and waist circumference all improved significantly at 3, 6, 9 and 12 months (all *p* < 0.0001), whereas improvements were seen in HDL-C levels only after 6 months (Appendix 3, available at www.cmajopen.ca/content/5/1/

E229/suppl/DC1). Reductions in fasting blood glucose were significant at 3 and 6 months, but not at 9 or 12 months.

PROCAM risk and cMetS scores

At 12 months, the mean PROCAM 10-year risk of myocardial infarction or acute coronary event decreased by 1.4% (95% CI 0.9%–2.0%, *p* < 0.0001) from a baseline risk of 8.4%. Patients with the highest baseline risk showed the most substantial improvement in the PROCAM risk score (Figure 2). The cMetS score decreased by 0.4 (95% CI 0.3–0.5, *p* < 0.0001) at 12 months.

Interpretation

In this multicentre feasibility project, we successfully enrolled 305 patients over 2 years across 3 diverse Canadian primary care settings. Most patients were able to continue for 12 months of observation (*n* = 253/293), and many of those who did not have a 12-month laboratory assessment were unable to have one owing to work-related issues (e.g., long-distance truck driving). Attendance at the intended diet and fitness visits was generally good. We showed a significant reversal rate of MetS and significant improvements in aerobic and diet indices at 3 months, which were sustained at 12 months. This was associated with a significant improvement in blood pressure, triglyceride levels and waist circumference at 3, 6, 9 and 12 months (all *p* < 0.0001). When the false discover rate was calculated to account for the multiplicity of outcome testing, all outcomes with a nominal *p* value of less than 0.05 had a false discover rate below 5%, thus all conclusions remained intact. This robustness to adjustment for multiple comparisons is a consequence of most of the *p* values being so highly significant.

The “lost to follow-up” rate of 14% in this study is within the ranges seen in other lifestyle intervention studies in primary care patients with MetS (11%²⁴ to 30%³²). The baseline HEI-C was similar to that found in the 2004 Canadian Community Health Survey among Canadians 2 years of age and older,²⁵ while no comparable Canadian data exists for MDS. The changes in the individual components of MetS in our study are also comparable to other studies.^{32,33} The improvements in fitness and cardiovascular risk factors are similar to those reported in the first year of follow-up in a recent multicentre randomized trial that promoted weight loss and physical activity in overweight patients with type 2 diabetes.³⁴ Contrary to the Look AHEAD trial, our intervention focused on reversing MetS (and not only weight loss) and emphasized changes in the dietary composition (e.g., the Mediterranean diet pattern).³⁵ The relevance of purely reversing MetS has been criticized by some^{6,7} and therefore it is noteworthy that our intervention was associated with a 17% relative risk reduction in the 10-year risk of acute myocardial infarction from baseline.¹¹ In addition, the reduction in the cMetS score by 0.4 at 12 months translates into a relative reduction of 19% and 17% in the incidence of cardiovascular disease and coronary heart disease over 9 years, respectively.²⁸ Of greater importance is that our results show that the program seemed to have had the great-

est effect on those with the highest risk of an acute myocardial infarction at baseline. In high-risk patients with insulin resistance, the use of a clinically approved drug aimed at targeting this resistance, pioglitazone, was associated with a sig-

nificantly lower incidence of stroke or myocardial infarction compared with placebo (9% v. 11.8%, $p < 0.007$) over 4.8 years, but was associated with serious side effects that included fractures, weight gain and edema.³⁶

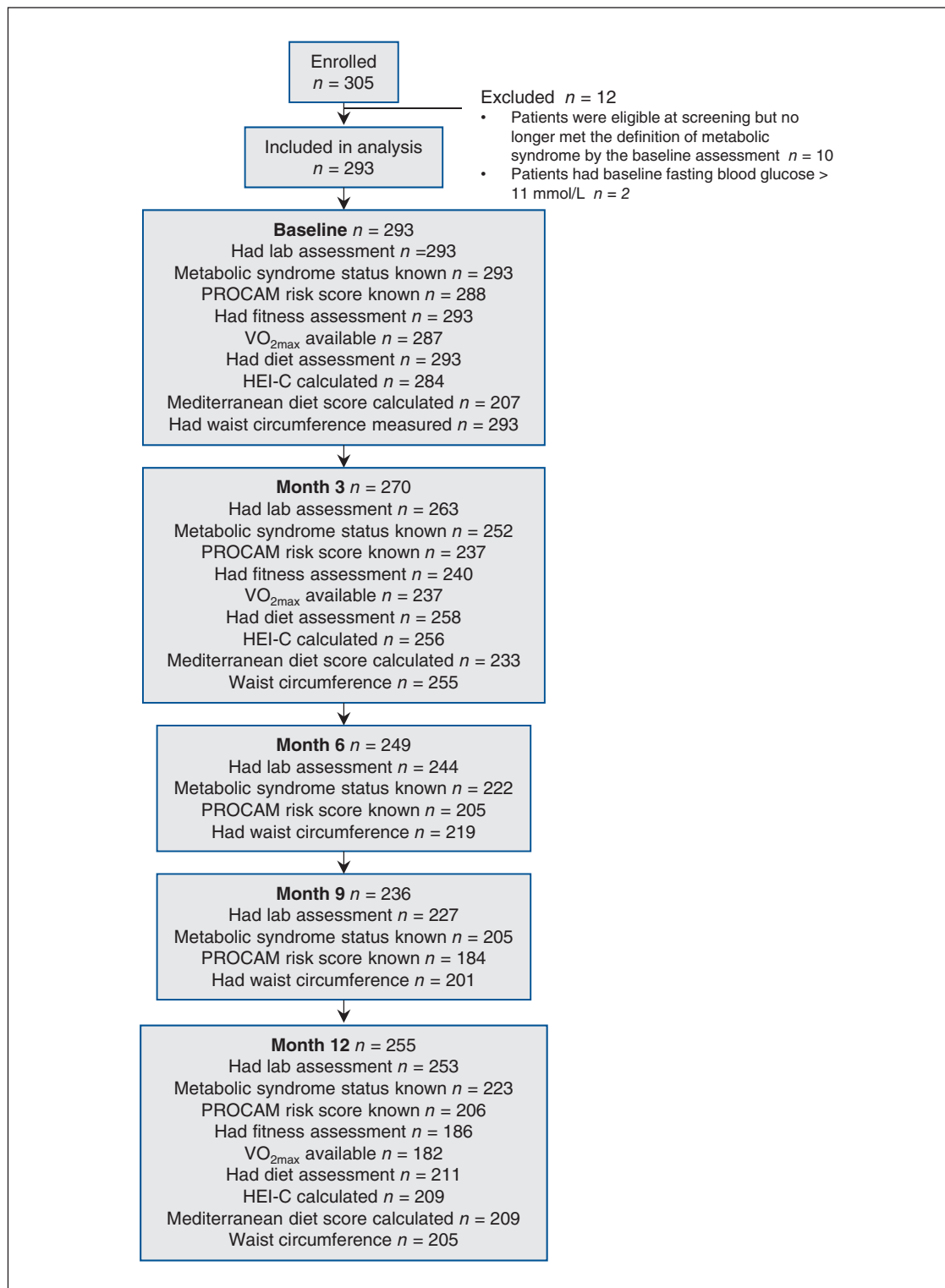


Figure 1: Flow of participants through the study. HEI-C = Canadian Health Eating Index, PROCAM = Prospective Cardiovascular Munster, VO_{2max} = maximal oxygen consumption.

In the present study, at baseline, 74% of the patients were receiving pharmacotherapy for hypertension and 44% for hyperglycemia, yet these patients continued to have uncontrolled hypertension and hyperglycemia, consistent with MetS. Hypertriglyceridemia was not usually treated with pharmaco-

therapy (4%) in our study population, and no effective pharmacotherapy exists for low HDL-C and abdominal obesity. Hence, despite the use of pharmacotherapy, there is a clear need for better control of MetS, and we have shown that this can be achieved through a feasible diet and exercise program in a primary care setting.

Table 2: Change in aerobic capacity and diet quality

| Month | Raw values no.* (mean ± SD) | Maximum likelihood, † mean ± SE | Maximum likelihood change from baseline, † mean (95% CI) | p value |
|--|-----------------------------------|---------------------------------------|---|----------|
| Age–sex standardized VO _{2max} percentile | | | | |
| 0 | 287 (46.8 ± 24.0) | 46.9 ± 1.2 | | |
| 3 | 238 (59.7 ± 22.4) | 60.5 ± 1.1 | 13.6 (11.7–15.6) | < 0.0001 |
| 12 | 182 (63.0 ± 20.6) | 62.5 ± 1.2 | 15.6 (13.3–17.9) | < 0.0001 |
| Canadian Healthy Eating Index (range 0–100) | | | | |
| 0 | 284 (57.9 ± 14.2) | 57.9 ± 0.8 | | |
| 3 | 256 (68.6 ± 12.4) | 68.5 ± 0.8 | 10.6 (8.8–12.4) | < 0.0001 |
| 12 | 209 (68.0 ± 14.1) | 67.5 ± 0.9 | 9.6 (7.6–11.6) | < 0.0001 |
| Mediterranean diet score range (0–14) | | | | |
| 0 | 207 (4.7 ± 1.6) | 4.8 ± 0.1 | | |
| 3 | 233 (6.1 ± 2.0) | 6.2 ± 0.1 | 1.4 (1.1–1.6) | < 0.0001 |
| 12 | 209 (6.2 ± 1.9) | 6.2 ± 0.1 | 1.4 (1.1–1.6) | < 0.0001 |

Note: CI = confidence interval, SD = standard deviation, SE = standard error.
*No. of patients where the variable was captured.
†The maximum likelihood mean and change use all available data to estimate the expected values using within patient correlations between outcomes and time points. The maximum likelihood mean is estimated for a 60-year-old assuming even numbers of men and women.

Table 3: Reversal of metabolic syndrome

| Month | Observed metabolic reversal rates | |
|-------|---|-------------------------|
| | Number reversed/total number assessed (% reversal) | 95% CI of % reversal |
| 0 | 0/293 (0) | 0 |
| 3 | 35/263 (13) | 9–17 |
| 6 | 53/244 (22) | 17–27 |
| 9 | 49/227 (22) | 16–27 |
| 12 | 48/253 (19) | 14–24 |

Note: CI = confidence interval.

Strengths and limitations

One strength of this study is the demonstration of the value of a primary care team to deliver an individualized approach for the management of MetS. In addition to a reversal of MetS, we have shown that a lifestyle intervention like the CHANGE program may have a positive effect on cardiovascular outcomes, with the greatest effect seen in patients with the highest risk. A recent Canadian study reported the infrequent assessment of cardiovascular risk and counselling on healthy behavioural changes, and concluded that a paradigm change in assessing and managing cardiovascular risk via aggressive lifestyle interventions is warranted.²⁰ The CHANGE program addresses these concerns within a primary care setting.

Limitations of this study include the lack of a control group; however, the intent of this study was to show the feasibility of this approach in real-life primary care settings. Furthermore, the before and after nature of our longitudinal cohort design allows us to make some, albeit weak, inferences about the effectiveness of the program.

Because the study was conducted at 3 centres, we acknowledge that the results may not be generalizable to all primary care teams across Canada, and that program modifications may need to be made to meet the needs of diverse primary care teams. Like any lifestyle intervention trial requiring patient consent, selection bias when enrolling patients likely occurred. Social desirability bias might affect reported food intake, but this would be comparable at all 3 points of diet assessment for each patient. Recall bias, generally under-reporting, was minimized by shortening the diet recall period to the past 24 hours and using the multipass method developed by the National Cancer Institute.³⁷ Two recalls were taken, about 1 week apart at each assessment point, and the mean values recorded owing to the high intra-individual variation in food intake day to day. Recall bias would not affect clinical indicators that were used to calculate reversion of MetS and the PROCAM score; although diet recall issues are relevant in diet counselling, they would have little to no impact on study results.

Conclusion

We have shown that it is feasible to recruit patients with MetS to a lifestyle program of diet and exercise in a primary care setting that includes a family physician, dietitian and kinesiologist. Such a program may be associated with a reversal of MetS and has the potential to improve clinical outcomes, such as the risk of acute myocardial events. Although not all primary care settings have access to dietitians and exercise specialists, several jurisdictions have recognized the importance of the patient's medical home incorporating an interdisciplinary team.³⁸ Our work raises the

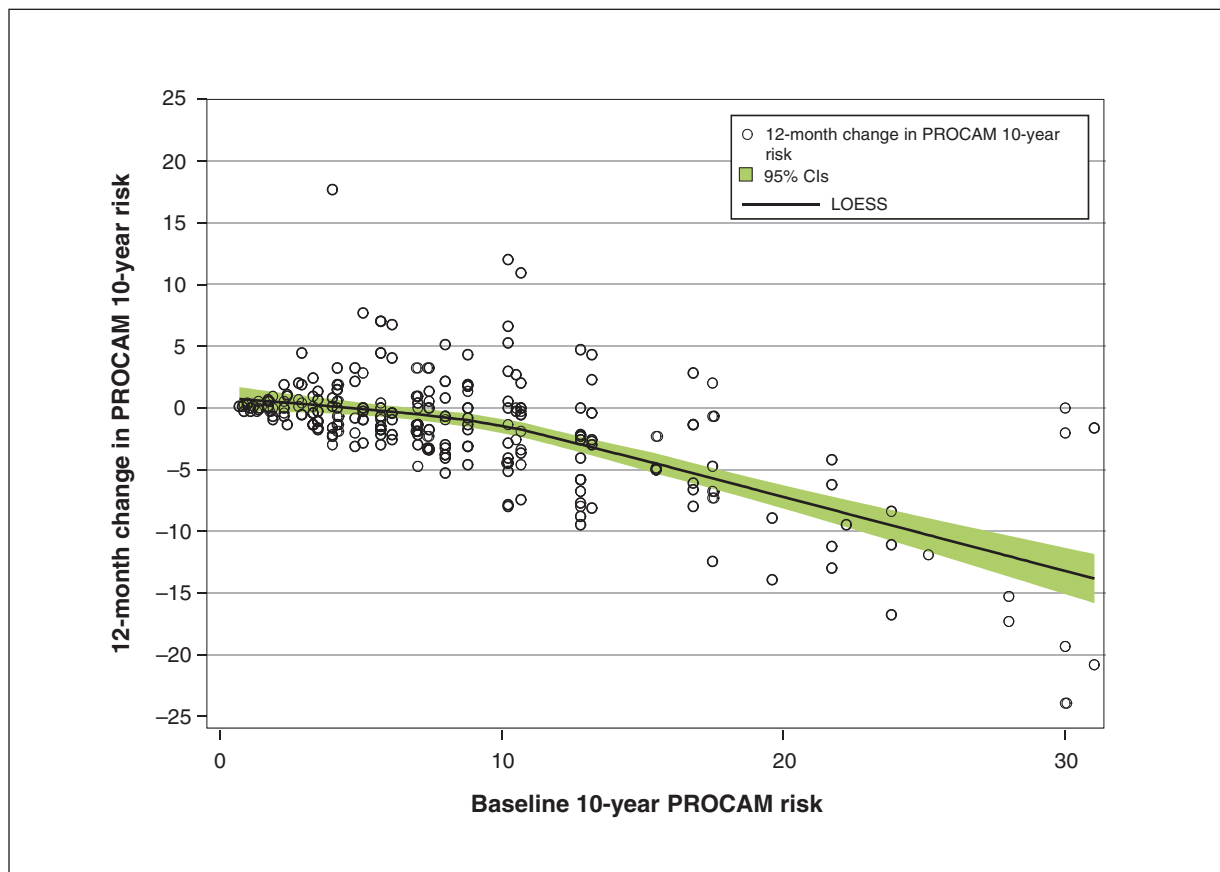


Figure 2: Change in PROCAM risk compared with baseline risk. CI = confidence interval, LOESS = locally weighted regression smoothing, PROCAM = Prospective Cardiovascular Munster.

need for family physicians to recognize lifestyle as highly relevant³⁹ and for dietitian and exercise specialists to be on primary care teams.

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Competing interests: Metabolic Syndrome Canada is a not-for-profit charitable organization that funded the current study. Daren Heyland received grant funds from Metabolic Syndrome Canada for program development, study coordination and data analyses. Rupinder Dhaliwal, Andrew Day and Roger Leung were 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. Lew Pliamm, Caroline Rhéame and Doug Klein received grants as participating sites for patient enrolment and data collection from Metabolic Syndrome Canada. Paula Brauer, Dawna Royall, David Mutch and Angelo Tremblay received grants for program development from Metabolic Syndrome Canada. Khursheed Jeejeebhoy is on the board of directors for Metabolic Syndrome Canada and will be involved in discussions about fundraising for this nonprofit organization.

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Contributors: All authors contributed substantially to conception and design, or acquisition of data, or analysis and interpretation of data; drafted the article or revised it critically for important intellectual content; gave final approval of the version to be published and agreed to act as guarantors of the work (ensuring that questions related to any part of the work are appropriately investigated and resolved).

Supplemental information: For reviewer comments and the original submission of this manuscript, please see www.cmajopen.ca/content/5/1/E229/suppl/DC1