Promoting Optimal Physical Exercise for Life (PROPEL) – aerobic exercise and self-management early after stroke to increase daily physical activity: a randomized trial

Site Principal Investigators

Avril Mansfield, PhD
Site PI – SRI and TRI
Scientist, Toronto Rehabilitation Institute
Affiliate Scientist, Sunnybrook Research Institute
550 University Ave, Toronto, ON, M5G 2A2
Tel: 416-597-3422 ext 7831
e-mail: avril.mansfield@uhn.ca

Dina Brooks, PhD
Site PI – West Park
Professor, University of Toronto
Senior Scientist, West Park Healthcare Centre
500 University Ave, Toronto, ON, M5G 1V7
Tel: 416-978-1739
e-mail: dina.brooks@utoronto.ca

Ada Tang, PhD
Site PI – Hamilton Health Sciences
Assistant Professor, McMaster University
1400 Main St W, Hamilton, ON, L8S 1C7
Tel: 905-525-9140 ext 27818
e-mail: atang@mcmaster.ca

Denise Taylor, MPH, BScPT
Site PI – St Joseph's Care Group
Box 3251 Thunder Bay, P7B 5G7
Tel: 807-343-2431 ext 2562
e-mail: taylord@tbh.net

Co-investigators

Elizabeth Inness, PhD, BScPT
Leader, Balance Mobility and Falls Clinic,
Toronto Rehabilitation Institute
550 University Ave, Toronto, ON, M5G 2A2
Tel: 416-597-3422 ext 7816
e-mail: liz.inness@uhn.ca

Alex Kiss, PhD
Scientist, Sunnybrook Research Institute
2071 Bayview Ave, Toronto, ON, M4N 3M5
Tel: 416-480-6100 ext 7509
e-mail: alex.kiss@ices.on.ca

Laura Middleton, PhD
Assistant Professor, University of Waterloo
200 University Ave West, Waterloo, ON, N2L 3G1
Tel: 519-888-4567 ext 33045
e-mail: lmiddlet@uwaterloo.ca

Collaborators

Louis Biasin, BScPT
Clinical Resource Specialist, Toronto Rehabilitation Institute
550 University Ave, Toronto, ON, M5G 2A2
Tel: 416-597-3422 ext 3111
e-mail: louis.biasin@uhn.ca

Mila Bishev,
Patient Care Manager A-3, St. John's Rehab – Sunnybrook Health Sciences Centre
285 Cummer Ave, Toronto, ON, M2M 1G1
Tel: 416-226-6780 ext 7029
e-mail: mila.bishev@sunnybrook.ca

Rebecca Fleck, MSc, BHSc (OT)
Clinical Manager, Regional Rehabilitation Centre, Regional Rehabilitation Outpatient Services, SCI Rehab (B2 South) & Hand Clinic
Hamilton Health Sciences, 237 Barton St East, Hamilton, ON, L8L 2X2
Tel: 905-524-4322 ext 44833
e-mail: fleckr@hhsc.ca

Esmé French
Regional Stroke Rehabilitation Specialist, Northwestern Ontario Regional Stroke Network
Medical Centre, 201 – 984 Oliver Road, Thunder Bay, ON, P7B 7C7
Tel: 807-684-6498
e-mail: frenche@tbh.net

Gina Lam
A3 Physiotherapist, St. Johns' Rehab – Sunnybrook Health Sciences Centre
285 Cummer Ave, Toronto, ON, M2M 1G1
Tel: 416-226-6780 ext 6218
e-mail: gina.lam@sunnybrook.ca

Kathryn LeBlanc
Director, Regional Rehabilitation Program, Hamilton Health Sciences
300 Wellington St North, Hamilton, ON, L8L 0A4
Tel: 905-527-4322 ext 40821
e-mail: leblanck@hhsc.ca

Vivien Poon, MScPT
Clinical Resource Specialist, Toronto Rehabilitation Institute
550 University Ave, Toronto, ON, M5G 2A2
Tel: 416-597-3422 ext 3111
e-mail: vivien.poon@uhn.ca

Cathy Pupo
Manager, St John's Rehab – Sunnybrook Health Sciences Centre
285 Cummer Ave, Toronto, ON, M2M 1G1
Tel: 416-226-6780
e-mail: cathy.pupo@sunnybrook.ca

Shannon Reid, MScPT
Physiotherapist, Neurological Rehabilitation and Spasticity Clinic, West Park Healthcare Centre
82 Buttonwood Ave, Toronto, ON, M6M 2J5
Tel: 416-243-3600 ext 2284
e-mail: shannon.reid@westpark.org

Lynn Sutter, MSc, BScPT
Clinical Practice Leader – Physiotherapy, Neurological Rehabilitation, West Park Healthcare Centre
82 Buttonwood Ave, Toronto, ON, M6M 2J5
Tel: 416-243-3600 ext 2378
e-mail: lynn.suter@westpark.org

Krista Trow
Clinical manager, Integrated Stroke Program, Hamilton Health Sciences
237 Barton St East, Hamilton, ON, L8L 2X2
Tel: 905-521-2100 ext 41187
e-mail: trow@hhsc.ca

Study Personnel

Kay-Ann Allen, BSc
Research Assistant
Sunnybrook Research Institute
285 Cummer Ave, Toronto, ON, M2M 2G1
Tel: 416-226-6780 ext 7614
e-mail: kay-ann.allen@sunnybrook.ca

1. ABBREVIATIONS

BBAQ – Barriers to Being Active Quiz
CMSA – Chedoke-McMaster Stroke Assessment
GAE – Group Aerobic Exercise
MOCA – Montreal Cognitive Assessment
NIH-SS – National Institutes of Health Stroke Scale
PASIPD – Physical Activity Scale for Individuals with Physical Disabilities
PROPEL – Promoting Optimal Physical Exercise for Life
SOEE – Short Self-Efficacy for Exercise scale
SSEE – Short Outcome Expectations for Exercise scale
SWT – Stepped Wedge Trial

2. INTRODUCTION

People often have low aerobic capacity after stroke,[1,2] which makes even light physical activity effortful and can limit activities of daily living.[1,3,4] Aerobic exercise is beneficial post-stroke for improving aerobic capacity,[5-7] maintaining or promoting recovery[8] and for general health, including reducing risk of another stroke or other cardiovascular events.[9] Importantly, aerobic exercise is beneficial even early after stroke,[6] and can be feasibly implemented during routine rehabilitation.[10] However, length of stay in stroke rehabilitation is relatively short, so ongoing self-directed exercise post-discharge is necessary to maintain these benefits.

People with stroke do not maintain adequate levels of long-term exercise. Community-living people with stroke walk, on average, 70-5800 steps/day;[11] less than the 6000 steps/day recommended for people with physical disabilities.[12] Data from heart rate monitors reveal that, even when individuals with stroke are active, the activity is not of sufficient intensity.[13] Chronic inactivity within this group means that any gains in aerobic fitness made during rehabilitation are quickly lost post-discharge.[14] A vicious cycle can ensue: limited activity results in de-conditioning, functional decline and greater difficulty being active.[4]

There is a need to establish strategies to promote long-term uptake of exercise after stroke.[15] Most studies aiming to increase self-directed exercise post-stroke have been implemented in the community after formal rehabilitation is complete.[16,17] While some community-based programs have reported increased physical activity after the program,[18-20] many people have difficulty accessing community programs[16] and consequently attendance can be low.[21] The early recovery period during rehabilitation may be an optimal time to not only deliver fitness programming to increase exercise capacity, but also to shape long-term self-directed exercise behaviour.[14] To our knowledge only one group has studied such a program during stroke rehabilitation.[22] This study found that 67% of those who completed the intervention met exercise recommendations, compared to 55% in the control group. However, this study is limited by a non-randomized design, high rates of withdrawal in the intervention group compared to the control group (28% versus 12%), and low rates of compliance with the intervention (<67%). Furthermore, this study included individuals receiving rehabilitation for various conditions and was not focused solely on people with stroke, who have unique challenges to participating in exercise.[23]

We developed Promoting Optimal Physical Exercise for Life (PROPEL) – an exercise and self-management program that aims to facilitate the transition to the community. Our pilot non-randomized study suggests that those who complete PROPEL are more physically active after discharge from rehabilitation than those who do not.[24] The primary aim of this study is to ***evaluate the effect of PROPEL delivered <u>during</u> stroke rehabilitation on participation in self-directed exercise <u>after</u> rehabilitation.*** Our secondary aims are to evaluate the effect of PROPEL on self-efficacy and outcome expectations for exercise, and barriers to exercise. We hypothesize that, compared to those who

complete group aerobic exercise only, those who complete PROPEL will: 1) be more likely to meet the recommended intensity and duration of self-directed physical activity in the community (i.e., ≥150mins/week of moderate intensity exercise[25]); and 2) report higher self-efficacy and outcome expectations for exercise, and fewer barriers to community activity.

3. METHODOLOGY

3.1.Design overview

This study involves a single-blind, continuous recruitment short exposure, stepped-wedge cluster randomized controlled trial (SWT).[26] Participants will be recruited from one of 6 sites in Ontario. Collectively, these 6 sites have approximately 710 admissions to out-patient stroke rehabilitation annually (St. John's – Sunnybrook: 150; Toronto Rehab – University Centre: 160; Toronto Rehab – Rumsey: 130; West Park: 150; St. Joseph's Care Group: 60; Hamilton Health Sciences: 60). At a randomly-determined time within the study period (see Figure 1), each site will transition from the control intervention (group aerobic exercise only; GAE) to the experimental intervention (PROPEL). New participants will be recruited continuously throughout the study period and will either complete the GAE or PROPEL intervention, depending on which program that site is administering at the time at which they are admitted to rehabilitation.

Each site will be staffed by a research assistant (RA) and a physiotherapist (PT). The RA will be responsible for recruiting participants and collecting data. The PT will administer the interventions.

	2017							2018							
	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10	G11	G12	G13	G14	G15
Site A	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
SIte B	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1
Site C	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1
Site D	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1
Site E	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
Site F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Figure 1: Intervention allocation schedule. G1, G2 etc. are the 6-week long group aerobic exercise (GAE) or PROPEL groups. Each site should be able to complete 8 groups per year; however, only 7 groups will be completed in 2017 to allow for additional time at the start of the year to obtain research ethics approval, inter-institutional agreements, and pilot implementation at all sites (see also Figure 3). '0' indicates that the site will complete GAE in that time period, whereas '1' indicates that they will complete PROPEL. A simple randomization procedure will be used to determine the time at which each site transitions from GAE to PROPEL. Sites will be allocated in order by drawing names from a hat; e.g., the 1st site to be drawn will be Site A, the 2nd will be Site B, etc.

3.2.Rationale for SWT design

The group format is essential to PROPEL (see below). We experienced from our pilot study[24] that there was often a delay to start the group until there were ≥3 people referred. Therefore, a study design whereby individual participants are randomly allocated to either GAE or PROPEL would be problematic as there would be even greater delays in starting the groups. Likewise, a traditional cluster randomized controlled trial, where sites are randomly assigned to either complete GAE or PROPEL, would not be ideal due to the relatively low number of sites (6), and thus, reduced statistical power.[27] Therefore, the SWT is a pragmatic trial design that is suitable for evaluating interventions that are implemented routinely at the level of cluster.[26,27] It balances the need for robust evaluation with logistic constraints in program evaluation, particularly in cases of inter-site variability.[28] Indeed, previous authors have argued that well-designed and executed SWTs can be as rigorous as traditional cluster randomized trials.[26]

3.3.Interventions

The interventions will be implemented as part of routine care at all sites according to the schedule outlined in Figure 1 (e.g., Site B is expected to implement GAE in mid-February 2017, and PROPEL in around mid-May 2017). The interventions will supplement, rather than replace, current practice; that is, patients will still complete their regularly-scheduled physiotherapy, occupational therapy, and speech and language pathology sessions, as required. However, for patients who are enrolled in the GAE or PROPEL interventions, physiotherapists might choose to not complete individualized aerobic exercise during patients' regularly scheduled physiotherapy sessions as this will be completed as part of GAE/PROPEL, and to spend this time instead focusing on other rehabilitation goals (e.g., balance or gait retraining).

Both interventions involve supervised, individualized, group aerobic exercise up to 3 days/week for 6 weeks. Patients will be referred by their treating physiotherapist. The interventions will be implemented as part of routine care in out-patient rehabilitation at each site, and will be delivered in a 'closed group' format. That is, participants referred to the program will be placed on a waiting list until there are a sufficient number of participants to form a group (≥3), and all participants in the group will start the program at the same time. This will ensure that the mean time post-stroke at study enrolment does not differ between the two phases of intervention. Prior to starting the group, participants may complete individualized or open-group aerobic exercise as part of their regular in- or out-patient rehabilitation.

3.3.1. Control intervention – GAE

The control intervention will involve group aerobic exercise only (GAE). The intensity and duration of exercise within a session will be determined from a sub-maximal aerobic capacity test conducted prior to entry into the program using a protocol developed by our team.[10] The choice of exercise modality for the submaximal test and for training (e.g., recumbent stepper, cycle ergometer, or treadmill) will be individually prescribed based on patients' sensori-motor recovery, postural control, functional abilities, and safety. Group exercise will be supervised by the PT. A typical exercise session will involve a 3-5 minute 'warm-up', 20-30 minutes of aerobic exercise at a target heart rate determined from the sub-maximal test, and a 3-5 minute 'cool-down' of low-intensity exercise, which we have shown to be feasible for this target population.[10] Heart rate, blood pressure, rate of perceived exertion, workload, and duration of training will be documented for each session. These data will be reviewed by the PT with appropriate progression of the intensity and/or duration of exercise as necessary.

Patients in the GAE program may receive general advice to keep physically active after discharge, and may receive an individualized home exercise program, as is currently routine care at all sites.

3.3.2. Experimental intervention – PROPEL

The PROPEL program,[24] involves both group aerobic exercise and group discussion aimed at enabling participation in exercise after discharge. Components of the PROPEL program were developed according to the Transtheoretical Model of health behaviour change[29] and Social Cognitive Theory.[30] Participants will complete group exercise up to 3 days/week (described above for GAE). Participants will also attend 1-hour small group discussion sessions once weekly to learn self-management skills for exercise in preparation for discharge from rehabilitation. These group sessions include discussions to: identify and problem-solve around barriers to exercise; understand personal and general benefits of exercise; explore appropriate community resources for exercise; and find individualized and realistic strategies for incorporating exercise in a regular routine. The group format allows *vicarious experiences*; seeing others' achievements, especially for those uncertain of their own capabilities, may improve beliefs in the individuals' own capabilities.[31] The group can also act as a motivator for

continued engagement in exercise to achieve personal goals,[32] offering encouragement to attempt new exercises and challenge negative perceptions of ability (*social persuasions*).[33] Exercise self-efficacy predicts exercise behaviour post-stroke;[32,34,35] to facilitate self-efficacy for exercise, patients will learn how to monitor their own heart rate and rate of perceived exertion. Patients will also become comfortable with progressing their aerobic exercise and will set short- and long-term exercise goals. Access to a health care professional (PT) leading the group can increase an individual's belief about personal skill,[31] and support in teaching stroke survivors how to exercise independently, promoting feelings of safety and confidence.[33,34] Supportive planning and problem-solving to achieve long-term goals of continued exercise in the community would be fostered as patients transition from the fitness group to independent community programming or exercise.

3.4.Participants & recruiting

Individuals who complete either GAE or PROPEL as part of routine care at one of the 6 sites will be invited to participate in the study. To be eligible for referral to GAE or PROPEL, patients must be admitted to the facility for rehabilitation after a diagnosed stroke, and must be able to understand instructions. Patients will be excluded from GAE or PROPEL if they have conditions that limit their ability to exercise, including uncontrolled hypertension, uncontrolled diabetes, other cardiovascular morbidity that limits exercise tolerance (e.g., heart failure, abnormal blood pressure responses or ST-segment depression >2mm, symptomatic aortic stenosis, or complex arrhythmias), unstable angina, orthostatic blood pressure decrease of >20mmHg, or musculoskeletal impairments or pain. Additionally, participants will be withdrawn from GAE or PROPEL if significant cardiovascular abnormalities are observed during the sub-maximal exercise test. We have used these criteria to successfully enrol patients with stroke in aerobic exercise during in-patient rehabilitation with no serious adverse events.[10] Referral to the group will be made by the patients' primary treating physiotherapists, who will document the patients' verbal consent for treatment, as is usual practice.

Participants will be considered for inclusion in the study if they are referred to the GAE or PROPEL program as part of their stroke rehabilitation. Participants will be excluded from the study if:

- They have a language or communication barrier that prevents completion of questionnaires (e.g., severe receptive or global aphasia or non-English speaking);
- They have cognitive impairment that would prevent participation in unsupervised exercise;
- They attend less than 50% of GAE/PROPEL sessions; and/or
- They attend less than 4 of the 6 group discussion sessions (for individuals referred to the PROPEL program).

Communication and cognitive capacity to participate in the study will be determined via consultation with participants' healthcare team.

Potential participants will be assessed for eligibility by the study PT within the final two weeks of the patients' participation in the GAE/PROPEL programs. The study PT, who is in the patients' circle of care, will ask eligible patients if they are interested in speaking with the RA about participating in the study. The RA will discuss the study at a time that is convenient for interested individuals. She will describe the study, as outlined in the consent form (Appendix A) and will answer any questions the patient may have about the study. The patient will be provided with a copy of the consent form and will be invited to discuss the study with friends or family members, and/or to take some time to think about being involved in the study. If a patient indicates that s/he would like to participate in the study, s/he will be asked to sign the consent form. At that time, the RA will arrange a time that is convenient for the participant to collect baseline data (see Section 3.6.3.). We will assume that patients who do not provide consent to the study within two weeks after they finish the GAE/PROPEL program are not interested in participating in the study.

In order to keep track of participants, we will request contact information of a friend or family member ('alternative contact'; Appendix B); this form will be completed by the alternative contact. Participants who provide consent for us to contact their friends or family members will be provided with this form at the time when written consent is obtained, and will be asked to return the form at the next visit or by mail (a stamped self-addressed envelope will be provided). This information will only be used to obtain information about the whereabouts of a research participant if we are unable to contact them after multiple attempts. Participants will primarily be contacted by telephone throughout the study, unless otherwise requested. Each time they are contacted, participants will be told when they should next expect to hear from the RA and will be asked to inform the RA of upcoming limited availability (e.g. due to vacation or scheduled surgery). A letter will be mailed to participants (Appendix L) who are unable to be reached: 1) because his/her telephone number is out of service; or 2) five attempts have been made to telephone the participant over the course of two weeks (with at least two voicemail messages for participants who have voicemail and have provided consent for us to leave voicemail). In the latter case, telephone calls will be placed at varying times of the day in an attempt to reach participants who are unavailable at the same time each day due to regular appointments. The letter will request that participants contact the RA. If the RA does not hear from the participant two weeks after the letter was mailed, the RA will contact the alternative contact.

In order to generate a CONSORT flow-diagram for participant recruiting,[36] RA will count the number of individuals who are admitted to the out-patient stroke program and, of these, the number who are referred to the GAE or PROPEL program (Appendix C). The RA will also maintain documentation related to screening and enrolment of potential participants (Appendix D). Note that any identifying or health-related information will not be documented for individuals who do not consent to participate in the study.

3.5.Blinding

Participants cannot be blinded to intervention allocation. Assessors (RA at each site) who collect data, including administering questionnaires, will be unaware of the time at which the site transitions from GAE to PROPEL. While it is more likely that a given site will be allocated to GAE at the start of the study period, and to PROPEL at the end of the study, inclusion of two sites that always complete either GAE or PROPEL will create uncertainty in intervention allocation at all time points. Furthermore, using objective methods to collect data pertaining to the primary outcome (i.e., heart rate and activity monitor) helps to protect against bias if assessors inadvertently become unblinded.

3.6.Outcomes

3.6.1. Primary outcomes – physical activity

Physical activity will be assessed using a step counter, heart rate monitor, and questionnaires for 7 continuous days at three time points: 1) one month, 2) four months, and 3) six months post-intervention (Figure 2). Because of the limitations of relying on a single method of data collection for physical activity data, combining data from these three sources is recommended.[13,23,24,35] Participants will be supplied with a commercial wrist-worn step counter and heart rate monitor (FitBit Charge HR). Our pilot data suggests that this device provides reasonably accurate measures of walking activity and heart rate among individuals with stroke (unpublished data). Individuals who typically use a rollator for ambulation may also be provided with an activity monitor to be worn at the ankle (FitBit One), which would be more accurate for measuring walking activity than a wrist-worn device for these individuals.[37] The devices will be configured to not provide participants with information regarding step counts and heart rate. While participants will not have access to activity data to reduce measurement bias, they may choose to purchase their own activity-monitoring device to augment self-management strategies. The devices will be mailed to participants with a postage-paid return envelope.

Participants will be instructed to wear the device at all times (except when bathing) for 7 days continuously (Appendix E).

The Physical Activity Scale for Individuals with Physical Disabilities (PASIPD)[38] will be conducted by telephone with a blinded RA at the end of the 7-day monitoring period. The PASIPD is a 13-item questionnaire in which participants are asked to indicate the frequency and duration of recreational, household and occupational physical activities completed in the previous 7 days. The PASID has been validated within a group of individuals with various physical disabilities, including individuals with stroke, showing good test-retest reliability (ρ=0.77) and criterion validity when compared to accelerometer-based activity monitoring (ρ=0.30).[39]

We will use the step activity, heart rate, and questionnaire data to determine if participants meet the recommended intensity and duration of physical activity in the community; that is, at least 150 minutes per week of moderate-vigorous intensity exercise.[25] Participants will be deemed to meet the recommendations within a given week if they meet at least two of three criteria: 1) record at least 150 'active minutes' (from the step activity monitor); 2) record at least 150 minutes of heart rate between 55-80% of age-predicted maximum;[9] and/or 3) report at least 150 minutes of moderate and/or vigorous intensity activity on the PASIPD.

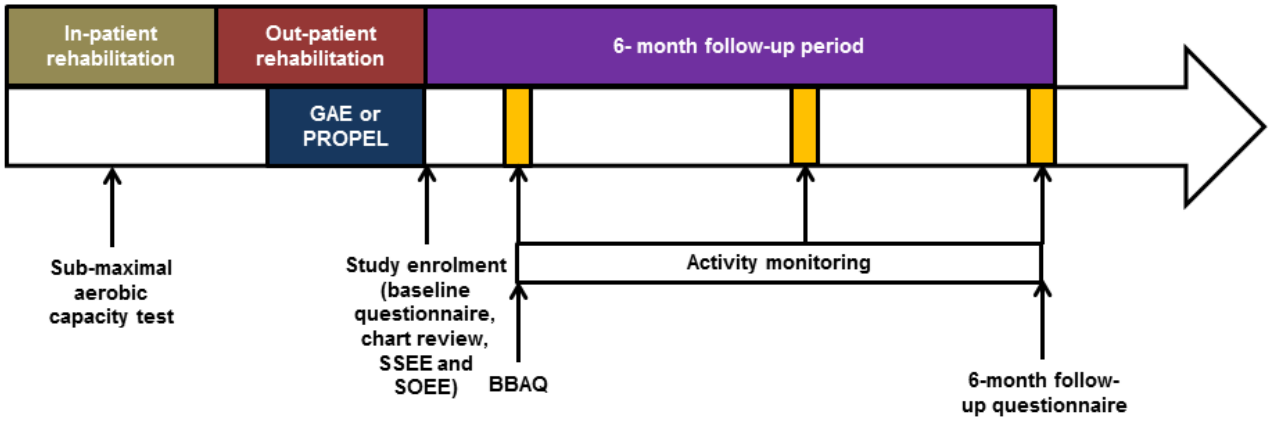

Figure 2: Hypothetical timeline for one participant. The exact timing of in- and out-patient rehabilitation will vary for each participant. The sub-maximal aerobic capacity test is completed during in-patient rehabilitation. After this point the participant could participate in individual or open-group aerobic exercise during in- and out-patient rehabilitation (while waiting to be enrolled in the study intervention). The closed-group study intervention (group aerobic exercise (GAE) only or PROPEL) will likely start during out-patient rehabilitation, though some patients may start during in-patient rehabilitation. The participant will be enrolled in the study at the end of the study intervention, at which point cohort descriptors, the Short Self-Efficacy for Exercise (SSEE) scale, and the Short Outcome Expectations for Exercise (SOEE) scale will be collected. Activity monitoring will be conducted for 7 days continuously at three time points: 1) one month; 2) 4 months; 3) and 6 months after the end of the study intervention. The Barriers to Being Active Quiz (BBAQ) will be conducted at the 1-month post-intervention time point.

3.6.2. Secondary outcomes - self-efficacy and outcome expectations for exercise, and barriers to activity

Exercise self-efficacy will be assessed using the Short Self-Efficacy for Exercise (SSEE) scale.[40] The SSEE is a four-item questionnaire where participants are required to rate their confidence exercising through pain and fatigue, and when alone and depressed on a five-point scale. The Short Outcome Expectation for Exercise (SOEE) scale[40] will be used to assess beliefs and attitudes related to exercise. The SOEE is a five-item questionnaire where participants are asked to rate their beliefs regarding the benefits of exercise on a five-point scale. The SSEE and SOEE will be assessed at enrolment into the study. The SSEE and SOEE have been shown to be valid and reliable among individuals with chronic stroke.[40]

Perceived barriers to physical activity will be assessed 1-month post-intervention with the Barriers to Being Active Quiz (BBAQ).[23,41] The BBAQ has previous been used to evaluate barriers to exercise among individuals with stroke.[23] The BBAQ is a 21-item scale where individuals are required to indicate how likely they are to make specific statements regarding barriers to exercise, for example "I'm getting older so exercise can be risky".[41] Items on seven categories of barriers are included in the questionnaire: lack of time, social influence, lack of energy, lack of willpower, fear of injury, lack of skill, and lack of resources. Each individual item is scored from 0-3 and scores for each barrier category are the sum of the scores for the three items in that category. Participants are considered to have a 'significant' barrier to being active if the score for a category is 5 or higher.[23] The average number of significant barriers per participant will be calculated.

3.6.3. Cohort descriptors

The following information will be obtained from chart review in order to characterize individuals who participate in the study: age, sex, time post-stroke (at enrolment into the study), lesion location, and medical conditions/history (Appendix F). The National Institutes of Health Stroke Scale (NIH-SS),[42] the Chedoke-McMaster Stroke Assessment (CMSA)[43] foot and leg scores, and the Montreal Cognitive Assessment[44] will be administered at enrolment into the study by the RA or study PT; however, if these measures were conducted as part of clinical care within 1-week of study enrolment, the scores will be extracted from the hospital charts to minimize participant burden. The NIH-SS is an 11-item scale that provides a gross measure of the effects and severity of stroke. The NIH-SS has good intra-rater (ICCs=0.93) and inter-rater (ICCs=0.95) reliability.[45] The CMSA assigns a score according to the level of motor recovery in the foot and leg and is frequently used to evaluate level of motor recovery post-stroke in clinical settings. The CMSA foot and leg scores have good intra-rater (ICCs=0.94-0.98) and inter-rater (ICCs=0.85-0.96) reliability.[43] The MOCA[44] is a paper-based test that can be used to screen for mild cognitive impairment; patients are scored on visuospatial and executive function, naming, memory, attention, language, abstraction, delayed recall, and orientation.

We will document the frequency and intensity of exercise during in- and out-patient rehabilitation by chart review (Appendix F). Participants will complete a questionnaire at baseline that asks about their social supports, employment, familial responsibilities, living situation etc (Appendix G), which are factors that could influence participation in physical activity. Many of these questions have been adapted from the Canadian Longitudinal Study on Aging.[46] Some questions will be repeated at the 6-month post-discharge time-point (Appendix H) to account for lifestyle changes since discharge from rehabilitation. Pre-morbid exercise behaviour will be evaluated with the Schmidt retrospective physical activity scale.[47] This scale shows good agreement with previously-completed questionnaires regarding physical activity.[47] We will use this scale to estimate participants' average amount of time (hours/day) prior to their strokes spent in sedentary activities (e.g., watching television, sedentary occupational activity) and in physical recreational activity or exercise.

3.7.Intervention allocation

The time at which each site transitions from GAE to PROPEL will be determined by drawing site names at random (see Figure 1 for full details). One site will implement PROPEL at the start of the study period, whereas one site will never transition to PROPEL; this will help to ensure blinding of assessors (see next section). The site that does not transition to PROPEL during the study period will be offered training in PROPEL at the end of the study period. Intervention allocation will be performed at the start of the study period by the principal investigator, who will not be directly involved in recruiting or data collection.

3.8.Statistical analysis

We will compare cohort descriptors between the two phases (GAE and PROPEL) using t-tests, Mann-Whitney *U* tests, or chi-square tests, as appropriate. If phases significantly differ at baseline on cohort descriptors these measures may be used as covariates in the analysis. To test our primary hypothesis, we will compare the proportion of active and inactive individuals at the final assessment point (6 months post-intervention) using mixed-model logistic regression, with fixed effects of time and phase and random effect of cluster (site).[48] We will also examine between-phase differences in physical activity at the 1-month and 4-month time points, which could reveal short-term benefits of PROPEL, even if there are no differences at 6-months. A similar mixed-model ANOVA will be used to compare SSEE, SOEE, and BBAQ scores between programs to test the secondary hypothesis.

3.9.Sample size

We expect that approximately 25% of people who complete GAE[49] and 50% of individuals who complete PROPEL[24] will be classified as 'active'. A sample of 96 per phase will provide 80% power to detect a 25% to 50% difference at alpha of 0.05 for the 6 sites taking into account an intracluster correlation of 0.05.[50] The sample size calculation was run using PASS Version 12 (Hintze, J, 2014, NCSS, LLC. Kaysville, Utah). We will aim to recruit 120 participants total per phase to account for a conservative 20% drop-out rate; note that in our previous studies where participants were recruited at discharge from rehabilitation and followed for up to 6 months, the rate of withdrawal was much lower (<12%[24,51,52]). There are 710 admissions annually to out-patient stroke rehabilitation at all sites combined. We conservatively estimate that approximately 40% of these individuals will be eligible for the study and, of these, 50% will consent to participate. Thus, we expect to recruit ~140 participants annually to meet the target sample size with ~2 years of recruiting (see timelines and milestones: Figure 3). Target sample sizes for each site are: St John's – 60, West Park – 60, Toronto Rehabilitation Institute (both sites) – 116, St Joseph's Care Group – 24, Hamilton Health Sciences – 24.

3.10. Timelines

This project is expected to take 3.5 years to complete (Figure 3). The first 6-7 months will be spent obtaining research ethics approval at all sites, establishing inter-institutional agreements, and hiring and training study staff. We will also pilot implement at least one GAE group at each site prior to the start of the study period. Interventions will begin around mid-February 2017 and will continue until the end of 2018. Data collection will continue for 6 months beyond the end of the interventions, and will be complete by June 2019. Clinical staff training in PROPEL will be 'rolled out' at each site according to the allocation schedule (see also Figure 1). Data analysis and writing will occur in the final 6 months.

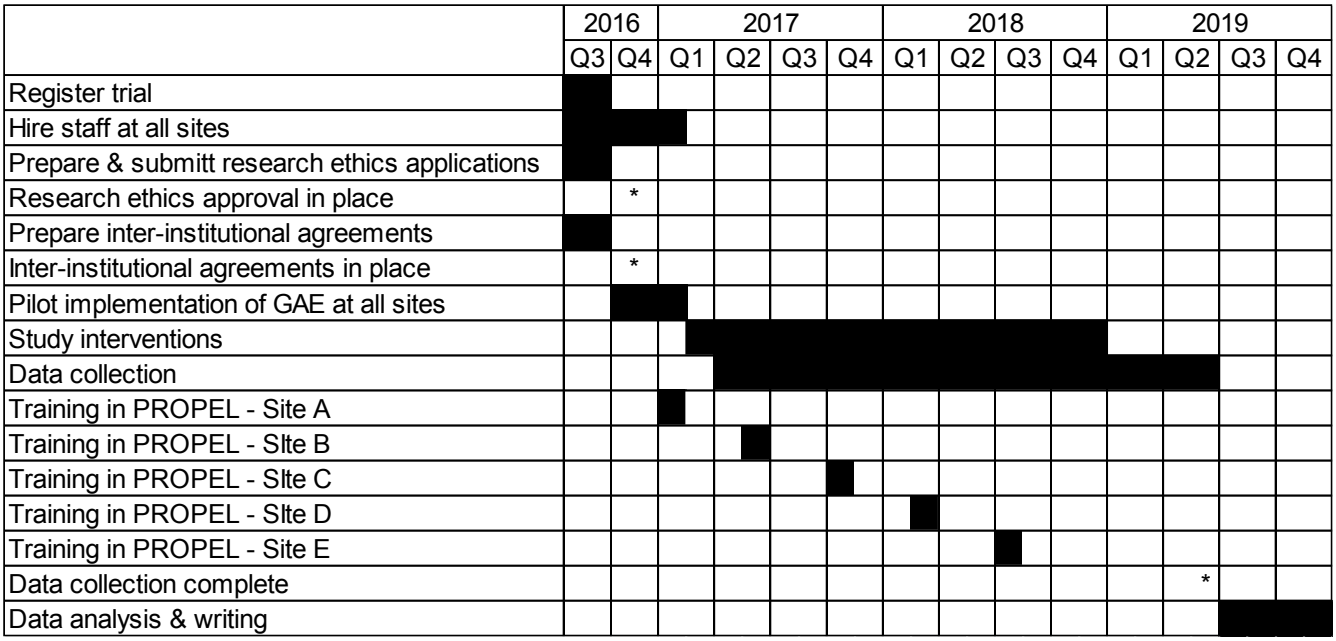

Figure 3: Gantt chart showing anticipated timelines for the study.

4. ROLE OF TEAM MEMBERS

Avril Mansfield will oversee the study, lead regular team meetings, and serve as site lead for St John's Rehab – Sunnybrook and the Toronto Rehab sites. Dina Brooks will be the site lead at West Park, Ada Tang will be the site lead at Hamilton Health Sciences, and Denise Taylor will be the site lead at St Joseph's Care Group. All site leads have prior experience leading clinical trials. Elizabeth Inness will lead knowledge translation activities and will coordinate training of sites in GAE or PROPEL. Alex Kiss will perform statistical analysis. Collaborators will facilitate implementing the interventions at each site. All team members will participate in dissemination activities (e.g., preparation of manuscripts and conference abstracts).

5. RISK MANAGEMENT

5.1.Patient safety and burden

Sites will implement two interventions as part of routine care (GAE or PROPEL). Some aerobic exercise is currently conducted at all sites, but might not be implemented in the systematic manner required for this study. However, aerobic exercise is recommended as part of stroke rehabilitation within the Canadian Stroke Best Practice Recommendations.[53] Furthermore, with appropriate screening and prescription, aerobic exercise is safe and feasible early after stroke.[10] Treating physiotherapists will screen patients, with appropriate consultation with the inter-professional team, and provide the exercise prescription following established guidelines for aerobic exercise after stroke,[54] prior to referring them to GAE or PROPEL. The interventions will be supervised by a trained registered physiotherapist, who will continue to monitor patients' response to exercise and may choose to adjust the intensity or duration of exercise to minimize risk to participants.

Heart rate and blood pressure will be measured at rest at the start of each intervention session to obtain a baseline measure of cardiovascular function. If measured blood pressure or heart rate is outside of an acceptable range (systolic blood pressure: 90-140 mmHg; diastolic blood pressure: 60-90 mmHg; heart rate: 60-100 bpm) a second measure will be obtained. If the 2nd measurement reveals elevated heart rate and/or blood pressure, the participant will be allowed to rest seated for 5 minutes, after which measurements will be retaken. If the 2nd measurement reveals low heart rate and/or blood pressure, the participant will be offered a glass of water and measurements will be retaken after 5 minutes.

Participants with heart rate/blood pressure measurements outside the acceptable range will also be questioned regarding recent medications (what they have taken and when, or if they have not taken their usual medications), when they last had something to eat and drink, and if they recently took caffeine or exercised. The decision to continue or terminate the session will be made by the PT considering factors such as the participants' usual resting heart rate/blood pressure, how far the measured values are outside of the acceptable range, the participants' usual medications (e.g., beta-blockers), and the participants' perception of how they are feeling. If the session is terminated, the PT may consult with the patients' physiatrist or other physician.

The Canadian Stroke Best Practice Recommendations also recommend including a plan to enable patients to continue to exercise post-discharge, including addressing barriers to physical activity.[53] However, the specific education, self-management, and problem-solving components of the PROPEL program are not part of routine care at all sites. The additional risk to participants in completing this component of the PROPEL program is minimal. Participants can opt out of any part of the discussion if they feel uncomfortable.

The additional measures conducted as part of the study pose minimal risk to participants. The CMSA, NIH-SS, and MOCA are frequently conducted as part of clinical care in stroke rehabilitation. Other measures are questionnaires which ask routine questions about physical activity behaviour and lifestyle. Despite the minimal risk involved in these measures, participants will be reminded that they can opt out of any testing and/or decline to answer any of the questions in the questionnaires. The activity monitoring also poses minimal risk to participants; the devices are available commercially and are worn daily by millions of individuals around the world. Participants may develop skin irritation from wearing the device daily; they will be instructed to remove the device if this occurs. Participants may feel burdened by donning and doffing the activity monitors each day.

The study PT will document any adverse events that occur during the interventions; the RA will document adverse events for participants who enrol in the study during the follow-up period (Appendix I).

5.2. Confidentiality

The study PT will run the GAE and PROPEL interventions as part of routine care at each site. Patients who are referred to GAE or PROPEL may decline participation in the study. Therefore, individuals who do not consent to the study may participate in GAE or PROPEL. The study PT will be an individual who also has a role in clinical care on the stroke program at the site and, therefore, will already be part of the circle of care. The study PT will not have a role in recruiting participants into the study, other than to introduce the RA to potential participants.

A number of steps will be taken to ensure protection of personal health information. Data will be initially stored at each site. Each activity monitor will be linked to an anonymous account, and activity monitor data will be stored on the manufacturer's servers linked to these anonymous accounts. We will document internally which participants' data are associated with which accounts; therefore, there will be no information about study participants (e.g., name, age, study ID number) stored on the manufacturer's servers. Activity data will be downloaded from the manufacturer's servers as soon as possible after collection. All other electronic data will be stored on secure institutional servers. Files containing patient names and contact information will be password protected. Hard copies of files containing de-identified data will be stored in locked cabinets and/or in offices that are locked when not occupied. Consent forms will be stored in locked cabinets/offices separately from other data. Only those individuals who require access to the data for the purpose of this study will be provided with the password to the file containing identifiers and/or the keys to the locked cabinet/office. Each site will use secure/encrypted methods approved by their institution to transfer data to the main site (Sunnybrook Research Institute).

6. IMPACT

This work addresses methodological limitations of studies aiming to increase exercise participation post-stroke[16,17] by: 1) basing the intervention on principles of behaviour modification; 2) using objective measures of exercise participation; and 3) evaluating long-term self-directed exercise (e.g., at least 6 months post-intervention). We expect that this study will find that a simple intervention delivered during stroke rehabilitation can encourage participation in exercise post-discharge. Ultimately, translation of this program into practice has the potential to reduce healthcare costs (by reducing risk of cardiovascular events) and increase independence for stroke survivors.

7. LIST OF APPENDICES

A. Consent form
B. Alternative contact form
C. Screening log
D. Enrolment log
E. Participant FitBit instructions
F. Chart review form
G. Baseline questionnaire
H. 6-month follow-up questionnaire
I. Adverse event reporting form
J. Overall study budget
K. Site budget
L. Follow-up letter draft

8. REFERENCES

1. Tang A, Sibley KM, Thomas SG, McIlroy WE, Brooks D. Maximal exercise test results in subacute stroke. *Arch Phys Med Rehabil.* 2006;87:1100-1105.

2. Brooks D, Tang A, Sibley K, McIlroy WE. Profile of patients at admission into an inpatient stroke rehabilitation program: cardiorespiratory fitness and functional characteristics. *Physiother Can.* 2008;60(2):171-179.

3. MacKay-Lyons MJ, Makrides L. Exercise capacity early after stroke. *Arch Phys Med Rehabil.* 2002;83:1697-1702.

4. Rimmer JH, Wang E. Aerobic exercise training in stroke survivors. *Top Stroke Rehabil.* 2005;12(1):17-30.

5. Tang A, Marzolini S, Oh P, McIlroy WE, Brooks D. Feasibility and effects of adapted cardiac rehabilitation after stroke: a prospective trial. *BMC Neurol.* 2010;10:40.

6. Tang A, Sibley KM, Thomas SG, et al. Effects of an aerobic exercise program on aerobic capacity, spatiotemporal gait parameters, and functional capacity in subacute stroke. *Neurorehabil Neural Repair.* 2009;23:389-397.

7. Stoller O, de Bruin ED, Knols RH, Hunt JJ. Effects of cardiovascular exercise early after stroke: systematic review and meta-analysis. *BMC Neurology.* 2012;12:45.

8. Saunders DH, Sanderson M, Brazzelli M, Gerig CA, Mead GE. Physical fitness training for stroke patients. *Cochrane Database Syst Rev.* 2013(10):CD003316.

9. Billinger SA, Arena R, Bernhardt J, et al. Physical activity and exercise recommendations for stroke survivors: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2014;45:2532-2553.

10. Biasin L, Sage MD, Brunton K, et al. Integrating aerobic training within sub-acute stroke rehabilitation: a feasibility study. *Phys Ther.* 2014;94(12):1796-1806.

11. Michael KM, Allen JK, Macko RF. Reduced ambulatory activity after stroke: the role of balance, gait, and cardiovascular fitness. *Arch Phys Med Rehabil.* 2005;86:1552-1556.

12. Tudor-Locke C, Craig CL, Aoyagi Y, et al. How many steps/day are enough? For older adults and special populations. *Int J Behav Nutr Phys Act.* 2011;8:80.

13. Baert I, Feys H, Daly D, Troosters T, Vanlandewijck Y. Are patients 1 year post-stroke active enough to improve their physical health? *Disabil Rehabil.* 2012;34(7):574-580.

14. Morris JH, Williams B. Optimising long-term participation in physical activities after stroke: exploring new ways of working for physiotherapists. *Physiotherapy.* 2009;95:227-233.

15. Rosenberg DE, Bombardier CH, Hoffman JM, Belza B. Physical activity among persons aging with mobility disabilities: shaping a research agenda. *J Aging Res.* 2011;2011:708510.

16. Jones TM, Dean CM, Hush JM, Dear BF, Titov N. A systematic review of the efficacy of self-management programs for increasing physical activity in community-dwelling adults with acquired brain injury. *Syst Rev.* 2015;4:51.

17. Morris JH, MacGillivray S, Mcfarlane S. Interventions to promote long-term participation in physical activity after stroke: a systematic review of the literature. *Arch Phys Med Rehabil.* 2014;95:956-967.

18. Kim H, Kim O. The lifestyle modification coaching program for secondary stroke prevention. *J Korean Acad Nurs.* 2013;43(3):331-340.

19. Damush TM, Ofner S, Yu Z, Plue L, Nicholas G, Williams LS. Implementation of a stroke self-management program: a randomized controlled pilot study of veterans with stroke. *Transl Behav Med.* 2011;1(4):561-572.

20. Gillham S, Endacott R. Impact of enhanced secondary prevention on health behaviour in patients following minor stroke and transient ischaemic attack: a randomized controlled trial. *Clin Rehabil.* 2010;24:822-830.

21. Huijbregts M, Myers A, Streiner D, Teasell R. Implementation, process and preliminary outcomes evaluation of two community programs for persons with stroke and their care partners. *Top Stroke Rehabil.* 2008;15:503-520.

22. van der Ploeg HP, Streppel KRM, van der Beek AJ, et al. Successfully improving physical activity behavior after rehabilitation. *Am J Health Promot.* 2007;21(3):153-159.

23. Zalewski KR, Dvorak L. Barriers to physical activity between adults with stroke and their care partners. *Top Stroke Rehabil.* 2011;18(Suppl 1):666-675.

24. Mansfield A, Knorr S, Poon V, et al. Promoting Optimal Physical Exercise for Life (PROPEL) - an exercise and self-management program to encourage participation in physical activity after discharge from stroke rehabilitation: a feasibilty study. *Stroke Res Treat.* 2016;2016:9476541.

25. Garber CE, Blissmer B, Deschenes MR, et al. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc.* 2011;43(7):1334-1359.

26. Copas AJ, Lewis JJ, Thompson JA, Davey C, Baio G, Hargreaves JR. Designing a stepped wedge trial: three main designs, carry-over effects and randomisation approaches. *Trials.* 2015;16:352.

27. Mdege ND, Man M-S, Taylor CA, Torgerson DJ. Systematic review of stepped wedge cluster randomized trials shows that design is particularly used to evaluate interventions during routine implementation. *J Clin Epidemiol.* 2011;64:936-948.

28. Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *Br Med J.* 2015;351:h391.

29. Prochaska JO, Di Clemente CC. Transtheoretical therapy: toward a more integrative model of change. *Psychother: Theor Res.* 1982;19(3):276-288.

30. Bandura A. Health promotion by social cognitive means. *Health Educ Behav.* 2004;31(2):143-164.

31. Bandura A. *Self efficacy. The exercise of control*. New York: W.H. Freeman; 1997.

32. Morris J, Oliver T, Kroll T, MacGillivray S. The importance of psychological and social factors in influencing the uptake and maintenance of physical activity after stroke: a structured review of the empirical literature. *Stroke Res Treat.* 2012;2012:195249.

33. Reed M, Harrington A, Duggan A, Wood VA. Meeting stroke survivors perceived needs: a qualitative study of community-based exercise and education scheme. *Clin Rehabil.* 2010;24(1):16-25.

34. Kinne S, Patrick DL, Maher EJ. Correlates of exercise maintenance among people with mobility impairments. *Disabil Rehabil.* 1999;21(1):15-22.

35. Resnick B, Michael K, Shaughnessy M, et al. Inflated perceptions of physical activity after stroke: pairing self-report with physiologic measures. *J Phys Act Health.* 2008;5(2):308-318.

36. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet.* 2001;357:1191-1194.

37. Klassen TD, Simpson LA, Lim SB, et al. "Stepping up" activity poststroke: ankle-positioned accelerometer can accurately record steps during slow walking. *Phys Ther.* 2016;96(3):355-360.

38. Washburn RA, Zhu W, McAuley E, Frogley M, Figoni SF. The Physical Activity Scale for Individuals with Physical Disabilities: development and evaluation. *Arch Phys Med Rehabil.* 2002;83:193-200.

39. van der Ploeg HP, Streppel KR, van der Beek AJ, van der Woude LH, Vollenbroek-Hutten M, van Mechelen W. The Physical Activity Scale for Individuals with Physical Disabilities: test-retest reliability and comparison with an accelerometer. *J Phys Act Health.* 2007;4(1):96-100.

40. Shaughnessy M, Resnick BM, Macko RF. Reliability and validity testing of the Short Self-Efficacy and Outcome Expectation for Exercise Scales in stroke survivors. *J Stroke Cerebrovasc Dis.* 2004;13(5):214-219.

41. Barriers to Being Active Quiz. http://www.cdc.gov/diabetes/ndep/pdfs/8-road-to-health-barriers-quiz-508.pdf. Accessed 23 March, 2012.

42. Goldstein LB, Bertels C, Davis JN. Interrater reliability of the NIH Stroke Scale. *Arch Neurol.* 1989;46(6):660-662.

43. Gowland C, Stratford P, Ward M, et al. Measuring physical impairment and disability with the Chedoke-McMaster Stroke Assessment. *Stroke.* 1993;24:58-63.

44. Nasreddine ZS, Phillips NA, Bédirian V, et al. The Montreal cognitive assessment (MoCA): a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc.* 2005;53:695-699.

45. Kasner SE. Clinical interpretation and use of stroke scales. *Lancet Neurol.* 2006;5:603-612.

46. Raina P, Wolfson C, Kirkland S. Canadian Longitudinal Study on Aging (CLSA) Protocol. 2013. https://clsa-elcv.ca/doc/511. Accessed 22 September 2016.

47. Schmidt ME, Slanger T, Chang-Claude J, Wahrendorf J, Steindorf K. Evaluation of a short retrospective questionnaire for physical activity in women. *Eur J Epidemiol.* 2006;21:575-585.

48. Davey C, Hargreaves J, Thompson JA, et al. Analysis and reporting of stepped wedge randomised controlled trials: synthesis and critical appraisal of published studies, 2010 to 2014. *Trials.* 2015;16:358.

49. Brown C, Fraser JE, Inness EL, et al. Does participation in standardized aerobic fitness training during inpatient stroke rehabilitation promote engagement in aerobic exercise after discharge? A cohort study. *Top Stroke Rehabil.* 2014;21(Suppl 1):S42-51.

50. Donner A, Klar N. *Design and analysis of cluster randomized trials in health research*. London: Arnold; 2000.
51. Mansfield A, Wong JS, McIlroy WE, et al. Do measures of reactive balance control predict falls in people with stroke returning to the community? *Physiotherapy.* 2015;101(4):373-380.
52. Mansfield A, Schinkel-Ivy A, Danells CJ, et al. Does perturbation training prevent falls after discharge from stroke rehabilitation? A prospective cohort study with historical control. Paper presented at: Canadian Stroke Congress; 15-17 September, 2016; Quebec City, QC.
53. Hebert D, Lindsay MP, McIntyre A, et al. Canadian stroke best practice recommendations: stroke rehabilitation practice guidelines, update 2015. *Int J Stroke.* 2016;11(4):459-484.
54. MacKay-Lyons M, Macko R, Eng J, et al. Aerobic exercise recommendations to optimize best bractices in care after stroke. 2012; http://strokebestpractices.ca/wp-content/uploads/2013/07/AEROBICS-FINAL-July-2013.pdf. Accessed 16 March, 2015.