Lifestyle interventions in primary care

Systematic review of randomized controlled trials

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ABSTRACT

Objective. *To determine whether lifestyle counseling interventions delivered in primary care settings by primary care providers to their low-risk adult patients are effective in changing factors related to cardiovascular risk.*

Data sources. *MEDLINE (PubMed), EMBASE, and CINAHL were searched from January 1985 to December 2007. The reference lists of all articles collected were checked to ensure that all suitable randomized controlled trials (RCTs) had been included.*

Study selection. *We chose RCTs on lifestyle counseling in primary care for primary prevention of cardiovascular disease. The search was limited to English-language articles involving human subjects. Studies had to have been conducted within the context of primary care, and interventions had to have been carried out by primary care providers, such as family physicians or practice nurses. Studies had to have had a control group who were managed with usual care. Outcomes of interest were cardiovascular risk scores, blood pressure, lipid levels, weight or body mass index, and morbidity and mortality.*

Synthesis. *Seven RCTs were included in the review. Only 4 studies showed any significant positive effect on the outcomes of interest, and only 2 of these showed consistent effects across several outcomes. The main effects were on blood pressure and lipid levels, but the size of these effects, while statistically significant, was small. There was no obvious benefit to one provider doing the intervention over another (eg, physician vs nurse), nor of the focus of the intervention (eg, on diet vs on exercise).*

Conclusion. *Lifestyle counseling interventions delivered by primary care providers in primary care settings to patients at low risk (primary prevention) appeared to be of marginal benefit. Resources and time in primary care might be better spent on patients at higher risk of cardiovascular disease, such as those with existing heart disease or diabetes.*

EDITOR'S KEY POINTS

- This systematic review was conducted to determine whether lifestyle interventions delivered in primary care settings by primary care providers to their adult patients were effective in changing factors related to cardiovascular risk.
- Overall, for cardiovascular risk scores, blood pressure, lipid levels, weight or body mass index, morbidity, and mortality outcomes, the studies found little benefit from lifestyle-orientated interventions compared with usual care.
- While it is difficult to suggest that primary care providers not counsel all their patients on how to lead healthy lives, their time might be better spent focusing on those patients at higher risk.

Elements of lifestyle, such as exercise, diet, smoking, and stress, are known to affect health and risk of cardiovascular disease. Various studies have identified relationships between lifestyle and health status, health care use, and costs to the health care system. (1-4) Interventions aimed at improving patients' lifestyles have resulted in improvements in health outcomes. (5-7) The best known study of these interventions was conducted by the Diabetes Prevention Program research group. (6) They found that lifestyle interventions prevented progression to diabetes in patients with prediabetes. Most of these interventions, however, involved intense exercise and diet programs delivered by exercise physiologists and dietitians.

The objective of this study was to determine whether lifestyle interventions delivered in primary care settings by primary care providers to their adult patients were effective in changing factors related to cardiovascular risk. Only patients without known cardiovascular disease or diabetes were included in the study (primary prevention situations only). Lifestyle interventions were limited to those related to exercise and diet. Outcomes of interest were cardiovascular risk scores, blood pressure, lipid levels, weight or body mass index, and morbidity and mortality. ❑

DATA SOURCES

Literature search

We searched MEDLINE (PubMed), EMBASE, and CINAHL from January 1985 to December 2007 for all randomized controlled trials (RCTs) and systematic reviews of lifestyle counseling in primary care for primary prevention of cardiovascular disease. Search terms used included *lifestyle counseling, dietary advice, exercise, physical activity, lifestyle intervention, behaviour modification, primary care, general* or *family practice,* and *primary prevention.* The reference lists of all articles retrieved were checked to ensure that all suitable RCTs had been included. The search was limited to English-language articles involving human subjects.

Study selection

We considered only RCTs that reported on outcomes at 12 months or longer of patients who did not have pre-existing cardiovascular disease or diabetes. Study participants had to be 18 years or older and could be of either sex. Trials involving drug treatment in combination with lifestyle counseling were excluded.

Interventions had to be lifestyle orientated and focused on healthy eating or increased physical activity. Smoking could not be a main focus of the trial. Trials must have been conducted within the context of primary care and carried out by primary care providers, such as family physicians or practice nurses. Trials had to have had control groups who were managed with usual care. Usual care could include distribution of basic lifestyle messages, such as the literature on healthy living typically handed out by health professionals.

Both authors reviewed the articles independently using the criteria outlined in the users guides by Guyatt et al. (8) Criteria used to assess the validity of the articles included randomization, accountability and follow-up after the study, intention-to-treat analysis, blinding and concealment, homogeneity, similarity of study and control groups, and evidence of contamination or simultaneous interventions. The reviewers were not blinded to the authors of the articles nor to the citation sources, but it turns out they were not familiar with any of the authors of the articles included. Reviewers considered both overall study validity and applicability to general practice. Overall assessment included details of studies' methodology, patient populations, interventions and controls, and clinical aspects. Agreement as to whether an article would be included was settled by consensus after the independent reviews.

As shown in the flow diagram (Figure 1), our initial literature search identified 37 articles of which 24 were excluded. The remaining 13 articles (9-21) were reviewed in more detail. Among these 13 articles, 4 were excluded because the study populations lacked homogeneity (9-12) (eg, they included primary and secondary prevention patients), 1 was excluded because it lacked a control group, (13) and another because of a lack of consistency in data reporting. (14) In the end, 7 studies were included in the review (Table 1). (15-21)

Because data were reported in various ways in the studies and because some information was missing (eg, no standard deviations, percentages without numbers), we could not adequately conduct a meta-analysis. We report outcome data in Table 2. (15-21) In addition to determining the statistical significance of the outcomes, we assessed the relevance or importance of differences, when they were found, using the definitions shown in Table 3. ❑

Table 1. Articles included in this review

STUDY	DESIGN	SAMPLE	INTERVENTION GROUP	CONTROL GROUP	OUTCOMES MEASURED
Baron et al,[15] 1990	RCT with 12-mo follow-up at a single general practice	368 subjects (189 men, 179 women) aged 25–60 y were recruited in England. Mean age for the intervention group was 41.2 y (SD 1.0 y) for men and 41.1 y (SD 1.0 y) for women, and for the control group was 41.6 y (SD 1.0 y) for men and 41.9 y (SD 1.1 y) for women	97 men and 90 women were given dietary advice and guidelines by a practice nurse in 30-min group or individual sessions. Subjects were given a diet booklet containing advice and recipes. There was a brief follow-up at 1 and 3 mo. Advice was to decrease intake of total fat and increase intake of polyunsaturated fatty acids and fibre. Retention rate was 89%	92 men and 89 were given usual care with no dietary advice. Retention rate was 93%	TC and LDL and HDL levels were assessed at 1-yr follow-up
OXCHECK study group,[16] 1995	RCT with 36-mo follow-up at 5 general practices	4121 subjects aged 35–64 y were recruited in the United Kingdom	2205 subjects received lifestyle advice from a practice nurse at 45- to 60-min health checkups with 10- to 20-min follow-ups. Advice was tailored to individual patients' risk factors. 1100 subjects received annual checkups, and 1105 did not. Retention rate was 81.7%	1916 subjects received usual care. Retention rate was 81.3%	TC, BP, and BMI were assessed at 3-y follow-up
Elley et al,[17] 2003	Cluster RCT with 12-mo follow-up at 23 intervention and 19 control practices	878 subjects (296 men, 582 women) aged 40–79 y were recruited from general practices in New Zealand. Mean age for the intervention group was 57.2 y (SD 10.8 y) and for the control group was 58.6 y (SD 11.5 y). Only subjects considered "less active" (<30 min of physical activity 5 d/wk) were enrolled	451 subjects (150 men, 301 women) received counseling on physical activity from a GP or practice nurse. Clinicians counseled verbally then gave out written advice on home-based exercise. Written advice and patient information were forwarded to exercise specialists who made 3, 10- to 20-min follow-up calls. Retention rate was 85%	427 subjects (146 men, 281 women) received usual care. Retention rate was 85%	Cardiovascular risk score, BP, and BMI were assessed at 1-y follow-up
Kastarinen et al,[18] 2002	Open RCT with 24-mo follow-up at 10 primary care centres	341 subjects (48% male in intervention group and 46% male in control group) aged 25–74 y with primary hypertension were recruited in primary care in Finland. Mean age was 54.4 y (SD 10.1 y) in the intervention group and 54.2 y (SD 9.9 y) in the control group	175 subjects in a no-drug treatment group were given lifestyle counseling (less sodium, alcohol, and saturated fat; weight reduction; physical activity) based on individual risk factors by practice nurses with visits at 1, 3, 6, 9, 15, 18, and 21 mo. Two 2-h group sessions on salt and weight reduction were held at 6 and 18 mo. Retention rate was 84%	166 subjects received usual care. Retention rate was 80%	BP was assessed at 2-y follow-up
Roderick et al,[19] 1997	RCT with 12-mo follow-up at 8 general practices	956 subjects (48% male in intervention group and 52% male in control group) 30–59 y were recruited from general practices in the United Kingdom. Spouses were encouraged to enrol. Mean age was 47.2 y in the intervention group and 47.4 y in the control group	473 subjects were given dietary advice based on negotiated change and healthy living literature by a practice nurse at an initial session. Nurses negotiated up to 5 diet changes based on a food-frequency questionnaire interpreted for individual cases. Overweight patients were given special diet plans with calorie-restricted diets. Retention rate was 80% overall	483 subjects received usual care with standard healthy living literature and annual follow-up. Retention rate was 80% overall	TC, BMI, and BP were assessed at 1-y follow-up

(Table 1 continued)

STUDY	DESIGN	SAMPLE	INTERVENTION GROUP	CONTROL GROUP	OUTCOMES MEASURED
Salkeld et al,[20] 1997	RCT with 12-mo follow-up at 75 general practices	755 subjects (387 men, 368 women) 18-69 y with ≥1 modifiable risk factors for CVD were recruited from general practices in Australia. Mean age in the group shown the video was 51 y for men and 52 y for women. Mean age in the group shown the video and given self-help materials was 50 y for men and 51 y for women. Mean age in the control group was 53 y for men and 56 y for women	2 separate interventions were conducted by physicians: 269 subjects were shown a video on lifestyle, and 231 subjects were shown the video and also given written self-help materials. The interventions targeted healthy eating, physical activity, and smoking cessation. Retention rate for the video group was 74%; retention rate for the video and self-help materials group was 67%	255 subjects received usual care. Retention rate was 51%	BP (diastolic only), TC, and BMI were assessed at 1-y follow-up
Steptoe et al,[21] 1999	Cluster RCT with 12-mo follow-up at 20 general practices	883 subjects (406 men, 477 women) with a mean age of 46.7 y (SE 0.4) were recruited from general practices in the United Kingdom. Subjects had ≥1 modifiable risk factor for CVD, such as high serum cholesterol or a high BMI	316 subjects received behavioural counseling in 2-3, 20-min sessions conducted by a practice nurse targeted at healthy eating (low-fat, high fruit and vegetable intake), physical activity (increased to 12 moderately intense sessions/mo), and smoking cessation. The intervention operated on a "stages of change" model where counseling is tailored to individual readiness to change behaviour. Nurses telephoned subjects to reinforce counseling between sessions. Retention rate was 53%	567 subjects received usual care. Retention rate was 62%	TC, BMI, and BP were assessed at 1-y follow-up

BP—blood pressure, BMI—body mass index, CVD—cardiovascular disease, HDL—high-density lipoprotein, LDL—low-density lipoprotein, RCT—randomized controlled trial, SD—standard deviation, SE—standard error, TC—total cholesterol.

SYNTHESIS

Overall, the studies found little benefit from lifestyle- orientated interventions compared with usual care. Three of the 6 studies that assessed blood pressure as an outcome found a small but significant benefit to lifestyle counseling versus usual care. (16,18,20) Two of the 5 studies that assessed cholesterol levels as an outcome found a small but significant benefit of lifestyle

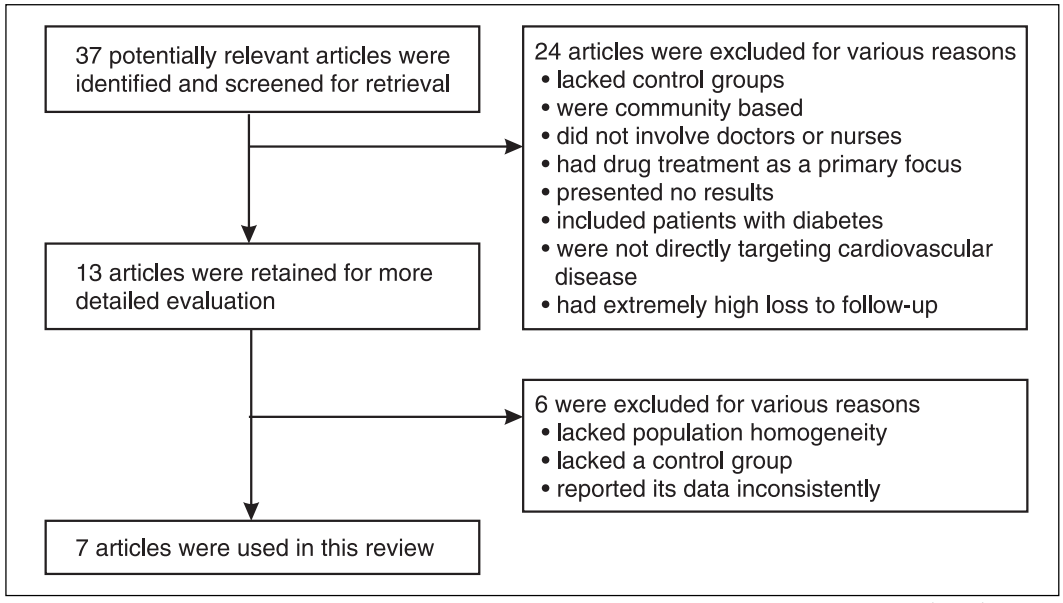

Figure 1. Study selection

counseling. (16,19) Only 1 of the 5 studies that assessed body mass index showed significant benefit of counseling, but again the effect was small. (16) Only 1 of the 7 studies included in this review measured cardiovascular risk scores as an outcome; it showed no significant improvement in risk between intervention and control groups. (17) None of the articles included in this review measured mortality or morbidity as an outcome.

The studies used a variety of lifestyle interventions. Two used dietary interventions only. (15,19) One study was strictly oriented toward physical activity. (17) The remaining 4 studies (16,18,20,21) used a combination of healthy-eating and staying-active messages. The interventions varied in duration from 1 to 9 months. There was also variation in who delivered the advice. In 1 study (20) it was physicians only, in 2 others (17,18) it was a combination of nurses and physicians, and in 4 studies (15,16,19,21) it was nurses only. Details of the studies are shown in Tables 1 and 2. (15-21) ❑

DISCUSSION

Usefulness of lifestyle interventions

This review allows us to answer, or at least get insight into, specific questions about the usefulness of lifestyle counseling interventions delivered in primary care settings.

Were outcomes affected by which primary care provider (physician or practice nurse) delivered the intervention? Among the 4 studies (15,16,19,21) in which a nurse alone delivered the intervention, only 1 showed a consistent positive benefit. (16) The benefit was small, however, and the achievement of statistical significance was helped by a large sample size. The 1 study (20) in which a primary care physician alone delivered the intervention showed the intervention was not effective at lowering cholesterol or body mass index, but did have a positive effect on diastolic blood pressure in men only. The intervention in this study was, however, complex and not easily generalizable to most practices. The 2 studies in which both physicians and nurses were involved (17,18) showed little positive effect of the intervention. One study showed no benefit on any of the outcomes measured; the other looked at blood pressure only and showed a small but significant reduction. It does not appear to matter which primary care provider delivers the intervention. The results are generally not impressive.

Did adding external supports to the provider-delivered intervention improve outcomes? Two studies (17,20) used additional services with the primary care providers' intervention. One study had exercise specialists follow up patients after initial counseling by physicians and nurses. The other had experts providing physicians with extra training. Neither of these studies showed benefit of the intervention except for a moderate improvement in diastolic blood pressure in men only.

Were overall cardiovascular risk scores affected by the lifestyle interventions? The 1 study (17) that looked at cardiovascular risk scores showed no benefit from the intervention, even though there was a reasonable sample size (N = 878), and the intervention was delivered by physicians and nurses with follow-up by exercise specialists.

Were specific components of risk (blood pressure, weight, lipid levels) affected by the lifestyle interventions? Only 4 (16,18-20) of the 7 studies in this review showed any positive effect of lifestyle interventions. The main effects were on blood pressure and to a lesser degree on lipids. In general, effects were small.

Were morbidity and mortality affected by the lifestyle interventions? These outcomes were not measured in any of the 7 studies included in the review.

Limitations

The main limitation of this review was the inability to conduct a meta-analysis because the study populations were not homogeneous and the presentation of results was done in a variety of ways. Since a meta-analysis was not done, we could not assess the likelihood of a negative result bias because we could not construct a funnel plot. We did not search non-English literature; it is possible that valid articles on the topic exist in other languages. We searched the 2 major medical databases (MEDLINE and EMBASE) and the major allied health database (CINAHL). It is unlikely that there is much primary care or family practice literature that has not been captured by the 3 databases we searched.

Future research

More sustained intensive programs of lifestyle counseling, delivered by health educators with backgrounds in nutrition and exercise, might be

Table 2. Summaries of outcome data in the 7 articles included in this study

STUDY	OUTCOME	INTERVENTION GROUP	CONTROL GROUP	P VALUE	COMMENTS	EFFECT SIZE*
Baron et al,[15] 1990	Mean TC (SE) men/women, mmol/L	4.52 (0.08)/4.80 (0.11)	4.50 (0.08)/4.84 (0.11)	NS	No significant effect for	None
	Mean LDL levels (SE) men/women, mmol/L	2.36 (0.07)/2.71 (0.09)	2.31 (0.08)/2.73 (0.10)	NS	women or men. Small sample	None
	Mean HDL levels (SE) men/women, mmol/L	1.41 (0.03)/1.49 (0.03)	1.48 (0.03)/1.53 (0.03)	NS	size might account for this	None
OXCHECK study group,[16] 1995	Mean TC (SD) attenders/all, mmol/L	5.93 (1.06)/5.99 (1.10)	6.18 (1.17)	<.05	A large sample size can show	Small
	Mean diastolic BP (SD) attenders/all, mm Hg	126.8 (19.6)/126.5 (19.3)	129.0 (20.4)	<.05	statistical significance	Small
	Mean systolic BP (SD) attenders/all, mm Hg	75.7 (11.5)/75.7 (11.6)	77.2 (11.7)	<.05	even when the absolute	Small
	Mean BMI (SD) attenders/all, kg/m²	25.89 (4.14)/25.88 (4.21)	26.26 (4.31)	<.05	difference is small	Small
Elley et al,[17] 2003	Mean change (95% CI) in systolic BP, mm Hg	-2.58 (-4.02 to -1.13)	-1.21 (-2.57 to 0.15)	NS	No effect despite	None
	Mean change (95% CI) in diastolic BP, mm Hg	-2.62 (-3.62 to -1.61)	-0.81 (-1.77 to 0.16)	NS	reasonable sample size and	None
	4-y cardiovascular risk score (95% CI)	0.42 (0.23 to 0.6)	0.52 (0.32 to 0.72)	NS	follow up by exercise	None
	Mean change (95% CI) in BMI, kg/m²	-0.11 (-.25 to 0.02)	-0.05 (-0.18 to 0.07)	NS	specialists	None
Kastarinen et al,[18] 2002	Mean change (95% CI) in systolic BP, mm Hg	-2.0 (-3.7 to -0.3)	-0.4 (-1.3 to 2.0)	<.05		Small
	Mean change (95% CI) in diastolic BP, mm Hg	-2.4 (-3.4 to -1.4)	-0.4 (-1.4 to 0.8)	<.05		Small
Roderick et al,[19] 1997	Mean differences† (95% CI) in TC, mmol/L	-0.20 (-0.38 to -0.03)		<.05	Use of practice nurses for	None
	Mean differences† (95% CI) in BMI, kg/m²	-0.12 (-0.03 to 0.05)		NS	dietary counseling to	None
	Mean differences† (95% CI) in systolic BP, mm Hg	-0.59 (-2.43 to 1.24)		NS	decrease cardiovascular	None
	Mean differences (95% CI) in diastolic BP, mm Hg	0.09 (-4.9 to 5.0)		NS	risk scores was ineffective in a low-risk population	None
Salkeld et al,[20] 1997	Mean change (95% CI) in diastolic BP‡ men/women, mm Hg	-4.0 (-6.02 to -1.97)/ -0.9 (-3.1 to 1.3)	-1.5 (-3.34 to 0.73)/ -4.0 (-6.37 to -1.7)	<.05/ <.05	Appears to be helpful only in improving	Moderate/ Negative
	Mean change (95% CI) in TC‡ men/women, mmol/L	-0.46 (-0.75 to -0.13)/ -0.83 (-1.15 to -0.51)	-0.58 (-0.88 to -0.27)/ -0.58 (-0.81 to -0.35)	NS	diastolic BP in men	None
	Mean change (95% CI) in BMI‡ men/women, kg/m²	0.1 (-0.57 to 0.38)/-0.03 (-0.6 to 0.53)	-0.6 (-1.23 to -0.001)/ -0.3 (-0.48 to -0.15)	NS		None
Steptoe et al,[21] 1999	Mean change (95% CI) in TC, mmol/L	-0.31 (-0.46 to -0.21)	-0.33 (-0.48 to -0.15)	NS	Appears to be helpful only in	None
	Mean change (95% CI) in BMI, kg/m²	0.23 (-0.6 to 0.12)	-0.07 (-0.3 to 0.14)	NS	improving diastolic BP in	None
	Mean change (95% CI) in systolic BP, mm Hg	-4.3 (-7.0 to -2.3)	-1.8 (-4.1 to 0.5)	NS	men	None
	Mean change (95% CI) in diastolic BP, mm Hg	-0.7 (-0.31 to 1.6)	-1.0 (-2.0 to 0.01)	NS		None

BP—blood pressure, BMI—body mass index, HDL—high-density lipoprotein, LDL—low-density lipoprotein, NS—not significant, SD—standard deviation, SE—standard error, TC—total cholesterol.
*See Table 3.
†Between intervention and control groups.
‡Video and self-help materials group.

Table 3. Definitions of effect size for each outcome

OUTCOME	NONE	SMALL	MODERATE	LARGE
Cholesterol levels (TC, LDL, HDL)	$P \geq .05$	$P < .05$ and < 5% decrease in mean level compared with control group	$P < .05$ and 5%–10% decrease in mean level compared with control group	$P < .05$ and > 10% decrease in mean level compared with control group
Systolic BP	$P \geq .05$	$P < .05$ and < 4 mm Hg decrease in mean BP compared with control group	$P < .05$ and 4–7 mm Hg decrease in mean BP compared with control group	$P < .05$ and > 7 mm Hg decrease in mean BP compared with control group
Diastolic BP	$P \geq .05$	$P < .05$ and < 2 mm Hg decrease in mean BP compared with control group	$P < .05$ and 2–4 mm Hg decrease in mean BP compared with control group	$P < .05$ and > 4 mm Hg decrease in mean BP compared with control group
Weight or BMI	$P \geq .05$	$P < .05$ and < 5% decrease in mean weight compared with control group	$P < .05$ and 5%–10% decrease in mean weight compared with control group	$P < .05$ and > 10% decrease in mean weight compared with control group

BMI—body mass index, BP—blood pressure, HDL—high-density lipoprotein, LDL—low-density lipoprotein, TC—total cholesterol.

more effective. This has been shown to be the case outside the primary care setting in the Diabetes Prevention Program7 study. A randomized controlled trial (the PROACTIVE study) (22) is currently under way in Canada, funded by the Canadian Institutes for Health Research, looking at the use of an intensive program of lifestyle counseling delivered during many visits over a 2-year period. The intervention is being delivered in primary care settings, but by providers referred to as *health educators* with backgrounds in exercise and health promotion. We await the results of this trial to know whether outcomes will be improved using this approach in primary care. ❑

CONCLUSION

This review looked at lifestyle counseling interventions delivered by primary care providers in primary care settings to patients at low risk of cardiovascular disease (primary prevention). The effects of the interventions were far from striking. Only 2 of the 7 studies showed consistently positive results, and these were primarily around improvements in blood pressure. The improvements were small, in the range of 2 mm Hg difference between intervention and control groups. While we did not formally look at high-risk patients, several of the studies we encountered looked at both high- and low-risk patients. It appears that patients at higher risk (those with pre-existing ischemic heart disease or diabetes) might benefit more from lifestyle counseling than the low-risk patients we studied. In general, while it is difficult to suggest that primary care providers not counsel all their patients on healthy lifestyles, their time might be better spent focusing on those at higher risk. It is possible that more sustained intensive programs of lifestyle counseling, delivered by health educators with backgrounds in nutrition and exercise, are more effective. ❑

Mr Fleming is a Research Assistant in the Primary Healthcare Research Unit, and Dr Godwin is a Professor of Family Medicine, both at Memorial University of Newfoundland in St John's.

Competing interests
None declared
Contributors
Mr Fleming and **Dr Godwin** contributed to concept and design of the study; data gathering, analysis, and interpretation; and preparing the article for submission.

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