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# Development of a chronic disease management program for stroke survivors using intervention mapping: The Stroke Coach

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# Abstract

**Objective**—To describe the systematic development of the Stroke Coach, a theory- and evidencebased intervention to improve control of lifestyle behaviour risk factors in stroke patients.

**Design**—Intervention development.

Setting—Community.

Participants-Individuals who have had a stroke.

**Intervention**—We used Intervention Mapping to guide the development of the Stroke Coach. Intervention Mapping is a systematic process used for intervention development and comprised of steps that progress from the integration of theory and evidence to the organization of realistic strategies to facilitate the development of a practical intervention supported by empirical evidence. Social Cognitive Theory was the underlying premise for behaviour change, while Control Theory methods were directed towards sustaining the changes to ensure long-term health benefits. Practical evidence-based strategies were linked to behavioural determinants to improve stroke risk factor control.

#### Main outcome measures—Not applicable.

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**Results**—The Stroke Coach is a patient-centred, community-based, telehealth intervention to promote healthy lifestyles after stroke. Over six months, participants receive seven 30 to 60 minute telephone sessions with a lifestyle coach who provides education, facilitates motivation for lifestyle modification, and empowers participants to self-management their stroke risk factors. Participants also receive a self-management manual and a self-monitoring kit.

**Conclusion**—Through the use of Intervention Mapping we developed a theoretically sound and evidence-grounded intervention to improve risk factor control in stroke patients. If empirical evaluation of the Stroke Coach produces positive results, the next step will be to develop an implementation intervention to ensure successful uptake and delivery of the program in community and outpatient settings.

#### **Keywords**

behaviour change; intervention mapping; stroke; secondary prevention; health promotion; chronic disease management

After 55 years of age, one in five women and one in six men will have a stroke.<sup>1</sup> Due to population aging the total number of people with first ever stroke is increasing.<sup>2</sup> After a stroke, there is a 13% risk of a subsequent stroke within one year, and a 25 to 33% risk after five years.<sup>3–5</sup> These high rates of recurrence, largely due to poor risk factor control,<sup>6,7</sup> place increasing emphasis on the importance of developing, evaluating, and implementing preventive strategies.

Stroke prevention guidelines<sup>8–10</sup> and epidemiological studies<sup>11</sup> consistently report both behavioural and physiological processes as stroke risk factors. The efficacy of behaviour modification at improving physiological factors is well established,<sup>12–14</sup> and therefore, the existing paradigm for secondary stroke prevention is to emphasize improvements to lifestyle behaviours, which in turn will lead to improved control of physiological risk factors, and eventually improved secondary prevention.

There is increasing recognition that interventions to change behaviour should have strong theoretical foundations because such programs will more likely target causal determinants of behaviour change, contribute to the testing and further development of theory, and lead to an increase in the understanding of strategies that facilitate change.<sup>15</sup> The majority of secondary stroke prevention programs, however, do not appear to be based on behaviour change theory.<sup>16</sup> Thus, it is not surprising that meta-analyses of results from existing behaviour modification programs after stroke show minimal effects on behavioural stroke risk factors,<sup>17</sup> and no effect on mortality, cardiovascular event rates, or cardio-metabolic risk factor profiles.<sup>18</sup>

The complex nature of behaviour change complicates the process of intervention development, evaluation, and implementation.<sup>19</sup> Several theoretical frameworks have been proposed to help researchers navigate through the complexities by providing guidance during the planning phases (e.g., Intervention Mapping,<sup>20</sup> Behaviour Change Wheel<sup>21</sup>). These frameworks are comprehensive in that they provide guidance on the development of theoretically sound and evidence-guided interventions, and also emphasize the importance

of considering implementation and evaluation strategies. Given the high rates of secondary stroke and inadequacies of existing prevention programs, the use of theoretical frameworks to aid in the development of new preventative interventions seems prudent.

In this paper, we report on the development of a theory- and evidence-based intervention, the Stroke Coach, using an Intervention Mapping approach.<sup>22</sup> The purpose of the Stroke Coach is to empower individuals to improve lifestyle behaviours and maintain the improvements after the conclusion of the intervention.

# Methods

Intervention Mapping is comprised of six steps that serves as a blueprint for designing, implementing and evaluating practical interventions supported by theory, empirical evidence, and clinical experiences.<sup>22</sup>

#### Step 1 - Needs assessment

We used several methods to assess needs, including: 1) Establishing and working with a planning group to provide input throughout intervention development; and 2) Conducting a detailed literature search to assess the issues associated with secondary prevention efforts, and conceptualize a framework for an intervention to address the needs derived from theory, empirical evidence, and practical knowledge.

# Step 2 - Proximal intervention objectives

To determine proximal objectives, we followed two steps: 1) Identify performance objectives that specify lifestyle behaviours to change to improve stroke risk factor control; and 2) Identify theoretical determinants of those behaviours as the proximal objectives.<sup>22</sup>

#### Step 3 - Theory-based intervention methods and practical strategies

We identified evidence-based intervention methods to target the proximal objectives, and then translated the methods into practical strategies for intervention delivery. Whereas methods are general evidence-based techniques (e.g. self-monitoring) used to influence behavioural determinants, strategies are more specific and practical techniques used to operationalize and deliver the method (e.g. using an activity monitor to track daily steps and instruction on how to use the monitor to provide motivation for continued physical activity). 22

#### Step 4 - Organizing the strategies into an intervention

We integrated the practical strategies into an organized intervention that addresses the proximal objectives. In doing so, we conceptualized the: 1) dose; 2) delivery; and 3) organization of the intervention. We also obtained 4) feedback from stakeholders, including end-users as well as from decision-makers from organizations that could potentially implement the intervention, and refined the program structure and materials based on the feedback.<sup>22</sup>

#### **Step 5 - Implementation Plan**

We initiated plans for initial implementation, including training materials for the coaches, as well as methods to assess program fidelity.

#### Step 6 - Evaluation Plan

We develop an evaluation plan to test whether the intervention is successful at addressing the proximal objectives.<sup>22</sup>

# Results

Below we present the considerations and decisions made during each of the six intervention mapping steps<sup>22</sup> in developing the Stroke Coach.

### Step 1: Needs Assessment

**1) Establish and work with a planning group**—Our planning group (n=8) was comprised of health care professionals, including a neurologist, psychologist, physiatrist, dietician, and physical therapist, and researchers with expertise in neurosciences, stroke and cardiac prevention, human nutrition, behaviour change theories, self-management, and research and evaluation methodologies. Three member of our planning group have health authority leadership roles in which they could potentially implement the program within their setting.

**2) Conduct a literature search**—We performed a literature search to develop an understanding of the population and health issue of secondary stroke prevention, which formed the basis of the introduction to this manuscript. Furthermore, we conceptualized the Stroke Coach to be theoretically sound and use evidence-based strategies. To guide our work in the development of the Stroke Coach, we followed the Causal Modelling Behaviour Change conceptual framework proposed by Hardeman et al..<sup>23</sup> This framework proposes a causal path in which behaviour change leads to physiological changes, which in turn lead to changes in health outcomes. As well, the Stroke Coach focuses on behaviour change and maintenance by targeting theoretical determinants of behaviour using evidence-based change and maintenance strategies. Figure 1 presents the general causal framework in parallel to the specific causal path for secondary stroke prevention hypothesized by Stroke Coach.

We also conceptualized the Stroke Coach to align with key principles of health care quality<sup>24,25</sup> to facilitate the program's eventual implementation, including:

**<u>i. Patient centred:</u>** Everyone has different beliefs about healthy living, as well as different personal and environmental issues that may influence behaviour change. For these reasons, we decided to use a one-on-one delivery method, and follow the concept of patient centredness.<sup>24</sup>

**ii. Highly accessible:** After stroke many individuals are reported to have transportation and geographic barriers to attending health service programs.<sup>26–29</sup> To address these possible

**<u>iii.</u>** Timely and Community-based: The highest incidence of secondary strokes is within one-year of the initial event.<sup>3</sup> It is during this time that patients have returned to community living and are receiving few or no follow-up health services.<sup>2</sup> For this reason, we decided to design an intervention that would be timely for secondary prevention (i.e., within one year) and could be easily implemented in a community-based setting.

#### Step 2: Proximal Intervention Objectives

- 1. We planned to develop a comprehensive and patient-centred intervention that would allow participants to focus on any behavioural stroke risk factor (i.e., physical activity, diet and nutrition, stress management, smoking and alcohol consumption).
- 2. The proximal intervention objectives were thus considered to be theoretical social cognitive determinants of behaviour change (e.g., knowledge, self-efficacy), as shown in Figure 1. We focus on social cognitive determinants because Social Cognitive Theory<sup>30,31</sup> is the most comprehensive theory of behaviour change<sup>32</sup> and has much evidence demonstrating the predictive value of its determinants.

#### Step 3: Evidence-based Intervention Methods and Practical Strategies

**1) Evidence-based intervention methods**—To modify the behavioural determinants and ensure sustained behaviour change, we identified evidence-based behaviour change methods originating from Bandura's Social Cognitive Theory<sup>31</sup> as well as Carver and Scheier's Control Theory.<sup>33</sup> Whereas social cognitive methods were deemed important to initiate modification of the determinants derived from the same theory, Control Theory methods were more directed towards sustaining the changes (i.e., self-management) to ensure long-term health benefits.

To help identify evidence-based intervention methods, we used the foundational works of Michie et al.<sup>15</sup> and Abraham and Michie,<sup>34</sup> who have created a taxonomy of behaviour change and maintenance methods and linked those methods to theoretical determinants of behaviour. Table 1 presents the evidence-based methods used in Stroke Coach, and identifies the behavioural determinants that each method is targeting.

**2) Practical strategies**—We use three practical strategies to deliver Stroke Coach's evidence-based intervention methods, and to serve as the foundation of the intervention. All participants will receive:

**i. Lifestyle Coaching:** Lifestyle coaching is a patient-centred approach to motivate patients to change behaviour and improve their health.<sup>35,36</sup> The coach's role involves active listening and non-judgmental inquiry to build patients' desire to become healthier.<sup>36</sup> Our coaches will be health workers who have experience working with individuals with stroke, knowledge of

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**<u>ii. Self-management manual</u>**: The purpose of the self-management manual is to provide detailed information on how to self-manage lifestyle behaviours for improved stroke risk factor control. This manual, prepared by the Stroke Coach development/research team will be given to participants as a resource and used as a discussion document during the coaching sessions.

**<u>iii. Self-monitoring kit:</u>** Self-monitoring is the single most important behaviour change and self-management method.<sup>37</sup> The purpose of the self-monitoring kit is for participants to monitor various behaviours (as well as physiological indicators) and keep track of progress. This kit includes a: health report card; pedometer (Fitbit Zip; Fitbit, Inc., San Francisco, CA, USA); blood pressure monitor (Omron 3 series model: BP710CANN; Omron Healthcare Inc., Hoffman Estates, IL, USA); tape measure for waist and hip measurement; food and physical activity diaries; body mass index chart; and instructions.

A key component of the self-monitoring kit is the health report card, shown in Figure 2. Health reports cards have successfully been used in previous cardiovascular prevention research,<sup>38</sup> and we have adapted the use of report cards for stroke prevention. Each participant receives grades varying from A to F on their 'lifestyle behaviour' and 'cardiovascular' stroke risk factors. They also receive information on the definition of each grade, which have been adapted from clinical guidelines (e.g., Canadian Physical Activity and Food Guidelines). Prior to enrolling in the program participants will complete a brief survey from which we will determine their grades.

Table 1 identifies which practical strategy is expected to deliver each of the evidence-based intervention methods.

#### Step 4: Organizing the Strategies into an Intervention

**1) Dose**—Participants will receive seven 30 to 45 minute coaching sessions on a one-to-one basis with a lifestyle coach over a six-month period. The duration, frequency, and intensity of our intervention are approximately the averages used in other stroke self-management programs reported in a recent systematic review.<sup>17</sup>

**2) Delivery**—To increase accessibility, Stroke Coach will be delivered via telehealth.<sup>39</sup> In our 2015 survey on willingness to receive stroke rehabilitation using technology, we found that telephones are one of the most widely owned and used communication technologies, and that people had a high interest to receive education through phone calls.<sup>40</sup> Evidence also exists that telephone coaching improves health behaviours and health status in people with chronic conditions.<sup>41</sup>

**3)** Organization—To structure the coaching sessions, we adopted the evidence-based Five A's (Assess, Advise, Agree, Assist, Arrange) organizational construct for clinical counselling.<sup>42</sup> In sessions one to six, the coaches will review the participants' health report card with them and assess their knowledge about stroke risks, and current behaviours

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(Assess). The coaches will also provide information about stroke risks and benefits of improving lifestyle behaviours (Advise). Any number of long-term health report card goals prioritized by the Health Report Card will be established through a collaborative process (Agree). The coaches and participants will discuss options for implementing short-term strategies to reach the long-term goals, and refer to the self-management manual for resources. Furthermore, participants will be informed about the benefits of self-monitoring, and instructed on how to monitor their own blood pressure, body composition, diet and physical activity (Assist). Follow-up will include the scheduling of the next monthly session (Arrange). At the last session (session 7) the coaches will work with the participants to determine long-term strategies to maintain or further improve lifestyle behaviours on their own.

**4) Stakeholder review and revision**—After conceptualizing the intervention, we sought feedback from various stakeholders including: stroke patient groups; advocacy groups; health professionals and other researchers. Feedback from stroke patients emphasized the importance that the service be free (which it will be). It was also felt that one month in-between sessions was too long and that participants needed more contact with their coach to review progress and revise action plans if needed. As a result, it was decided to add in brief (5 to 10 minute) follow-up phone calls to check on progress in between the longer monthly sessions. Thus, in the final Stroke Coach intervention, participants have either a telephone coaching session or a follow-up call every two weeks for six months.

#### **Step 5: Implementation Plan**

We devised written materials that describe how the Stroke Coach is to be delivered, as well as a training presentation and coaching manual for the coaches to use during each session (available upon request). The training presentation included information on stroke epidemiology, stroke risk factors and the importance of lifestyle behaviour modification to improve secondary prevention, all components of the Stroke Coach, the delivery of each of the telephone sessions using the 5A counseling model, as well as review of the coaching manual and practice. To assess our training materials, and to ensure fidelity of the delivery of the program in our evaluation, we decided that the coaches would record various sessions for the intervention developers to listen to and critique, or developers would listen to 'live' sessions. The lead researcher would then review the coaching sessions to ensure the dose, delivery, and organization (as noted above) of the sessions are implemented as detailed in the coaching manual. Any discrepancies would be brought to the coaches' attention immediately after review. It was also decided that the coaches and developers would meet on an on-going basis to discuss progress, challenges, and issues.

#### Step 6: Evaluation Plan

We developed a research protocol detailing the evaluation of Stroke Coach using a multi-site single-blind randomized controlled trial study design.<sup>43</sup> Our primary hypothesis is that among stroke patients within one-year post stroke, the Stroke Coach intervention will improve a global measure of lifestyle behaviour (i.e., Health Promoting Lifestyle Profile II<sup>44</sup>) compared to an attention-control program. Our secondary hypotheses will test the effects of the Stroke Coach on specific lifestyle behaviours, depressive symptoms,

cardiovascular risk, cognition, and health-related quality of life. To obtain information on the experiences and satisfaction with Stroke Coach, all participants will also complete an exit survey to determine their perspectives. Furthermore, we will undertake a qualitative study to explore the coaches' perceptions of their skills to coaching and ability to provide coaching that is consistent over time and across participants. Such knowledge will inform the recruitment of coaches, the development of supplementary materials to train the coaches and help ensure reliable delivery of the intervention. While ethics approval was not necessary during intervention development, we will seek ethics approval from all participating sites prior to beginning the trial.

# Discussion

In this paper we describe the development of a theoretically driven and evidence-based Stroke Coach intervention to improve lifestyle behaviours and thus risk factor control in stroke patients using an Intervention Mapping approach. Intervention Mapping has been previously used to develop effective self-management, prevention and health promotion programs for people with various conditions,<sup>22</sup> however up until now it has not been used to guide the development of secondary stroke preventions programs.

In our experience, the principles and steps delineated by Intervention Mapping are useful to address current issues regarding the development, implementation, and evaluation of secondary stroke prevention programs. First, Intervention Mapping provides a systematic approach for the development of health programs and establishes a clear set of tasks that help to focus developers. It enabled us to systematically report on the use theory, empirical evidence, and practical perspectives in the development of the Stroke Coach, which at present is lacking in the existing secondary stroke prevention literature. It also helped facilitate a clear description of the different components of the intervention which will enable meaningful replication. Second, the formation of our multidisciplinary planning group proved to be valuable. With expert knowledge, input, and shared decision making throughout the process, though to engaging our stakeholder group that included patients, we were able to develop a highly relevant and patient-oriented program. Third, Intervention Mapping facilitated early consideration of program implementation. As such, the Stroke Coach adheres to key principles of health service quality, and we have developed materials to train the lifestyle coaches to help ensure a standardized delivery, as well as considered methods to test for and ensure program fidelity. Finally, given the amount of consideration the Intervention Mapping process required for the development of the Stroke Coach, we have developed a detailed research protocol to evaluate the program.

#### Limitations

There are several limitations to our intervention development process that are worth noting. For example, the participation of patients in the development of the Stroke Coach was to review and comment on a program that had already been conceptualized. While there was widespread interest and support of the program, had patients been more involved at the conceptualization stage, the program might have been developed differently. However, our planning group had three health authority stakeholders who were in leadership roles where

they could potentially implement the program within their setting. As well, the program itself utilizes only a few methods deemed to modify theoretical determinants of behaviour. There are other existing evidence-based methods, such as peer support and mentoring, that the program does not include. In future, it is likely worthwhile to test alternative delivery models where peers are the coaches, and possibly group formats that make use of group video or teleconferencing technologies. Next, because of the complexity of the program, its delivery by different coaches with diverse skill sets and personalities may lead to variable outcomes. To understand these issues, we will formally evaluate the implementation of the program (including the fidelity of the intervention and perceptions of the coaches) and develop supplemental training materials for the coaches as needed to ensure consistent delivery of Stroke Coach. Finally, because we wanted to develop a comprehensive yet patient-oriented program, we identified target lifestyle behaviours for change at a global level, and not on specific behaviours. We decided on this approach to avoid prescription and to encourage patient to self-identify specific behaviours as goals to focus on and work with their coaches to develop meaningful action plans to achieve those goals.

# Conclusion

Stroke Coach is a novel secondary prevention program designed to improve stroke risk factor control via lifestyle behaviour modification. By working with participants to actively improve the management of their behavioural stroke risk factors, it is postulated that the study participants will be empowered to improve their behaviours during the 6-month program, and importantly to maintain the improvements after the program has ended. If the evaluation of Stroke Coach produces positive results, the next step will be to develop an implementation intervention to ensure successful uptake and delivery of the program in community and outpatient settings.

# Acknowledgments

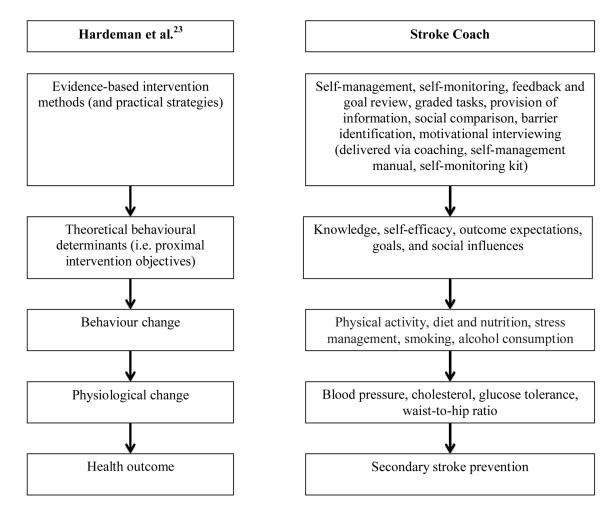
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#### Figure 1.

Framework for causal behavioural modeling. This figure presents the general Causal Modelling Behaviour Change conceptual framework on the left, and the specific causal path towards secondary prevention hypothesized by the Stroke Coach intervention on the right.

Lifestyle Factor	You	Your Grade	Your target level	Grade A
Physical Activity (frequency)	3x/week	С	4x/week	> 5x/week
Physical Activity (duration)	10 min	D	20 min	> 30 min
Fruit & Vegetables	4 servings/day	D	6 servings/day	7 servings/day
High fat	2 servings/day	С	1 serving/day	< 1 serving/day
Reduce sodium	Usually	В	Always	Always
% Whole grain	20%	D	30%	> 50%
Stress Management Strategies (Use)	Always	А	Maintain	Always
Waist measure	95 cm	С	< 92 cm	88 cm
Smoking Status	Non-smoker	А	Maintain	Non-smoker
Body Mass Index	28.5 kg/m <sup>2</sup>	overweight	24.9 kg/m <sup>2</sup>	$\leq$ 24.9 = healthy weight

Heart Disease Risk	You	Your Grade	Target Level	Grade A
Total cholesterol	6.4 mmol/L	D	5.16-6.20 mmol/L	< 4.14 mmol/L
HDL cholesterol	1.1 mmol/L	С	1.29-1.55 mmol/L	> 1.56 mmol/L
LDL cholesterol	3.3 mmol/L	С	2.1-2.5 mmol/L	< 2.0 mmol/L
Systolic BP mmHg	136 mmHG	С	120-129 mmHG	< 120 mmHG
Fasting Glucose	4.2 mmol/L	Low risk	Maintain	4.0 to 7.0 mmol/L (diabetic) or 4.0 to 5.5 mmol/L (non-diabetic)

#### Figure 2.

Example of a health report card. This figure presents a completed health report card that participants would receive and discuss with their coach.

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# Table 1

Linking evidence-based intervention methods to practical strategies and behavioural determinants

			Beha	Behavioural determinants	inants		
Theory	Evidence-based intervention methods	Practical strategies for delivery	Knowledge	Self-efficacy	Outcome expectations	Goals	<u>Sociostructural</u> <u>factors – social</u> <u>influences</u>
Control Theory to sustain/maintain	Self-management (goal setting; decision making/problem solving; action planning)	Self-management manual; Coaching		х		x	
behaviour	Self-monitoring	Self-monitoring kit; Coaching		х	х		
	Feedback and goal review	Coaching		х	х		
Social Cognitive	Graded tasks	Coaching		х		х	
I heory to initiate new behaviour	Information about behaviour, outcome, consequences	Self-management manual; Coaching	x		Х	×	
	Social comparison and encouragement	Coaching		х		х	x
	Barrier identification	Coaching		x	×	×	х
Various	Motivational interviewing	Coaching		х		x	

model;<sup>42</sup> Self-management manual: Used to increase knowledge about behavioural stroke risk factors and the concept of self-management, and detail important self-management skills; Self-monitoring NOTE: Coaching: A patient-centred approach used to motivate patients to change behaviour, and achieve goals that improve health using the 5A (Assess, Advise, Agree, Assist, Arrange) counselling kit: Used to monitor various behavioural stroke risk factors and keep track of progress.