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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, VO₂max 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 points (1.1–1.6) on a 14 point scale, 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.

Background

Metabolic Syndrome and Lifestyle modification in primary care

- Metabolic syndrome is a cluster of five risk factors that greatly increase an individual's likelihood of developing cardiovascular disease and type 2 diabetes¹
- Approximately 21% of Canadian adults have MetS² and its prevalence increases to 39% of adults aged 60–79³
- Those with MetS are reported to have double the annual health care costs and use health services more frequently than those without⁴
- Diet and exercise trials have shown the potential to improve clinically relevant outcomes and lifestyle modification is being emphasized as key therapy in primary care⁵
- Uptake of lifestyle preventive care for cardiovascular risk in Canadian primary care settings is limited⁶
- An efficacious diet and exercise intervention aimed at

Visceral Obesity

Excess fat around your waist, or having an “apple-shaped” body.

Low HDL-Cholesterol

HDL is the “good” cholesterol in your blood and removes the bad cholesterol and fat. You want HDL to be high. Good levels for HDL are >1.0 mmol/L for men and >1.3 mmol/L for women.

High Triglycerides

Triglycerides are a type of bad fat in the blood. Your triglycerides are high if your levels ≥ 1.7 mmol/L, or you are on medicine for this.

Metabolic Syndrome

Insulin Resistance

You know insulin is not being used well by your body if you have a high fasting blood sugar (5.6 mmol/L or more) or are on medication for this.

Hypertension

High blood pressure is when your top reading is higher than 130 and bottom reading is higher than 85, or you are on medication for this.

improving MetS in primary care is needed

- The Canadian Health Advanced by Nutrition and Graded Exercise, The CHANGE program is an evidence based program designed by Metabolic Syndrome Canada to reverse MetS in primary care settings

Study Hypothesis

A team-based program (The CHANGE Program) led by the family physician that educates patients about the risks of MetS, and with a dietitian and exercise specialist, empowers them to undertake an

individualized supervised program of diet modification and exercise, would be feasible, improve aerobic capacity and diet quality, reverse MetS and improve its components at 12 months.

Methods

Setting & Design

Prospective, longitudinal before–after feasibility study conducted from 2012-2015 at 3 Canadian clinics:

- Edmonton Oliver Primary Care Network
- Unité de médecine familiale Laval, Québec & Polyclinic
- Family & Specialty Medicine, Toronto

Inclusion criteria:

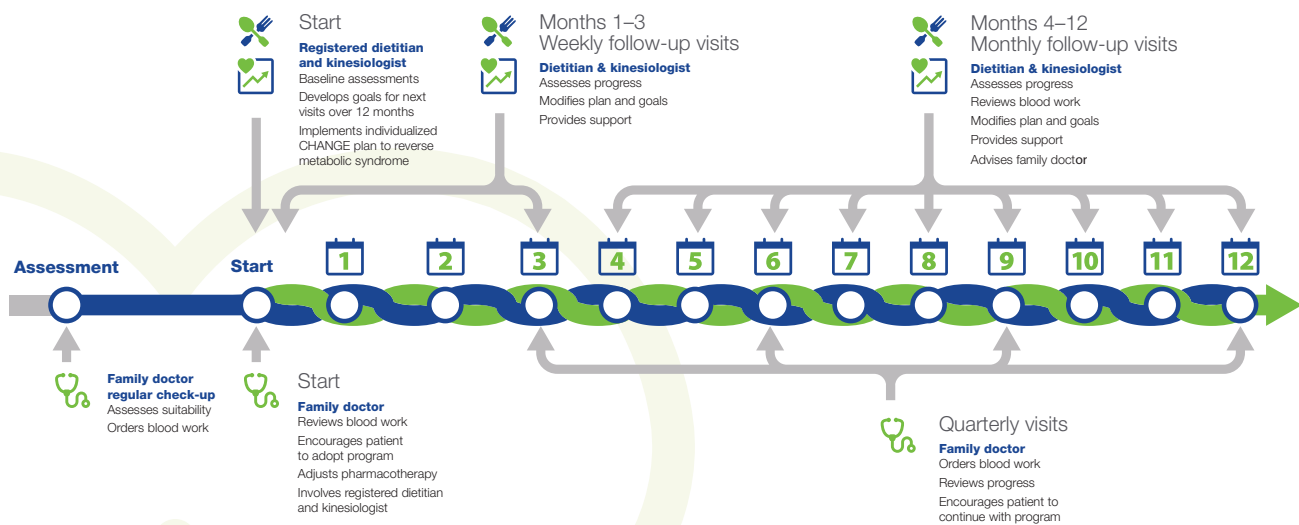
1. at least 18 yrs age
2. Presence of 3 out of 5 criteria for MetS (see figure on page 1)

Exclusion Criteria:

- inability to adhere to longitudinal study due to medical, safety or logistic reasons
- those deemed not to benefit from the intervention

Program Overview

Eligible patients were approached for consent, placed in the CHANGE Program and followed for 12 months. Individualized diet and exercise counselling and ongoing encouragement was provided to support the patient in making lifestyle changes based on progress achieved in MetS components.



Evaluations

At every diet and fitness visit (baseline, weekly X12, monthly X9)

Attendance, setting of visit, delivery method, food behaviour goals, type duration & intensity of exercise

At Baseline, 3 months, 6 months, 9 months and 12 months

- Fasting blood glucose, fasting lipids, blood pressure, waist circumference, weight
- Medications for blood glucose, blood pressure or lipids

At Baseline, 3 months and 12 months

- barriers to dietary behaviour changes, goals, 24 hr recall, Healthy Eating Index⁷ and Mediterranean Diet Score,⁸ validated diet quality tools
- aerobic capacity (estimated Vo₂ max), resistance and flexibility tests

At Baseline and 12 months

Cardiovascular diseases risk scores i.e. Prospective Cardiovascular Munster Score (PROCAM)⁹ and continuous Metabolic Score (cMetS)¹⁰

Statistical Analyses

- All patients with any follow-up data regardless of compliance with the program were included
- All p values are 2-sided without adjustment for multiplicity of tests. All analyses were performed using SAS version 9.4

Patient Recruitment and Feasibility

- Patients enrolled at mean rate of 4 patients per month per site over 2 yrs
- Of 293 patients, 40 (14%) did not have laboratory data at 12 months
- Diet contacts over 12 months: 90% of the 21 prescribed visits
- Fitness contacts over 12 months: 76% of the 21 prescribed visits

Results

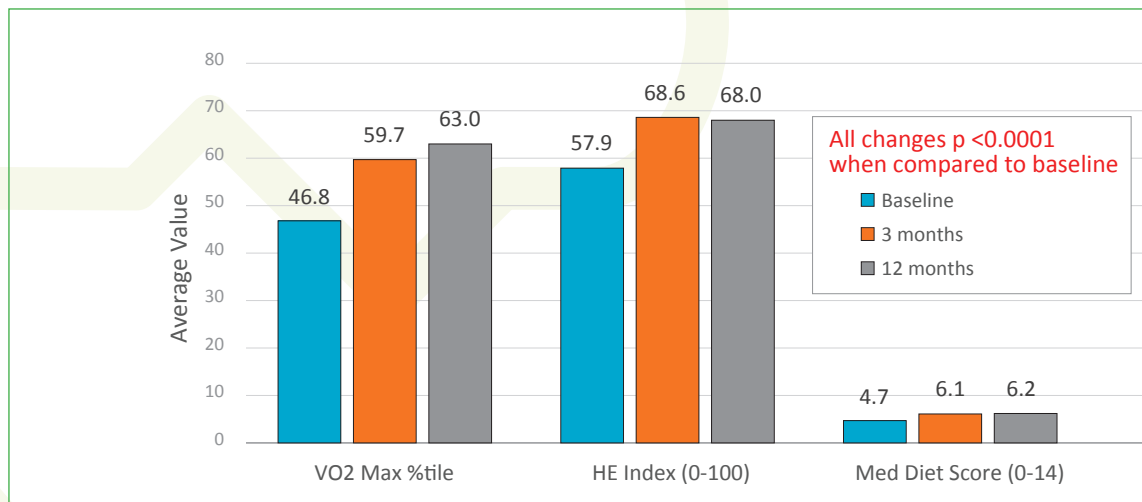
From 2012–2014, of 305 patients enrolled, 293 met the inclusion criteria at baseline

Baseline patient characteristics	All patients (n=293)
Age (years)	59.1±9.7
Female	152 (52%)
Height (meters)	1.7±0.1
Weight (kg)	90.8±14.7
BMI (kg/m ²)	31.9±3.3
Metabolic Syndrome Criteria Met n (%)	
1. Blood pressure or pharmacotherapy	256 (87%)
Systolic blood pressure (mmHg)	133.5±14.5
Diastolic blood pressure (mmHg)	80.6±9.1
On pharmacotherapy for blood pressure	218 (74%)
2. Fasting blood glucose or pharmacotherapy	240 (82%)
Blood glucose (mmol/L)	6.6±1.4
On pharmacotherapy for blood glucose levels	129 (44%)
3. Triglyceride or pharmacotherapy	187 (64%)
Triglyceride level (mmol/L)	2.2±1.7
On pharmacotherapy for triglycerides	11 (4%)
4. High density lipoprotein cholesterol	138 (47%)
HDL-C (mmol/L)	1.2±0.3
5. Waist circumference	277 (95%)
Waist circumference (cm)	108.1±9.4

Continuous outcome data at each time point are presented as raw mean and standard deviation (SD)

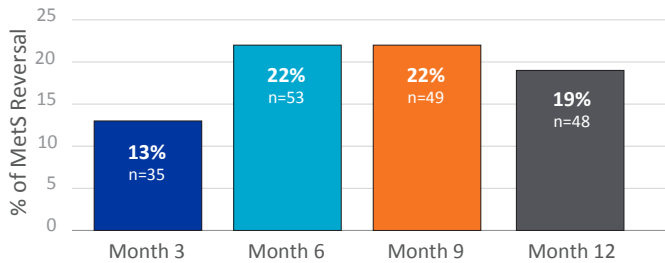
Aerobic Capacity and Diet Quality

The aerobic capacity (measured by estimated VO₂max), Healthy Eating Index and the Mediterranean Diet Score all improved significantly at 12 months compared to baseline (16%, 9.6% and 1.4 points respectively, all p<0.0001)



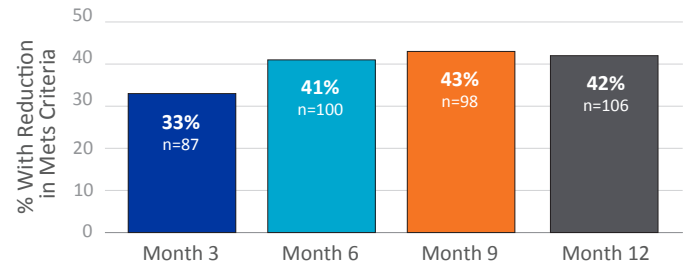
Metabolic Reversal

Defined as <3/5 criteria for MetS



Metabolic Syndrome Components

Patients with fewer MetS criteria compared to baseline



PROCAM and continuous Metabolic 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. The cMetS score decreased by 0.4 (95% CI 0.3–0.5, $p < 0.0001$) at 12 months which translates into a significant reduction in coronary heart disease over 9 years.

Conclusions and interpretation

This multicentre feasibility study shows that the CHANGE Program:

- is feasible in a primary care setting with diet and exercise visits being well attended
- was associated with significant improvements in V02 max, Healthy Eating Index and Mediterranean diet scores at 12 months (all $p < 0.0001$)
- was associated with improvements in blood pressure, triglyceride levels and waist circumference at 12 months (all $p < 0.0001$)
- was associated with a significant reversal rate in MetS at 3 months that was sustained at 12 months
- was associated with a 17% relative risk reduction in 10 yr. risk of acute myocardial infarction at 12 months (as per changes in the PROCAM risk score)
- was associated with a 19% relative reduction in incidence of cardiovascular disease and 17% reduction in coronary heart disease over 9 years (as per changes in the cMetS score)

Our work confirms that structured lifestyle programs are feasible and effective in primary care. Such programs should be available to all Canadians with metabolic syndrome from their family doctors offices.

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