Research

Therapeutic lifestyle and disease-management interventions: pushing the scientific envelope

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Therapeutic lifestyle and disease-management interventions are complex in design, composition and application. Many are multidisciplinary, comprising several individual components[1] (Table 1). An intervention's specific recommendations should be supported by evidence-based practice guidelines and its delivery sequenced using established adult-learning theories based on behavioural readiness to change. Lifestyle programs focus on exercise, diet, stress management and smoking cessation, whereas disease-management programs place greater emphasis on the management of the complications of chronic disease, of symptoms, and of health-seeking behaviours. Some programs are more comprehensive than others, incorporating elements related to both lifestyle and disease management, while others focus on selected elements.

At their core, therapeutic lifestyle and disease-management programs aim to modify patient behaviour and to improve the quality, consistency, comprehensiveness and outcomes of care. However, there is debate as to how best to achieve such ambitious goals. Some argue for a full complement of services covering all components and elements related to lifestyle and disease-management.[2] Others contend that the scientific evaluation of disease management has been undermined by inconsistencies related to semantics, definitions and composition, which makes comparisons between programs more challenging.[3]

In this issue of *CMAJ*, Wister and colleagues[4] test the efficacy of a home-based lifestyle intervention for 2 groups of individuals, one at risk for cardiovascular disease and another with already established cardiovascular disease. Their program was modelled after the Stanford Coronary Risk Intervention Project and has commonalities with many therapeutic lifestyle interventions. For example, the program incorporated health-risk assessments, used adult behavioural learning theories, provided educational materials and supportive, counselling in accordance with evidence-based guidelines and integrated summary and follow-up reports to physicians. However, unlike other programs, which have incorporated more frequent encounters between mentors and patients, that of Wister and colleagues was of low intensity, allowing for only 2 telehealth sessions over the 1-year intervention (with 4 additional encounters applied specifically to smoking cessation issues where applicable). Using a stratified randomized design, the authors evaluated their intervention against changes in 1-year Framingham risk scores, differentiating the primary prevention population from the secondary prevention population.

Key points of the article

- Variation in the results of studies of therapeutic lifestyle and disease management interventions probably relate to the heterogeneity and complexity of such programs, their populations and their evaluation
- Programs that are more comprehensive, flexible, personalized and intensively supported by trained, experienced health care professionals can be expected to have greater efficacy
- Baseline risks, behaviours and sociocultural diversity will ultimately determine the successful application and cost-effectiveness of such programs
- Such interventions may require more rigorous and creative risk-stratification techniques based not only on predictors of adverse outcomes, but also on predictors of downstream costs

A significant reduction in global risk favouring the intervention group was observed in the at-risk populations, but there were no significant changes in risk among individuals with established heart disease. Yet, even where the changes achieved statistical significance, the overall magnitude of the risk improvements were modest (e.g., absolute changes in score for those receiving the intervention of 3.1%, with 1-year absolute Framingham scores similar between the intervention and control groups). Significant improvements in biometric parameters and self-reported behaviours in the primary prevention group were limited to changes in total cholesterol, blood pressure, diet and health confidence. Smoking cessation rates were disappointingly low and equivalent between the intervention and control groups. The authors conclude that their low-intensity, multiple risk factor

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DOI:10.1503/cmaj.071230

intervention was efficacious for the primary prevention group, but not for the secondary prevention group. Do these results pose serious challenges to the merit of therapeutic lifestyle interventions?

When examined in context, this study further underscores the heterogeneity associated with evaluation of therapeutic lifestyle and disease-management interventions. Setting aside the variability associated with program composition, study heterogeneity arises from differences in the baseline characteristics of the populations themselves.[3] Even among patients with similar diseases, disease-management interventions have been tested at different stages of illness and different stages of life.[5,6] Many studies have enrolled small, selected samples, which accentuates random variation in outcomes.[2,3] Some studies have used more rigorous randomized controlled designs,[7] whereas others have relied on retrospective analyses using before–after designs in which patients served as their own controls.[8] The outcomes have ranged from short-term changes in biometric measures to longer-term, "harder" outcome measures, such as readmission to hospital and death. Accordingly, it comes as little surprise that some disease-management evaluations have demonstrated profound improvements in cardiovascular health risk, clinical outcomes (including death and recurrent hospital admissions) and costs,[5,7,8] but others have been less compelling and, in some cases, overtly negative.[6,9]

Wister and colleagues used global risk assessment and changes in Framingham risk scores as their primary outcome measure, even among patients with established heart disease. Yet Framingham risk scores were never intended to be applied to secondary prevention populations. Indeed, in this study, the baseline global risk scores were almost 2 times higher among patients without documented heart disease than among those with established heart disease, a counterintuitive finding that challenges the validity of the authors' interpretations. Moreover, changes in risk scores have not been

Table 1: Selected examples of therapeutic lifestyle and disease-management interventions

Intervention	Program element or personnel	Examples
Identification of target population	Assessment of health risks	• Age and sex • Cardiovascular and noncardiovascular risk factors • Biometric measures (blood pressure, body mass index, waist circumference, fasting blood glucose level, lipid profile) • Behavioural readiness-to-change scales • Framingham risk scores
	Recommendations	• Guidelines for management of risk factors • Recommendations for lifestyle change
Education about self-management	Educational kits	• Potential topics include self-awareness with respect to disease; exercise and diet; smoking cessation; medications
Coordinated care	Information technology (e.g., Web-based and electronic records)	• Appointment bookings • Physician updates and referral letters • Compliance tracking • Patient monitoring and surveillance (through mentors who administer routine surveillance questions, modify patient recommendations and generate physician update reports) • Patient reminders
Provision of support services	Allied health personnel or mentors	• Dietitian • Kinesiologist • Physiotherapist • Nurse • Pharmacist • Social worker • Case manager • Care coordinators
Evaluation and management of process and patient outcomes	Assessment by allied health personnel or mentors	• Surveillance of symptoms and behaviours (e.g., by questionnaire); modification of treatment plan (with physician approval)
	Database tracking	• Biometric changes; quality of life; health services utilization
Routine reporting and feedback loops	Summary reports	• Follow-up outcome reports
	Appointments and referrals	• Primary care providers • Specialty care providers

*Program recommendations follow evidence-based guidelines.

adequately validated against long-term clinical outcomes, such as death and hospital readmission.

Wister and colleagues used an intention-to-treat analysis, which is an appropriate and accepted method for the analysis of randomized clinical trials. However, the authors do not adequately define or report on program compliance. Since one of the central objectives of therapeutic lifestyle and disease-management programs is to modify and shape healthy lifestyle behaviours, compliance measures are both primary behavioural outcome measures and important intermediary determinants of biological responsiveness. The identification and tracking of identical behavioural compliance measures in both the intervention group and the control group is therefore important when evaluating the efficacy of disease-management programs, especially when using intention-to-treat designs.

Wister and colleagues sought to evaluate a "low-intensity" intervention. One could speculate that a higher-intensity intervention might have had more impact on health behaviours and outcomes. Moreover, program intensity may need to be tailored differently according to the sociodemographic, cultural and biological risk profiles of a population. Delivery of disease-management interventions should not follow a "one-size-fits-all" approach, which is inconsistent with some of the intended objectives associated with population-risk stratification. For example, in a recent systematic review of disease-management interventions among socially vulnerable patients with diabetes, Glazier and associates[10] determined that 10 or more mentored calls over a period of 6 months or longer were needed for a positive impact on outcomes in such high-risk populations, an intensity level significantly greater than that used by Wister and colleagues. If the efficacy of an intervention is positively correlated with mentorship intensity, then, presumably, so too will be its associated program costs. Thus, the interrelationship between program intensity and efficacy has direct implications for cost-effectiveness. Beyond some minimum threshold of mentorship intensity, one might even hypothesize that return on investment diminishes. Consequently, identifying such mentorship intensity thresholds becomes imperative in the application of lifestyle and disease-management interventions and must serve as a priority research question in future evaluations.

Much remains to be learned about the science and application of therapeutic lifestyle and disease-management interventions. Pushing the envelope of disease-management science will necessitate a better understanding of the variability, heterogeneity and complexity associated with these interventions. Nevertheless, doing so will bring about evolution in the field that will lead the way to broader real-world effectiveness evaluations. Given the potential impact on population outcomes and health-service expenditures, the rewards of research investment may be enormous. Notwithstanding many of the methodologic and interpretative caveats of their study, Wister and colleagues must be commended for expanding our awareness, insights and critical appraisal of these interventions and for pushing the scientific disease-management envelope.

This article has been peer reviewed.

Competing interests: David Alter is the Scientific Director of and a limited partner in PrevCan[LP] (INTERxVENT Canada), a cardiovascular lifestyle and disease-management program. He has also received reimbursement from the program for travel expenses to 2 meetings.

Acknowledgements: David Alter is a Career Scientist with the Heart and Stroke Foundation of Ontario. The Institute for Clinical Evaluative Sciences is supported in part by the Ministry of Health and Long-Term Care of Ontario.

This commentary does not necessarily reflect the views of the Heart and Stroke Foundation, the Institute for Clinical Evaluative Sciences, The Ministry of Heath and Long-Term Care of Ontario or INTERxVENT Canada, and no endorsements should be inferred.

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