Int J Stroke. Author manuscript; available in PMC 2018 August 01.

Published in final edited form as:

Int J Stroke. 2018 February ; 13(2): 217–222. doi:10.1177/1747493017729266.

A telehealth intervention to promote healthy lifestyles after stroke: The Stroke Coach protocol

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Abstract

Rationale—Recurrent stroke is prevalent and associated with high mortalityrates, disability, and social and economic costs. Adequate management of risk factors may reduce recurrent stroke, however, many stroke survivors have poor control of risk factors. We have developed a theoretically sound and evidence-based lifestyle modification program called the Stroke Coach, a telephone-based self-management program to improve control of risk factors.

Hypothesis—Individuals who participate in Stroke Coach will achieve more lifestyle improvements than individuals in an attention controlled Memory Training Program.

Design—In this single blind randomized controlled trial, 126 community-living stroke survivors will be randomized to Stroke Coach or the attention control group. Participants randomized to the six-month Stroke Coach will receive seven telephone lifestyle coaching sessions, self-management education and practice, and a self-monitoring kit, comprised of a health report card, with blood pressure and activity monitors.

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Author Contributions:

BMS, JJE: conception and design, drafting of the manuscript, critical review of the manuscript; SAL, SIB, OB, CHG, NDS, JY: critical review of the manuscript. All authors approved final version to be published.

Declaration of competing interests: None

Study Outcomes—The primary outcome will be measured using the Health Promoting Lifestyle Profile II. Secondary outcomes include behavioural and physiological risk factors, quality of life, cognitive status, health and social service use. Measurements will be taken at baseline, immediately after the intervention, and 6-month post-intervention.

Summary—The results of this trial will add to our understanding of the use of self-management to improve control of risk factors, and may facilitate the development of a larger trial evaluating the effect of Stroke Coach on endpoints such as recurrent stroke or cardiac events as the primary outcome.

Keywords

secondary prevention; health promotion; chronic disease management; behaviour change

Introduction and rationale

Stroke prevention is largely behavioural.[1] Many stroke survivors, however, have low long-term adherence to protective behaviours resulting in poor control of risk factors,[2] which has likely contributed to a high incidence of secondary stroke (i.e., 30% will have another stroke within 5 years).[3] Given the increasing prevalence of stroke survivors, new approaches to modify behavioural (i.e., lifestyle) risk factors for stroke are warranted as existing lifestyle modification programs show minimal effects.[4, 5] A recent American Heart Association Statement commented that “there are currently no nationwide systematic efforts aimed at ensuring control of risk factors after stroke.”[6] Such efforts would need to be based on high quality RCTs and this study proposes to provide such evidence.

We report here on the study protocol to evaluate the Stroke Coach,[7] a theoretically- and evidence-grounded telehealth self-management intervention to improve lifestyle behaviours after stroke. Self-management used to improve control of stroke risk factors is an emerging area of research that may improve secondary prevention efforts. Our primary hypothesis is that individuals who have had a stroke who participate in the Stroke Coach will experience lifestyle behaviour improvements that are significantly greater than individuals in an attention-controlled Memory Training Program. We also investigate the effects of Stroke Coach on specific behavioural and physiological stroke risk factors, quality of life, and health outcomes.

Methods

The reporting of this protocol follows the Standard Protocol Items: Recommendations for Intervention Trials[8] guidelines.

Trial design

This multi-site study uses a randomized, controlled, open-label, single-blinded (assessor), study design. Figure 1 presents an overview of trial procedures.

Patient population

Volunteer participants will be recruited from acute, rehabilitation, and outpatient stroke units. Individuals will be included for study if they: are within 1-year following a confirmed stroke (ischemic or hemorrhagic diagnosis either by computerized tomography scan or magnetic resonance imaging); ≥50 years of age; have a modified Rankin Scale (mRS)[9] score varying from 1 to 4; live in the community and have phone access; and are able to communicate in English. Individuals will be excluded if they: had a stroke due to non-vascular origin (e.g., tumour); are engaged in stroke rehabilitation services; have clinically important musculoskeletal or other neurological conditions; severe aphasia or dysarthria; are not medically stable; have co-morbidities that preclude activity; live in long-term residential care; or have a cognitive impairment and are dependent for activities of daily living with no caregiver participation.

Sample size estimate

Fifty subjects per group will achieve 85% power at a level of significance of 0.05 to detect a group mean difference of 12 points (i.e., effect size=0.26) on our primary outcome, the Health Promoting Lifestyle Profile II scale, based on previous evidence and our pilot data[10–12]. We assumed a standard deviation of 25 (based on our pilot data), and a correlation of 0.6 between repeated measures. To ensure 50 subjects per group, 63 subjects per group (total=126) will be recruited to adjust for a potential 20% dropout.

Enrolled participants will meet with a trained and blinded study assessor who will administer each of the outcome measures, at three times: 1) baseline (T1=0 months); 2) post-intervention (T2=6 months); and 3) 6-month follow-up (T3=12 months). Each participant will meet with the same study assessor at all time points to ensure consistency in the administration of outcome measures.

Baseline evaluation (T1)

A participant information form will be completed to gather demographic and health characteristics, as well as stroke related information (e.g., type of stroke, hemisphere affected, limbs affected, stroke location, and vessel affected). The following outcomes will then be collected:

Primary Behavioural Outcome—Lifestyle will be measured using the Health Promoting Lifestyle Profile II questionnaire,[13] a revised version of the original Health Promoting Lifestyle Profile[14] which has established test-retest reliability (r=0.89), internal consistency (alpha=0.94), and construct validity, in adults aged 18 to 92.[14]

Secondary Behavioural Outcomes—Daily walking physical activity (four-days) will be measured using the StepWatch Activity Monitor, diet (fibre and fat intake) will be measured using the Canadian Version of the SmartDiet Questionnaire, [15] and medication adherence will be measured using the Morisky Medication Adherence Scale.[16–18] Use of the ©MMAS is protected by US Copyright laws. Permission for use is required. A license agreement is available from Donald E. Morisky, MMAS Research LLC 14725 NE 20. St. Bellevue WA 98007 or from dmorisky@gmail.com.

Secondary Physiological Outcomes—Blood pressure measurements will be taken following the American Heart Association recommendations for blood pressure measurement.[19] Cholesterol, glucose, C-reactive protein, and homocysteine levels will be measured using hospital outpatient blood work services. Body composition will be assessed using both waist-to-hip ratio and body mass index.

Tertiary Health Outcomes—Health-related quality of life will be measured using the Medical Outcomes Study: Short Form-36,[20] depressive symptoms will be measured using the Center for Epidemiologic Studies Depression Scale,[21] cognitive function will be assessed using the Montreal Cognitive Assessment,[22] and health and social service utilization will be assessed using the Health and Social Service Utilization Inventory.[23] We will also determine the cost of health and social service use using current medical and social service price lists.

Study outcomes were selected based on empirical evidence of their association with stroke risk, and are detailed in Appendix A. We use the causal behavioural modelling framework[24] shown in Figure 2 to organize the outcomes.

Randomization and interventions

After baseline evaluation, participants will be randomized using a 1:1 allocation ratio to one of the following programs, the descriptions of which follow the Template for Intervention Description and Replication (TIDieR) Checklist.[25] Randomization will be blocked, and stratified by age (i.e., < 65 and ≥ 65 years), and stroke severity at time of enrollment (i.e., mRS scores 1–2 and 3–4). RANDOMIZE.net (Interrand Inc., Ottawa, ON) will be used to create a central computerized randomization algorithm.

Stroke Coach (experimental)—The Stroke Coach is a patient-centred telehealth self-management intervention to improve lifestyle behaviours after stroke that was developed using an Intervention Mapping process.[7, 26]. Participants randomized to Stroke Coach receive:

1. Self-management manual – It provides information on how to self-manage post-stroke physical and functional complications, as well as lifestyle behaviours for improved control of stroke risk factors.
2. Self-monitoring kit – Self-monitoring is the most important behaviour change and self-management method.[27] The purpose of the self-monitoring kit is for participants to monitor various stroke risk factors. This kit includes a: a 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 and normative values; food and physical activity diaries; body mass index chart; and instructions. As well, participants receive a health report card with grades varying from A to F on behavioural (physical activity, diet, stress, smoking) and physiological (blood pressure, fasting glucose, cholesterol) stroke risk factors.

Prior to randomization participants will complete a brief survey and get their bloodwork done from which their grades will be determined.

3. Lifestyle coaching - Lifestyle coaching is a patient-centred approach to motivate patients to achieve goals and change behaviour that improve health, originating from Miller and Rollnick's concept of motivational interviewing.[28] Over six months, participants will receive seven 30 to 60 minute telephone sessions (as well as five brief 5 to 10 minute 'check-in' calls) with a lifestyle coach who will work with them to improve control of their stroke risk factors. Two coaching sessions will occur in the first month after baseline assessment, and one coaching session per month for the remainder of the program. 'Check-in' calls begin after the second coaching session and end after the sixth session, resulting in contact with participants every two weeks for six months.

To structure the coaching sessions, the coaches follow the evidence-based Five A's (Assess, Advise, Agree, Assist, Arrange) model for clinical counselling.[29] In each of the coaching sessions, the coaches will review the participants' health report card with them and assess their beliefs and knowledge about stroke risks, and current behaviours. Using a patient-centred approach, the coaches will then collaboratively work with participants to develop long-term health report card goals, prioritizing areas with poorer grades from the report card. The coaches and participants will then discuss realistic short-term strategies to reach the long-term goals, and refer to the self-management manual for resources and self-monitoring kit for motivation and to keep track of progress. Follow-up will include the scheduling of the next monthly session.

Lifestyle coaches go through a training protocol to ensure program fidelity. They each receive written materials that describe how the Stroke Coach is to be delivered, as well as a training presentation and coaching manual to use during each telephone session. The training presentation includes 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, as well as review of the coaching manual and 'hands-on' practice, totaling between three to five hours. As well, to further ensure coaches have skills to administer our patient-centred program, they will have some experience with motivational interviewing or will take a local course on the basics and fundamentals of motivational interviewing.

Figure 2 presents the mechanisms in which behaviour change leads to improved health as hypothesized by Stroke Coach.

Memory Training Program (attention control)—The purpose of the attention control Memory Training Program is to help stroke survivors develop strategies to help with memory. Participants randomized to this program receive: 1) memory coaching; 2) a memory training manual consisting of seven lesson plans, homework, and cognitive exercises; and 3) an agenda to schedule appointments and make reminder notes. This program follows the same schedule and frequency of telephone calls as the Stroke Coach arm.

To ensure program fidelity, memory coaches receive written materials that describe how the program is to be delivered, as well as a training presentation and coaching manual to use during each telephone session. Memory coaches also practice the delivery of the program prior to working with participants.

The Stroke Coach and Memory Training programs each have their own dedicated coaches. All coaches will be health professionals or research assistants with university training, experienced working with individuals with stroke.

Follow-up evaluations (T2, T3)

All of the primary, secondary, and tertiary outcomes collected at T1 will be collected at T2 (i.e., post-intervention) and T3 (i.e., 6-month post-intervention follow-up). Participants will complete an exit survey at T2 to determine their experience in the program they were allocated to.

Statistical analyses

Descriptive statistics will be used to characterize the sample. Estimates of effect on all outcomes at T2 and T3 will be analyzed using linear mixed models. Missing data will be handled using multiple imputation.[30] Sensitivity analyses will be conducted to assess the impact of the missing data.[30] Statistical analyses will be performed using R software (R Foundation for Statistical Computing, Vienna, Austria) with statistical significance set at 0.05.

Study organization and funding

This study is funded by the Canadian Institutes of Health Research, the Canadian Partnership for Stroke Recovery, and the Andison Family Foundation, and registered with Clinicaltrials.gov (study ID:NCT02207023). All study staff have been hired and trained, and recruitment is currently underway.

Summary

The Stroke Coach is a novel program aimed towards improving self-management and control of stroke risk factors. The results of this trial will add to our understanding of the use of self-management to improve control of risk factors, and may facilitate the development of a larger trial evaluating the effect of Stroke Coach on endpoints such as recurrent stroke or cardiac events as the primary outcome. Furthermore, if the results are as hypothesized, Stroke Coach will represent an opportunity to think differently about traditional stroke rehabilitation settings which typically provide at least three hours of therapy per day over two to three weeks. It is possible that removing one day of inpatient therapy and spreading these hours over the six months through a coaching model may be more beneficial in improving long-term outcomes, especially in risk factor control, including improving physical activity, diet and medication adherence.

Acknowledgments

This work was supported by: Canadian Institutes of Health Research Postdoctoral Fellowship (BMS) and Operating Grant; Michael Smith Foundation for Health Research Postdoctoral Fellowship (BMS) and Senior Scholar Award (JJE); Canada Research Chair in Neurological Rehabilitation (JJE); Pfizer/Heart and Stroke Foundation Chair in Cardiovascular Prevention Research at St. Paul's Hospital (SAL); and the Heart and Stroke Foundation Canadian Partnership for Stroke Recovery Operating Grant.

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Appendix A. Variables/Measures Organized by the Causal Behaviour Modeling Framework

Variable	Measure	# of items	Focus and Scoring	Populations with measurement evidence
Primary Behavioural Outcome				
Global Lifestyle Behaviour	Health Promoting Lifestyle Profile II[14]	52	Six domains of lifestyle behaviour (physical activity, stress management, nutrition, health, interpersonal support, spiritual growth) are assessed using a 1	- Stroke; - General population; - Metabolic syndrome; - Diabetes; - Obesity

Variable	Measure	# of items	Focus and Scoring	Populations with measurement evidence
			(never) to 4 (routinely) response scale. Items are summed (6 to 208) or averaged (1 to 4) to obtain total and domain scores. Higher scores indicate better lifestyle behaviour.	
Secondary Behavioural Outcomes				
Daily walking physical activity	StepWatch Activity Monitor	n/a	Participants will wear the StepWatch Activity Monitor attached for the waking hours of 4 consecutive days. The monitors will be individualized for each person's walking speed (e.g. slow, normal, or fast walking), pattern (e.g. normal, no variation in speed, lots of variation in speed), and gait (e.g. normal, shuffled). Daily step counts will be multiplied by 2 to obtain total daily steps (for both legs) and divided by 4 days to obtain the mean daily steps. Higher scores indicate more steps taken.	- Stroke
Diet – Fibre and Fat intake	SmartDiet Questionnaire – Canadian Version[15]	26	Weekly number of fibre (grain products; fruits, vegetables, and legumes) and fat (dairy products; meats; added fats; and desserts) servings are assessed and used to estimate total weekly grams of fibre and fat eaten. Higher grams of fibre and lower grams of fat indicate a more optimal diet (i.e. 25–35 grams/day = optimum fibre intake, < 13 grams/day = low fibre intake; 100 (male) and 90 (female) grams/day = high fat diet, 75 and 65 grams/day = lower fat diet.	- Cardiac rehab population
Medication adherence	Morisky Medication Adherence Scale[16–18]	8	Medication adherence and barriers to taking medication are assessed using 8 items. Use of the ©MMAS is protected by US Copyright laws. Permission for use is	- Hypertensive patients

Variable	Measure	# of items	Focus and Scoring	Populations with measurement evidence
			required. A license agreement is available from Donald E. Morisky, MMAS Research LLC 14725 NE 20. St. Bellevue WA 98007 or from dmorisky@gmail.com.	
Secondary Physiological Outcomes				
Blood pressure	Omron HEM-907XL using the American Heart Association blood pressure recommendations[19]	n/a	After 5 minutes of resting in the sitting position, the participant's systolic and diastolic blood pressure (mmHg) will be taken at the brachial artery using a digital blood pressure monitor (Omron HEM-907XL; Omron Healthcare Inc., Hoffman Estates, IL, USA). Two subsequent measurements will be taken, two minutes apart, and the three measurements will be averaged. If there is >5 mm Hg difference between consecutive measurements, additional measurements (to a maximum of five in total) will be taken. Higher blood pressure (over 140/90 mmHg) is indicative of higher stroke risk.	- National recommendations
Cholesterol	High and Low Density Lipoprotein; Total cholesterol	n/a	Cholesterol profiles (mmol/L) will be obtained using hospital outpatient bloodwork services.	n/a
Glucose	12-hour Fasting Glucose; HbA1c	n/a	Glucose profiles (mmol/L and HbA1c %) will be obtained using hospital outpatient bloodwork services.	n/a
Inflammation	C-Reactive Protein	n/a	C-Reactive Protein levels (mg/L) will be obtained using hospital outpatient bloodwork services.	n/a
Micronutrients (folate, B_{12})	Homocysteine	n/a	Homocysteine levels (umol/L) will be obtained using hospital outpatient bloodwork services.	n/a
Body composition	Body Mass Index; Waist-to-hip ratio	n/a	Body weight (kilograms) and height (metres) will be measured using a calibrated digital scale	n/a

Variable	Measure	# of items	Focus and Scoring	Populations with measurement evidence
			(Seca Robusta 813; Seca North America, Chino, CA, USA) and a wall-mounted measuring tape. Body mass index is calculated as body weight/height squared. Waist circumference will be measured at the level of the umbilicus. A non-stretch, flexible measuring tape will be placed in a horizontal plane around the participant's umbilicus while standing. Measurement will be taken at the end of a normal expiration. Hip circumference will be measured at the level of the greater trochanters.	
Tertiary Health Outcomes				
Health-related quality of life	Medical Outcomes Study: Short Form-36[20]	36	Two domains of health-related quality of life (Physical and Mental) are assessed using various response scales. The Physical and Mental scores are linearly transformed to a standardized score varying from 0 (negative health) to 100 (positive health).	- Various
Depressive symptoms	Center for Epidemiologic Studies Depression Scale[21]	20	Frequency of depressive symptoms over the past week is assessed using a 0 (rarely or none of the time) to 3 (most of the time) response scale. Items responses are summed to obtain a total score varying from 0 to 60. Higher scores indicate more frequent depressive symptoms.	- Stroke
Cognitive function	Montreal Cognitive Assessment[22]	22	Eight domains of cognitive function (Attention and concentration; Executive function; Memory; Language; Visuoconstructional skills; Conceptual thinking; Calculations; and Orientation) are assessed. Participants are given a point for correctly completing a	- Stroke

Variable	Measure	# of items	Focus and Scoring	Populations with measurement evidence
			task or providing a correct response. Total scores vary from 0 to 30 with higher scores indicating greater cognitive function. An additional point is given if the participant's level of education is 12 years or less.	
Health and social service utilization	Health and Social Service Utilization Inventory[23]	15	Frequency of hospital admissions/visits over the last 6 months are collected as are other health and social services over the last 2 weeks (e.g., lab procedures, family doctor, therapist, homemaker), and prescription drugs over the last 4 days. Costs of each health and social service will be assigned based on the current BC Medical Service Plan price list.	n/a
Experience survey	Study specific exit survey	27	Staff communication, usefulness of the program, and program structure are assessed using a 0 (strongly disagree) to 5 (strongly agree) response scale. Participants are also asked: 1) What aspects of the program did you like the most? 2) Which aspects of the program did you not like? and 3) What suggestions do you have for improving the program?	n/a

n/a = not applicable

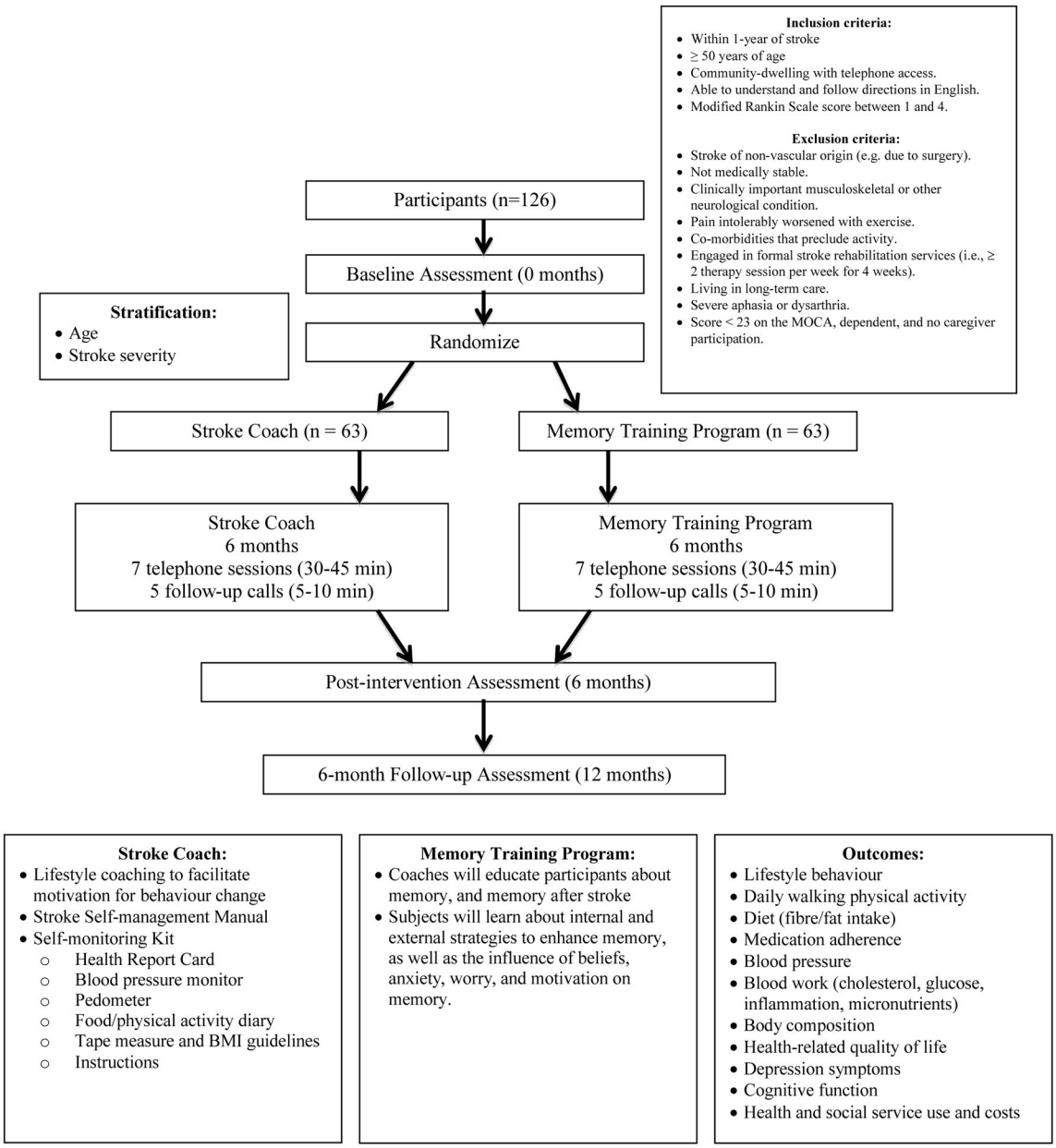

Figure 1.

Overview of trial procedures

This figure presents an overview of trial procedures, outcomes, and programs being evaluated.

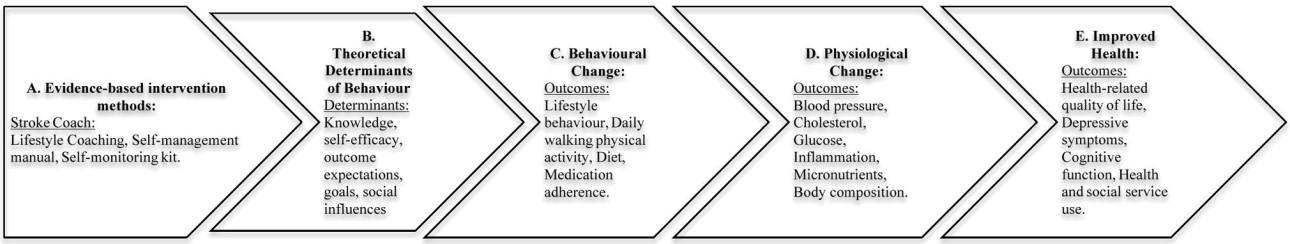

Figure 2.

Causal behavioural modeling framework[24]

This figure presents a conceptual framework that outlines the mechanism in which behaviour change leads to improved health, as hypothesized by Stroke Coach.