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



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## 1. ADMINISTRATIVE INFORMATION

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

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this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

**Roles:** AM conceived of the study, is the grant holder, and drafted the manuscript. AM, DB, AT, and DT will lead implementation of the study at each site, with assistance from ELI, LB, RF, EF, KL, and CD. ELI, LB, and CD developed the intervention. AK provided statistical expertise and will conduct the primary statistical analysis. AM, DB, AT, DT, ELI, AK, LM, LB, RF, EF, KL, AA, and CD contributed to refining the study protocol and approved the final manuscript.

## 2. WHO DATASET

1. **Trial registration:** clinicaltrials.gov, NCT02951338
2. **Date of registration:** 31 October 2016
3. **Secondary identification numbers:** Not applicable
4. **Sources of monetary or material support:** This study is supported by the Canadian Institutes of Health Research (PJT-148906). AM holds a New Investigator Award from the Canadian Institutes of Health Research (MSH-141983). DB holds a Canada Research Chair. AT is supported by a personnel award from the Heart and Stroke Foundation, Ontario Provincial Office (CS I 7468). The views expressed are not necessarily those of the funders.
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9. **Public title:** Promoting Optimal Physical Exercise for Life (PROPEL) in people with stroke
10. **Scientific title:** Promoting Optimal Physical Exercise for Life (PROPEL) – aerobic exercise and self-management early after stroke to increase daily physical activity: study protocol for a stepped-wedge randomized trial
11. **Countries of recruitment:** Canada
12. **Interventions:** Group aerobic exercise only (Active Comparator): Supervised group exercise up to 3-times/week for 6 weeks. 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 a sub-maximal or maximal aerobic capacity test, and a 3-5 minute 'cool-down' of low-intensity exercise. 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. 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 physiotherapist with appropriate progression of the intensity and/or duration of exercise as necessary. Participants 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. PROPEL program (experimental): The PROPEL program involves both group aerobic exercise (as described above) 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 and Social Cognitive Theory. In addition to group exercise participants will attend 1-hour small group discussion sessions once weekly to learn self-management skills for exercise in preparation for discharge from rehabilitation. These discussions include: identifying and solving problems around barriers to exercise; understanding personal and general benefits of exercise; exploring appropriate community resources for exercise; and finding individualized and realistic strategies for incorporating exercise in a regular routine. Participants will become comfortable with progressing their exercise and will set short- and long-term goals for engaging in physical activity and exercise after discharge.

13. **Key inclusion and exclusion criteria:** Inclusion criteria: Adults with stroke who are referred to the group aerobic exercise or PROPEL programs as part of their stroke rehabilitation. Exclusion criteria: Language or communication barrier that prevents completion of questionnaires (e.g., severe receptive or global aphasia or non-English speaking); cognitive impairment that would prevent participation in unsupervised exercise; attend less than 50% of group aerobic

exercise/PROPEL sessions; and/or attend less than 4 of the 6 group discussion sessions (for individuals referred to the PROPEL program).

14. **Study type:** Interventional stepped-wedge cluster randomized trial.
15. **Date of first enrolment:** February 2017 (anticipated)
16. **Target sample size:** 192
17. **Recruitment status:** Pending: participants are not yet being recruited or enrolled at any site.
18. **Primary outcomes:** Number of patients who meet recommended intensity, frequency, and duration of physical activity; that is, at least 150 minutes per week of moderate-to-vigorous intensity exercise. Physical activity will be assessed using a step counter, heart rate monitor, and questionnaire for 7 continuous days at 1-month, 4-months, and 6-months post-discharge.
19. **Secondary outcomes:** Short Self-efficacy for Exercise Scale; Short Outcome Expectation for Exercise Scale; and Barriers to Being Active Quiz

## 3. ABSTRACT

**Introduction:** Physical exercise after stroke is essential for improving recovery and general health, and reducing future stroke risk. However, people with stroke are not sufficiently active upon return to the community after rehabilitation. We developed the Promoting Optimal Physical Exercise for Life (PROPEL) program, which combines exercise with self-management strategies within rehabilitation to promote ongoing physical activity in the community after rehabilitation. This study aims to evaluate the effect of PROPEL on long-term participation in exercise after discharge from stroke rehabilitation. We hypothesize that individuals who complete PROPEL will be more likely to meet recommended frequency, duration, and intensity of exercise compared to individuals who do not complete the program up to 6-months post-discharge from stroke rehabilitation.

**Methods and analysis:** Individuals undergoing outpatient stroke rehabilitation at one of 6 hospitals will be recruited (target n=192 total). A stepped wedge design will be employed; i.e., the PROPEL intervention (group exercise plus self-management) will be 'rolled out' to each site at a random time within the study period. Prior to roll-out of the PROPEL intervention, sites will complete the control intervention (group aerobic exercise only). Participation in physical activity for 6-months post-discharge will be measured via activity and heart-rate monitors, and standardized physical activity questionnaire. Adherence to exercise guidelines will be evaluated by: 1) number of 'active minutes' per week (from the activity monitor); 2) amount of time per week when heart rate is within a target range (i.e., 55-80% of age-predicted maximum); and 3) amount of time per week completing 'moderate' or 'strenuous' physical activities (from the questionnaire).

**Ethics and dissemination:** Research ethics approval has been received from two of the six sites. Results will be disseminated directly to study participants at the end of the trial, and to other stake holders via publication in a peer-reviewed journal.

## 4. ARTICLE SUMMARY

- This multi-centre trial will determine if an exercise and self-management intervention can increase participation in physical activity after stroke rehabilitation.
- The novel 'stepped wedge' trial design is suitable given the group-based delivery of the intervention and relatively small number of sites involved.
- Participation in physical activity will be determined with three methods: self-report (activity questionnaire), daily heart rate monitoring, and daily activity monitoring.
- The trial is single-blinded (participants cannot be blinded to intervention allocation), which potentially introduces a source of bias.

## 5. INTRODUCTION

### 5.1 Background and rationale

People often have low aerobic capacity after stroke,[1 2] which can limit the stroke survivors' ability to complete 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] Indeed, aerobic exercise is beneficial and feasible even early after stroke and during routine rehabilitation[6 10] However, due to the brief length of stay in stroke rehabilitation (4-6 weeks), ongoing self-directed physical activity 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 to 5800 steps/day,[11] which is less than the 6000 steps/day recommended for people with physical disabilities.[12] Data from heart rate monitors revealed that, even when individuals with stroke were active, the activity was not of sufficient intensity for aerobic benefit.[13] This chronic inactivity means that gains in aerobic fitness made during rehabilitation will be lost post-discharge.[14]

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 was 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) – a combined group exercise and self-management program that aims to promote long-term engagement in exercise and physical activity after stroke. 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]

**5.2 Objectives**

The primary aim of this study is to evaluate the effect of PROPEL delivered during stroke rehabilitation on participation in self-directed exercise after 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.

**5.3 Trial design**

This study involves a single-blind (assessor blinded), continuous recruitment short exposure, stepped-wedge cluster randomized controlled superiority trial (SWT).[26] Six sites will be involved in the study; at a randomly-determined time within the study period (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.

The group format is essential to PROPEL (see below). In our pilot study[24] there was often a delay to start the group in order to have ≥3 people enrolled. 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 since twice as many people would be required to be enrolled in order to run concurrent 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]

## 6. METHODS: PARTICIPANTS, INTERVENTIONS, AND OUTCOMES

### 6.1 Study setting

Participants will be recruited from one of 6 rehabilitation hospitals in Ontario: 1) Hamilton Health Sciences, Hamilton, Ontario; 2) St. Joseph's Care Group, Thunder Bay, Ontario; 3) Sunnybrook Health Sciences Centre – St. John's Rehab, Toronto, Ontario; 4) Toronto Rehabilitation Institute – Rumsey Centre, Toronto, Ontario; 5) Toronto Rehabilitation Institute – University Centre, Toronto, Ontario; and 6) West Park Healthcare Centre, Toronto, Ontario. 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.

**6.2 Eligibility criteria**

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 enrolled in the PROPEL program).

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

**6.3 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 not to 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 informed by a sub-maximal or maximal aerobic capacity test. Patients will be referred by their treating physiotherapist. The interventions 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 and end the program at the same time. The closed-group format is essential for the PROPEL phase as the education and group discussion topics will be presented in a specific order. An open-group format could be used for GAE; however, this would result in participants in the GAE phase being recruited to the study, on average, sooner post-stroke than those in the PROPEL phase.[24] Therefore, using a closed-group format for both

phases will help to 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.

*6.3.1 Control intervention – GAE*

The control intervention will involve group aerobic exercise only (GAE). The intensity and duration of exercise will be determined from the results of a sub-maximal or maximal aerobic capacity test conducted prior to entry into the program. 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. 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.

*6.3.2 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). Additionally,

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 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 helps to promote vicarious experiences. To promote independence, 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.[32 33]

**6.4 Outcomes**

*6.4.1 Primary outcomes – physical activity*

Physical activity will be assessed using a step counter and heart rate monitor for 7 continuous days, as well as a physical activity questionnaire 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 34] Participants will be supplied with a commercial wrist-worn step counter and heart rate monitor (FitBit Charge HR). Our pilot data suggest 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.[35] The devices will be configured to not provide participants with information regarding step counts and heart rate. 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.

The Physical Activity Scale for Individuals with Physical Disabilities (PASIPD)[36] 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 ($\rho$=0.77) and criterion validity when compared to accelerometer-based activity monitoring ($\rho$=0.30).[37]

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.

*6.4.2 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.[38] 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[38] 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.[38]

Perceived barriers to physical activity will be assessed 1-month post-intervention with the Barriers to Being Active Quiz (BBAQ).[23 39] 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".[39] 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.

*6.4.3 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, mobility status, and medical conditions/history. The National Institutes of Health Stroke Scale (NIH-SS),[40] the Chedoke-McMaster Stroke Assessment (CMSA)[41] foot and leg scores, and the Montreal Cognitive Assessment[42] 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.[43] 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.[41] The MOCA[42] 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. Participants will complete a questionnaire at baseline that asks about their social supports, employment, familial responsibilities, living situation etc, which are factors that could influence participation in physical activity. Many of these questions have been adapted from the Canadian Longitudinal Study on Aging.[44] Some questions will be repeated at the 6-month post-discharge time-point to account for lifestyle changes since discharge from rehabilitation. Pre-morbid exercise behaviour will be evaluated with the Schmidt retrospective physical activity scale.[45] This scale shows good agreement with previously-completed questionnaires regarding physical activity.[45] 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.

**6.4 Sample size**

We expect that approximately 25% of people who complete GAE[46] 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.[47] 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.

### 6.5 Recruitment

There are approximately 710 admissions annually to out-patient stroke rehabilitation at all sites combined. We conservatively estimate that 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. Target sample sizes for each site are: Hamilton Health Sciences – 24; St Joseph's Care Group – 24; Sunnybrook Research Institute - St John's Rehab – 60, Toronto Rehabilitation Institute – Rumsey Centre – 58, Toronto Rehabilitation Institute – University Centre – 58, West Park Healthcare Centre – 60. To encourage recruitment to the study, participants will receive a gift card ($30 CAD value) as a modest incentive to participate.

In order to generate a CONSORT flow-diagram for participant recruiting,[48] 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. The RA will also maintain documentation related to screening and enrolment of potential participants. Identifying or health-related information will not be documented for individuals who do not consent to participate in the study.

## 7. METHODS: ASSIGNMENT OF INTERVENTIONS

### 7.1 Intervention allocation

The time at which each site transitions from GAE to PROPEL will be determined by drawing site names at random (Figure 1). 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 Section 7.2). 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. The Site Leads and PTs at each site will be informed of the transition to PROPEL approximately 3 months prior to the transition to allow for sufficient time for training and planning.

### 7.2 Blinding

Participants cannot be blinded to intervention allocation, although they will not be aware of the existence of another intervention arm. 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.

## 8. METHODS: DATA COLLECTION, MANAGEMENT, AND ANALYSIS

### 8.1 Data collection methods

Data will be collected primarily by the RA either directly from the participant or by chart review (see Table 1 for further details). RAs at each site will receive training regarding data collection from the Principal Investigator (AM) and central Study Coordinator (AA). Questionnaires will be completed via in person interview at enrolment, and over the telephone at the follow-up time points. Activity monitors will be sent to participants and returned to the site via mail. Participants will be contacted via telephone just prior to mailing the activity monitors to remind them that they will be receiving the activity monitors, and to ensure that they will be home to receive them (e.g., that they are not planning to be on vacation at that time).

In order avoid losing participants to follow-up, we will request contact information of a friend or family member. Participants who provide consent for us to contact their friends or family members will be provided with a contact 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 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.

**8.2 Data management**

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 at each site on secure institutional servers. Files containing patient names

and contact information will be password protected and stored separately from other data. 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. De-identified electronic data will be transferred to the main site (Sunnybrook Research Institute) using secure file transfer protocols.

### 8.3 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).[49] 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 hypotheses. All recruited participants who comply with data collection will be included in the analysis; participants with missing data for one time point will be excluded from analysis of that variable for that time point.

## 9. METHODS: MONITORING

### 9.1 Data monitoring

There is no data monitoring committee for this study, as the safety of aerobic exercise has already been established for this population,[6 10] and the additional risk of the discussion components of the PROPEL program and other study components (e.g., questionnaires or activity monitoring) is minimal (see Section 9.2). Adverse events that meet all three of the following criteria will be reported immediately to the local research ethics board(s), as is routine practice: 1) unexpected in terms of nature, severity, or frequency; 2) related or possibly related to participation in the research; and 3) suggests an potential increase in risk of harm to research participants or to others. All adverse events will be collated and evaluated bi-annually by the Principal Investigator (AM).

There is no plan for any interim analysis; interim analysis is not feasible with a SWT design due to the fact that the experimental intervention is 'rolled out' gradually to each site, which means that the number of participants per phase will be uneven until the end of the trial. The trial will be stopped when one of the following criteria are met: 1) we have recruited at least 120 participants per phase; 2) 6-month follow-up data are available for at least 96 participants per phase; or 3) all site investigators (AM, DB, AT, and DT) agree that continuing the trial will not be feasible (e.g., due to lower than expected recruiting and lack of funding to continue the trial).

**9.2 Potential harms and auditing**

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.[50] 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,[51] 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.[50] 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.

## 10. ETHICS AND DISSEMINATION

### 10.1 Research ethics approval

Research ethics approval has been received by the Research Ethics Board of the University Health Network (Study ID: 16-5916, approved 14 November 2016), which covers two sites (Toronto Rehabilitation Institute – University Centre, and Toronto Rehabilitation Institute – Rumsey Centre). As of this writing, research ethics approval is pending at the other four sites.

### 10.2 Protocol amendments

Substantive changes to the design or conduct of the study will require a formal amendment to the study protocol. Such substantive amendments will be agreed upon by the site investigators (AM, DB, AT and DT) and will be approved by the local Research Ethics Boards prior to implementation locally. Minor

administrative changes to study documents (e.g., correcting a typographical error or clarifying a questionnaire item) may also be implemented, with the Research Ethics Boards notified of the changes.

**10.3 Consent**

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. S/he will describe the study, as outlined in the consent form (Appendix) 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 6.4.3). 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.

**10.4 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 study and, if interested, introduce the RA to potential participants.

Identifiable information (participant names and contact information) will be stored separately from health information and study data (see also Section 8.2) in a password protected file, with the password only known to those individuals who are responsible for data collection. A participant ID number will be used to link identifiable information with health information and study data. The link between the participant ID number and name will be destroyed after data have been collected and verified. De-identified data will be kept in a secure and confidential location for 10 years.

**10.5 Declaration of interests**

The authors declare that they have no competing interests related to this study.

**10.6 Access to data**

The Principal Investigator (AM) and biostatistician (AK) will have access to the full dataset. The site investigators will have access to data collected locally. A study co-investigator or collaborator may be granted access to the full dataset for secondary analysis with approval of all site investigators (AM, DB, AT, and DT) and the coordinating institution (Sunnybrook Research Institute).

**10.7 Ancillary and post-trial care**

Each site will be responsible for providing out-of-pocket expenses to ensure that a participant receives immediate medical care in the event that the participant experiences an adverse health event (e.g. injury) as a result of participation in the study.

**10.8 Dissemination policy**

Study participants will receive a letter of appreciation at the end of the study, which may include a very brief summary of the study results. Study results will be disseminated to others via publication in a

peer-reviewed journal. We will aim to submit a paper describing analysis of the primary and secondary outcomes within 6 months of completing data collection. All individuals who meet the International Committee of Medical Journal Editors criteria for authorship will be included as authors on any publications arising from this work. There is no current plan to make the participant-level dataset available publicly; however, the dataset may be made available in future via a Data Access Committee, if such a committee is established by the coordinating institution.

## 11. 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, Bayley M, Richardson D, McIlroy WE, 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, Eng JJ, Franklin BA, Mortag Johnson C, 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, Fraser JE, Mileris R, Howe J, 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, Bell RC, Croteau KA, De Bourdeaudhuij I, 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. *Systematic Reviews* 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, van der Woude LHV, Vollenbroek-Hutten MMR, van Harten WH, et al. Successfully improving physical activity behavior after rehabilitation. *American Journal of Health Promotion* 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, Inness EL, Middleton L, Biasin L, 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, Franklin BA, Lamonte MJ, Lee I-M, 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. Kinne S, Patrick DL, Maher EJ. Correlates of exercise maintenance among people with mobility impairments. *Disabil Rehabil* 1999;21(1):15-22.

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

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

36. 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.

37. 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.

38. 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.

39. Barriers to Being Active Quiz: Centers for Disease Control and Prevention.

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

41. Gowland C, Stratford P, Ward M, Moreland J, Torresin W, Van Hullenaar S, et al. Measuring physical impairment and disability with the Chedoke-McMaster Stroke Assessment. *Stroke* 1993;24:58-63.

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

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

44. Raina P, Wolfson C, Kirkland S. Canadian Longitudinal Study on Aging (CLSA) Protocol, 2013.

45. 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.

46. Brown C, Fraser JE, Inness EL, Wong J, Middleton LE, Poon V, 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.

47. Donner A, Klar N. *Design and analysis of cluster randomized trials in health research*. London: Arnold, 2000.

48. 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.

49. Davey C, Hargreaves J, Thompson JA, Copas AJ, Beard E, Lewis JJ, 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.

50. Hebert D, Lindsay MP, McIntyre A, Kirton A, Rumney PG, Bagg S, et al. Canadian stroke best practice recommendations: stroke rehabilitation practice guidelines, update 2015. *Int J Stroke* 2016;11(4):459-484.

51. MacKay-Lyons M, Macko R, Eng J, Billinger S, Hafer-Macko C, Suskin N, et al. Aerobic exercise recommendations to optimize best practices in care after stroke, 2012.

## 12. TABLES

**Table 1: Overview of data collection time points.**

| | Study enrolment | 1-month post-discharge | 4-months post-discharge | 6-months post-discharge |
|---|---|---|---|---|
| ***Cohort descriptors*** | | | | |
| Chart review form | RA-CR | | | |
| NIH-SS | RA-P | | | |
| CMSA | RA/PT-CR/P | | | |
| MOCA | RA-P | | | |
| Baseline questionnaire | RA-P | | | |
| 6-month follow-up questionnaire | | | | RA-P |
| Schmidt questionnaire | RA-P | | | |
| ***Primary outcomes*** | | | | |
| FitBit activity monitoring* | | RA-P | RA-P | RA-P |
| FitBit heart rate data* | | RA-P | RA-P | RA-P |
| PASIPD** | | RA-P | RA-P | RA-P |
| ***Secondary outcomes*** | | | | |
| SSEE | RA-P | | | |
| SOEE | RA-P | | | |
| BBAQ | | RA-P | | |

Outcomes: BBAQ=Barriers to Being Active Quiz; CMSA=Chedoke-McMaster Stroke Assessment; MOCA=Montreal Cognitive Assessment; NIH-SS=National Institutes of Health Stroke Scale; PASIPD=Physical Activity Scale for Individuals with Physical Disabilities; SOEE=Short Outcome Expectations for Exercise scale; SSEE=Short Self-Efficacy for Exercise scale.

Data collection: PT-CR=data collected by the physiotherapist by chart review; PT-P=data collected by the physiotherapist directly from the participant; RA-CR=data collected by the research assistant from chart review; RA-P=data collected by research assistant directly from the participant.

*Activity and heart rate monitoring for 7 days continuously

**PASIPD questionnaire should be done at the end of the 7-day activity/heart rate monitoring period.

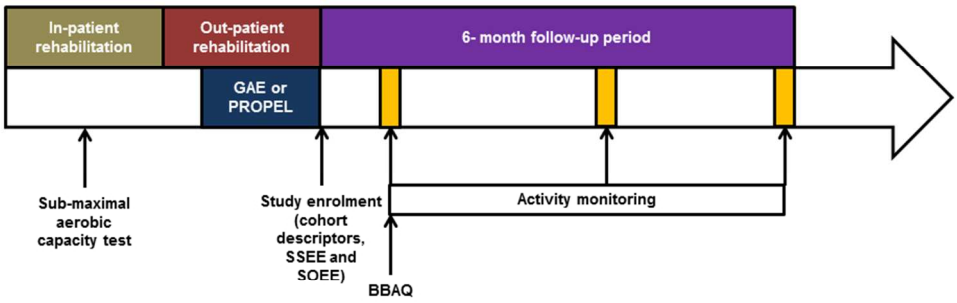
## 13. FIGURE CAPTIONS

**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.

**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.

| | 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.

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# CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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

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**Funding**
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## Introduction

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

## Background and purpose

Research shows that physical exercise is good for people with stroke. However, many people with stroke do not perform enough exercise. The purpose of this study is to see if a fitness program delivered during rehabilitation helps people with stroke to be more physically active *after* leaving the rehabilitation hospital. You are being asked to participate in this study because you completed this fitness program during your rehabilitation stay at the Toronto Rehabilitation Institute.

## Study visits and procedures

If you agree to participate in this study, we will measure how much physical activity you do over the 6-months after you finish out-patient rehabilitation at the Toronto Rehabilitation Institute. We will do this by asking you to wear an activity monitor on your wrist for three 1-week periods: 1-month, 4-months, and 6-months after you finish rehabilitation. The activity monitor looks like a watch and counts how many steps you take during the day. It also measures how fast your heart is beating. We will mail the activity monitor to you and ask you to return it in a postage-paid envelope. You can remove the activity monitor before you go to bed. You should remove the activity monitor before bathing/showing, if you go swimming, if it becomes uncomfortable to wear, or if you are requested to do so for any medical care.

**Wrist activity monitor**

| Time | Time commitment | Tests and procedures | Location |
|---|---|---|---|
| Around the time of discharge from the hospital | ~30 minutes | Tests of leg function, and memory<br>Questionnaires about previous exercise habits and how you feel about exercise | Toronto Rehab |
| 1-month post-discharge | ~30 minutes | Activity monitoring<br>Questionnaire about your physical activities | Your home (telephone call) |
| 4-months post-discharge | ~30 minutes | | |
| 6-months post-discharge | ~30 minutes | | |

Some types of exercise might not be recorded by the activity monitor; for example, if you go swimming or do exercises where you don't walk around a lot (like seated exercises at home). For this reason, we will also ask you to complete a questionnaire about your physical activities. A research assistant will call you to ask you to complete this questionnaire three times: 1-month, 4-months, and 6-months after you finish rehabilitation. The questionnaire will take about 10-15 minutes to complete. At these time points, the research assistant will also ask you if there have been any changes to your health since he last spoke to you.

With your permission we will obtain information from your clinical chart such as your age, gender, height, weight, information about your stroke and the effects it has had

on you, and information about your medical conditions and medications. You do not have to do anything extra for this chart review. Before you are discharged from the rehabilitation hospital, we will also measure your leg function, and you memory and will ask you some questions about yourself, your previous exercise habits, and how you feel about exercise. It will take about 30 minutes to perform these measures; we will schedule the testing at a time that is convenient for you. This information is necessary in order to describe the group of people who are participating in this study.

**Potential harms, discomforts and inconveniences**

There is some extra time involved with participating in this study. You might find this a burden. We think it will take about 3 hours to complete all of the parts of this study. This time commitment will be spread out over 6 months. You might find that it is a burden to wear the activity monitor every day for three 1-week periods or to mail the activity monitors back to us.

There is a small chance that you will feel uncomfortable answering some of the questions related to the study. You are free to choose not to answer any question.

There is a small chance you will develop a skin irritation from wearing the activity monitor. Removing the activity monitor at night might help to prevent this from happening. If you do develop a skin irritation on your wrist, remove the activity monitor and call the research assistant to let him know.

**Potential benefits**

You will not directly benefit from being in this study. Information learned from this study may give us more information about how to increase participation in exercise in people with stroke after they leave rehabilitation. These results could be used to benefit other people with stroke in the future.

**Reminders and responsibilities**

It is important to remember the following things during the study:

- Tell the study staff your health history and medications as accurately as possible. This will help to prevent any harm to you.
- Ask the study staff about anything that worries you.
- Tell the study staff if anything about your health has changed.
- Wear the activity monitors every day for a week on three different occasions, and return them to us in the postage-paid envelope.

## Confidentiality

*Personal Health Information*

If you agree to join this study, the research team will collect your personal health information. Personal health information is any information that could identify you and includes your:

- name,
- age,
- telephone number, and
- existing medical records, including types, dates and results of medical tests or procedures.

Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines.

The research team will keep any personal health information about you in a secure and confidential location for 10 years. A list linking your study number with your name will be kept by the research team in a secure place, separate from your study file.

*Study information that does not identify you*

This is a multi-site study; Sunnybrook Research Institute is the lead site for this study. Some study information will be sent outside of the hospital to Sunnybrook Research Institute. Any information that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you.

All information collected during this study, including your personal health information, will be kept confidential. Information from the activity monitors will be stored on the manufacturer's web servers; however, this information will be completely anonymous and will not be associated with any information that could identify you. Your personal health information will not be shared with anyone outside of the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

## Voluntary participation

You are encouraged to ask any questions that you may have about this study. If you do not wish to participate in this study, it will not affect any treatment that you receive at Toronto Rehabilitation Institute – UHN, either now or in the future.

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. We will give you any new information that is learned during the study that might affect your decision to stay in the study.

**Withdrawal from study**
If you chose to participate initially but wish to withdraw at a later date, for any reason, it will not affect the current or future care that you receive at Toronto Rehabilitation Institute – UHN. If you decide to withdraw from the study, the information that was collected before you leave the study will still be used in order to help answer the research question. No new information will be collected without your permission.

**Costs and reimbursement**
Participation in this study will not involve any additional costs to you. You will receive a $30 gift card after completing all parts of the study as a token of our appreciation for your participation.

**Rights as a participant**
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**Conflict of interest**
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

**Questions about the study**
If you have any questions, concerns or would like to speak to the study team for any reason, please call the Principal Investigator Avril Mansfield at 416-597-3422 extension 7831. **If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849**. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.
You will be given a copy of this form.

## Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

In some cases when we are unable to contact you directly, may we leave a voice message (if applicable)? No personal health information will be included in the voice message.

❑ Yes_____(initials) ❑ No_____(initials)

If we have been unable to contact you after repeated attempts by telephone or mail, may we contact a friend or family member? We will ask for your friend or family member's contact information in a separate document. We will not share any of your personal health information with your friend or family member.

❑ Yes_____(initials) ❑ No_____(initials)

| _____ | _____ | _____ |
|---|---|---|
| Study participant's name | Signature | Date |

My signature means that I have explained the study to the participant named above. I have answered all questions.

| _____ | _____ | _____ |
|---|---|---|
| Name of person obtaining consent | Signature | Date |

**Was the participant assisted during the consent process? ❑YES ❑NO**
If **YES**, please check the relevant box and complete the signature space below:

❑The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

| _____ | _____ | _____ |
|---|---|---|
| Name of witness | Signature | Date |

_____
Relationship to participant


SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | 3-5 |
| Protocol version | 3 | Date and version identifier | 1 |
| Funding | 4 | Sources and types of financial, material, and other support | 1-2 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 |
| | 5b | Name and contact information for the trial sponsor | 3 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 1-2 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | N/A |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 8-9 |
| | 6b | Explanation for choice of comparators | 8 |
| Objectives | 7 | Specific objectives or hypotheses | 9 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 9-10 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 10 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 11-12 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 12-14 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 12-14 |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | N/A |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | N/A |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 14-17 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Figure 2 |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 17 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 18 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 18-19 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 18-19 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 18-19 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 19 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 19 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 19-20 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 20 |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 20-21 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 21 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 21 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 21 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | N/A |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 22 |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 22-24 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 22-24 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 24 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 24-25 |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 25 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | N/A |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 25-26 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 26 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 26 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | 26 |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 26-27 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 27 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 27 |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Appendix |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | N/A |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

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



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|---|---|
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| Primary Subject Heading: | Rehabilitation medicine |
| Secondary Subject Heading: | Neurology |
| Keywords: | Stroke < NEUROLOGY, Exercise, Behaviour change, Physical activity, Physiotherapy |
| | |

## 1. ADMINISTRATIVE INFORMATION

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

**Authors:** Avril Mansfield,[1-3] Dina Brooks,[1,3,4] Ada Tang,[5] Denise Taylor,[6,7] Elizabeth L Inness,[1,3] Alex Kiss,[2] Laura Middleton,[1,8] Louis Biasin,[1,3] Rebecca Fleck,[9] Esmé French,[10] Kathryn LeBlanc,[9] Anthony Aqui,[1] Cynthia Danells[1,3]

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**Key words:** Stroke; Exercise; Physical Activity; Behaviour Change; Physiotherapy

**Word count:** 6,704

**Protocol version date:** 6 March 2017; Original

**Funding:** This study is supported by the Canadian Institutes of Health Research (PJT-148906). AM holds a New Investigator Award from the Canadian Institutes of Health Research (MSH-141983). DB holds a Canada Research Chair. AT is supported by a personnel award from the Heart and Stroke Foundation, Ontario Provincial Office (CS I 7468). These funding sources had no role in the design of

this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

**Roles:** AM conceived of the study, is the grant holder, and drafted the manuscript. AM, DB, AT, and DT will lead implementation of the study at each site, with assistance from ELI, LB, RF, EF, KL, and CD. ELI, LB, and CD developed the intervention. AK provided statistical expertise and will conduct the primary statistical analysis. AM, DB, AT, DT, ELI, AK, LM, LB, RF, EF, KL, AA, and CD contributed to refining the study protocol and approved the final manuscript.

## 2. WHO DATASET

1. **Trial registration:** clinicaltrials.gov, NCT02951338
2. **Date of registration:** 31 October 2016
3. **Secondary identification numbers:** Not applicable
4. **Sources of monetary or material support:** This study is supported by the Canadian Institutes of Health Research (PJT-148906). AM holds a New Investigator Award from the Canadian Institutes of Health Research (MSH-141983). DB holds a Canada Research Chair. AT is supported by a personnel award from the Heart and Stroke Foundation, Ontario Provincial Office (CS I 7468). The views expressed are not necessarily those of the funders.
5. **Primary sponsor:** Avril Mansfield
6. **Secondary sponsors:** Dina Brooks, Ada Tang, Denise Taylor
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8. **Contact for scientific queries:** Avril Mansfield; address: 550 University Ave, Toronto, ON, M5G 2A2; tel: 416-597-3422 ext 7831; e-mail: avril.mansfield@uhn.ca
9. **Public title:** Promoting Optimal Physical Exercise for Life (PROPEL) in people with stroke
10. **Scientific title:** Promoting Optimal Physical Exercise for Life (PROPEL) – aerobic exercise and self-management early after stroke to increase daily physical activity: study protocol for a stepped-wedge randomized trial
11. **Countries of recruitment:** Canada
12. **Interventions:** Group aerobic exercise only (Active Comparator): Supervised group exercise up to 3-times/week for 6 weeks. 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 a sub-maximal or maximal aerobic capacity test, and a 3-5 minute 'cool-down' of low-intensity exercise. 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. 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 physiotherapist with appropriate progression of the intensity and/or duration of exercise as necessary. Participants 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. PROPEL program (experimental): The PROPEL program involves both group aerobic exercise (as described above) 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 and Social Cognitive Theory. In addition to group exercise participants will attend 1-hour small group discussion sessions once weekly to learn self-management skills for exercise in preparation for discharge from rehabilitation. These discussions include: identifying and solving problems around barriers to exercise; understanding personal and general benefits of exercise; exploring appropriate community resources for exercise; and finding individualized and realistic strategies for incorporating exercise in a regular routine. Participants will become comfortable with progressing their exercise and will set short- and long-term goals for engaging in physical activity and exercise after discharge.

13. **Key inclusion and exclusion criteria:** Inclusion criteria: Adults with stroke who are referred to the group aerobic exercise or PROPEL programs as part of their stroke rehabilitation. Exclusion criteria: Language or communication barrier that prevents completion of questionnaires (e.g., severe receptive or global aphasia or non-English speaking); cognitive impairment that would prevent participation in unsupervised exercise; attend less than 50% of group aerobic

exercise/PROPEL sessions; and/or attend less than 4 of the 6 group discussion sessions (for individuals referred to the PROPEL program).

14. **Study type:** Interventional stepped-wedge cluster randomized trial.
15. **Date of first enrolment:** February 2017 (anticipated)
16. **Target sample size:** 192
17. **Recruitment status:** Pending: participants are not yet being recruited or enrolled at any site.
18. **Primary outcomes:** Number of patients who meet recommended intensity, frequency, and duration of physical activity; that is, at least 150 minutes per week of moderate-to-vigorous intensity exercise. Physical activity will be assessed using a step counter, heart rate monitor, and questionnaire for 7 continuous days at 1-month, 4-months, and 6-months post-discharge.
19. **Secondary outcomes:** Short Self-efficacy for Exercise Scale; Short Outcome Expectation for Exercise Scale; and Barriers to Being Active Quiz

## 3. ABSTRACT

**Introduction:** Physical exercise after stroke is essential for improving recovery and general health, and reducing future stroke risk. However, people with stroke are not sufficiently active upon return to the community after rehabilitation. We developed the Promoting Optimal Physical Exercise for Life (PROPEL) program, which combines exercise with self-management strategies within rehabilitation to promote ongoing physical activity in the community after rehabilitation. This study aims to evaluate the effect of PROPEL on long-term participation in exercise after discharge from stroke rehabilitation. We hypothesize that individuals who complete PROPEL will be more likely to meet recommended frequency, duration, and intensity of exercise compared to individuals who do not complete the program up to 6-months post-discharge from stroke rehabilitation.

**Methods and analysis:** Individuals undergoing outpatient stroke rehabilitation at one of 6 hospitals will be recruited (target n=192 total). A stepped wedge design will be employed; i.e., the PROPEL intervention (group exercise plus self-management) will be 'rolled out' to each site at a random time within the study period. Prior to roll-out of the PROPEL intervention, sites will complete the control intervention (group aerobic exercise only). Participation in physical activity for 6-months post-discharge will be measured via activity and heart-rate monitors, and standardized physical activity questionnaire. Adherence to exercise guidelines will be evaluated by: 1) number of 'active minutes' per week (from the activity monitor); 2) amount of time per week when heart rate is within a target range (i.e., 55-80% of age-predicted maximum); and 3) amount of time per week completing 'moderate' or 'strenuous' physical activities (from the questionnaire). We will compare the proportion of active and inactive individuals at 6 months post-intervention using mixed-model logistic regression, with fixed effects of time and phase and random effect of cluster (site).

**Ethics and dissemination:** To date, research ethics approval has been received from five of the six sites, with conditional approval granted by the sixth site. Results will be disseminated directly to study participants at the end of the trial, and to other stake holders via publication in a peer-reviewed journal.

## 4. ARTICLE SUMMARY

- This multi-centre trial will determine if an exercise and self-management intervention can increase participation in physical activity after stroke rehabilitation.
- The novel 'stepped wedge' trial design is suitable given the group-based delivery of the intervention and relatively small number of sites involved.
- Participation in physical activity will be determined with three methods: self-report (activity questionnaire), daily heart rate monitoring, and daily activity monitoring.
- The trial is single-blinded (participants cannot be blinded to intervention allocation), which potentially introduces a source of bias.

## 5. INTRODUCTION

### 5.1 Background and rationale

People often have low aerobic capacity after stroke,[1 2] which can limit the stroke survivors' ability to complete 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] Indeed, aerobic exercise is beneficial and feasible even early after stroke and during routine rehabilitation[6 10] However, due to the brief length of stay in stroke rehabilitation (4-6 weeks), ongoing self-directed physical activity 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 to 5800 steps/day,[11] which is less than the 6000 steps/day recommended for people with physical disabilities.[12] Data from heart rate monitors revealed that, even when individuals with stroke were active, the activity was not of sufficient intensity for aerobic benefit.[13] This chronic inactivity means that gains in aerobic fitness made during rehabilitation will be lost post-discharge.[14]

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 was 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) – a combined group exercise and self-management program that aims to promote long-term engagement in exercise and physical activity after stroke. 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]

**5.2 Objectives**

The primary aim of this study is to evaluate the effect of PROPEL delivered during stroke rehabilitation on participation in self-directed exercise after 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.

**5.3 Trial design**

This study involves a single-blind (assessor blinded), continuous recruitment short exposure, stepped-wedge cluster randomized controlled superiority trial (SWT).[26] Six sites will be involved in the study; at a randomly-determined time within the study period (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.

The group format is essential to PROPEL (see below). In our pilot study[24] there was often a delay to start the group in order to have ≥3 people enrolled. 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 since twice as many people would be required to be enrolled in order to run concurrent 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]

## 6. METHODS: PARTICIPANTS, INTERVENTIONS, AND OUTCOMES

### 6.1 Study setting

Participants will be recruited from one of 6 rehabilitation hospitals in Ontario: 1) Hamilton Health Sciences, Hamilton, Ontario; 2) St. Joseph's Care Group, Thunder Bay, Ontario; 3) Sunnybrook Health Sciences Centre – St. John's Rehab, Toronto, Ontario; 4) Toronto Rehabilitation Institute – Rumsey Centre, Toronto, Ontario; 5) Toronto Rehabilitation Institute – University Centre, Toronto, Ontario; and 6) West Park Healthcare Centre, Toronto, Ontario. 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.

**6.2 Eligibility criteria**

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 have sufficient cognitive capacity to understand and follow instructions and to convey adverse symptoms with exercise (e.g., pain, excessive exertion). 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.

Patients will be screened for eligibility for the study within the final two weeks of the GAE/PROPEL programs. 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 9 group exercise sessions; and/or
- They attend less than 4 of the 6 group discussion sessions (for individuals enrolled in the PROPEL program).

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

**6.3 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 not to 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 3 days/week for 6 weeks informed by a sub-maximal or maximal aerobic capacity test. Patients will be referred by their treating physiotherapist. The interventions 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 and end the program at the same time. The closed-group format is essential for the PROPEL phase as the education and group

discussion topics will be presented in a specific order. An open-group format could be used for GAE; however, this would result in participants in the GAE phase being recruited to the study, on average, sooner post-stroke than those in the PROPEL phase.[24] Therefore, using a closed-group format for both phases will help to 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.

PTs at each site will receive training in sub-maximal aerobic capacity testing for individuals with stroke, exercise prescription, and leading the PROPEL program from the study investigators (ELI, LB, CJD, and AT).

*6.3.1 Control intervention – GAE*

The control intervention will involve group aerobic exercise only (GAE). The intensity and duration of exercise will be determined for each individual patient from the results of a sub-maximal or maximal aerobic capacity test conducted prior to entry into the program, and considering patients' medical history and stroke-related impairments.[10] In general, the duration of exercise will be 20-30 minutes, and the intensity will be 50-70% of age-predicted maximum heart rate or a rating of 3/10 ('moderate') on the Borg category ratio (CR-10) scale.[29] 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. Each exercise session will begin with a 3-5 minute 'warm-up', and end with a 3-5 minute 'cool-down' of low-intensity exercise. 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.

*6.3.2 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[30] and Social Cognitive Theory.[31] Participants will complete group exercise 3 days/week (described above for GAE). Additionally, 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. Specific objectives of the discussion sessions are to: 1) increase participant knowledge regarding the benefits of exercise and physical activity after stroke; 2) build participant skill and self-efficacy for exercise; and 3) establish a feasible post-discharge exercise plan. Through interactive discussions, individualized problem solving, and goal setting, the following topics will be addressed, such that a feasible personal exercise plan is iteratively developed:

- Risks and benefits of exercise;
- Current guidelines and recommendations for exercise;
- Personal barriers to and preferences for exercise;
- Components of an exercise prescription (i.e., frequency, intensity, type and time);
- How to monitor exercise intensity (e.g., using heart rate and rating of perceived exertion);
- How to progress an exercise program;
- How to set short- and long-term goals;
- Strategies to sustain and/or re-engage in exercise;

Additionally, individuals are encouraged to identify and trial appropriate community resources for exercise, and find individualized and realistic strategies for incorporating exercise in a regular routine. The group format helps to promote vicarious experiences. The PROPEL discussions will be led by the PT; access to a health care professional leading the group can increase an individual's belief about personal skill,[32] and support in teaching stroke survivors how to exercise independently, promoting feelings of safety and confidence.[33 34]

**6.4 Outcomes**

*6.4.1 Primary outcomes – physical activity*

Physical activity will be assessed using a step counter and heart rate monitor for 7 continuous days, as well as a physical activity questionnaire 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 suggest 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.[36] The devices will be configured to not provide participants with information regarding step counts and heart rate. 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.

The Physical Activity Scale for Individuals with Physical Disabilities (PASIPD)[37] 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).[38]

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.

*6.4.2 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.[39] 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[39] 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.[39]

Perceived barriers to physical activity will be assessed 1-month post-intervention with the Barriers to Being Active Quiz (BBAQ).[23 40 41] The BBAQ has previously 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".[40] 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. The BBAQ has good internal consistency among older adults (Cronbach's $\alpha$=0.87).[42]

*6.4.3 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, mobility status, and medical conditions/history. The National Institutes of Health Stroke Scale (NIH-SS),[43] the Chedoke-McMaster Stroke Assessment (CMSA)[44] foot and leg scores, and the Montreal Cognitive Assessment[45] 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.[46] 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.[44] The MOCA[45] 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, intensity, and duration of exercise during in- and out-patient rehabilitation by chart review. We will also document details of any home exercise program or general advice to be physically active that participants receive (outside of the PROPEL intervention). Participants will complete a questionnaire at baseline that asks about their social supports, employment, familial responsibilities, living situation etc, which are factors that could influence participation in physical activity. Many of these questions have been adapted from the Canadian Longitudinal Study on Aging.[47] Some questions will be repeated at the 6-month post-discharge time-point to account for lifestyle changes since discharge from rehabilitation. Pre-morbid exercise behaviour will be evaluated with the Schmidt retrospective physical activity scale.[48] This scale shows good agreement with previously-completed questionnaires regarding physical activity.[48] 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.

**6.4 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.

### 6.5 Recruitment

There are approximately 710 admissions annually to out-patient stroke rehabilitation at all sites combined. We conservatively estimate that 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. Target sample sizes for each site are: Hamilton Health Sciences – 24; St Joseph's Care Group – 24; Sunnybrook Research Institute - St John's Rehab – 60, Toronto Rehabilitation Institute – Rumsey Centre – 58, Toronto Rehabilitation Institute – University Centre – 58, West Park Healthcare Centre – 60. To encourage recruitment to the study, participants will receive a gift card ($30 CAD value) as a modest incentive to participate.

In order to generate a CONSORT flow-diagram for participant recruiting,[51] 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. The RA will also maintain documentation related to screening and enrolment of potential participants. Identifying or health-related information will not be documented for individuals who do not consent to participate in the study.

## 7. METHODS: ASSIGNMENT OF INTERVENTIONS

### 7.1 Intervention allocation

The time at which each site transitions from GAE to PROPEL will be determined by drawing site names at random (Figure 1). 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 Section 7.2). 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. The Site Leads and PTs at each site will be informed of the transition to PROPEL approximately 3 months prior to the transition to allow for sufficient time for training and planning.

### 7.2 Blinding

Participants cannot be blinded to intervention allocation, although they will not be aware of the existence of another intervention arm. 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.

## 8. METHODS: DATA COLLECTION, MANAGEMENT, AND ANALYSIS

### 8.1 Data collection methods

Data will be collected primarily by the RA either directly from the participant or by chart review (see Table 1 for further details). RAs at each site will receive training regarding data collection from the Principal Investigator (AM) and central Study Coordinator (AA). Questionnaires will be completed via in person interview at enrolment, and over the telephone at the follow-up time points. Activity monitors will be sent to participants and returned to the site via mail. Participants will be contacted via telephone just prior to mailing the activity monitors to remind them that they will be receiving the activity monitors, and to ensure that they will be home to receive them (e.g., that they are not planning to be on vacation at that time).

In order avoid losing participants to follow-up, we will request contact information of a friend or family member. Participants who provide consent for us to contact their friends or family members will be provided with a contact 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 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.

**8.2 Data management**

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 at each site on secure institutional servers. Files containing patient names

and contact information will be password protected and stored separately from other data. 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. De-identified electronic data will be transferred to the main site (Sunnybrook Research Institute) using secure file transfer protocols.

### 8.3 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).[52] 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 hypotheses. Only individuals who complete at least a minimum amount of the intervention will be included in the study; therefore, analysis will necessarily be 'per protocol'. All recruited participants who comply with data collection will be included in the analysis; participants with missing data for one time point will be excluded from analysis of that variable for that time point.

## 9. METHODS: MONITORING

### 9.1 Data monitoring

There is no data monitoring committee for this study, as the safety of aerobic exercise has already been established for this population,[6 10] and the additional risk of the discussion components of the PROPEL program and other study components (e.g., questionnaires or activity monitoring) is minimal (see Section 9.2). Adverse events that meet all three of the following criteria will be reported immediately to the local research ethics board(s), as is routine practice: 1) unexpected in terms of nature, severity, or frequency; 2) related or possibly related to participation in the research; and 3) suggests an potential increase in risk of harm to research participants or to others. All adverse events will be collated and evaluated bi-annually by the Principal Investigator (AM).

There is no plan for any interim analysis; interim analysis is not feasible with a SWT design due to the fact that the experimental intervention is 'rolled out' gradually to each site, which means that the number of participants per phase will be uneven until the end of the trial. The trial will be stopped when one of the following criteria are met: 1) we have recruited at least 120 participants per phase; 2) 6-month follow-up data are available for at least 96 participants per phase; or 3) all site investigators (AM, DB, AT, and DT) agree that continuing the trial will not be feasible (e.g., due to lower than expected recruiting and lack of funding to continue the trial).

### 9.2 Potential harms and auditing

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. 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. 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.

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.

## 10. ETHICS AND DISSEMINATION

### 10.1 Research ethics approval

Research ethics approval has been received by the Research Ethics Boards of Sunnybrook Research Institute (Study ID: 472-2016, approved 31 January 2017), the University Health Network (Study ID: 16-5916, approved 14 November 2016), which covers two sites (Toronto Rehabilitation Institute – University Centre, and Toronto Rehabilitation Institute – Rumsey Centre), St. Joseph's Care Group (Study ID: 2016011, approved 13 February 2017), and Hamilton Health Sciences (Study ID: 2274, approved 6 April 2017). Additionally, conditional approval has been granted by the Joint West Park Heathcare Centre-Toronto Central CCAC-Toronto Grace Health Centre Research Ethics Board, pending some clarifications in the protocol and minor site-specific edits to the consent documents (conditional approval: 20 April 2017). Due to one investigator's affiliation, research ethics approval was also received from Thunder Bay Regional Health Sciences Centre (Study ID: 2016139, approved 4 January 2017), although no recruiting or data collection will occur at this site.

### 10.2 Protocol amendments

Substantive changes to the design or conduct of the study will require a formal amendment to the study protocol. Such substantive amendments will be agreed upon by the site investigators (AM, DB, AT and DT) and will be approved by the local Research Ethics Boards prior to implementation locally. Minor administrative changes to study documents (e.g., correcting a typographical error or clarifying a questionnaire item) may also be implemented, with the Research Ethics Boards notified of the changes.

### 10.3 Consent

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. S/he will describe the study, as outlined in the consent form (Appendix) 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 6.4.3). 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.

**10.4 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 study and, if interested, introduce the RA to potential participants.

Identifiable information (participant names and contact information) will be stored separately from health information and study data (see also Section 8.2) in a password protected file, with the password only known to those individuals who are responsible for data collection. A participant ID number will be used to link identifiable information with health information and study data. The link between the participant ID number and name will be destroyed after data have been collected and verified. De-identified data will be kept in a secure and confidential location for 10 years.

### 10.5 Declaration of interests

The authors declare that they have no competing interests related to this study.

### 10.6 Access to data

The Principal Investigator (AM) and biostatistician (AK) will have access to the full dataset. The site investigators will have access to data collected locally. A study co-investigator or collaborator may be granted access to the full dataset for secondary analysis with approval of all site investigators (AM, DB, AT, and DT) and the coordinating institution (Sunnybrook Research Institute).

### 10.7 Ancillary and post-trial care

Each site will be responsible for providing out-of-pocket expenses to ensure that a participant receives immediate medical care in the event that the participant experiences an adverse health event (e.g. injury) as a result of participation in the study.

### 10.8 Dissemination policy

Study participants will receive a letter of appreciation at the end of the study, which may include a very brief summary of the study results. Study results will be disseminated to others via publication in a peer-reviewed journal. We will aim to submit a paper describing analysis of the primary and secondary outcomes within 6 months of completing data collection. All individuals who meet the International Committee of Medical Journal Editors criteria for authorship will be included as authors on any publications arising from this work. There is no current plan to make the participant-level dataset available publicly; however, the dataset may be made available in future via a Data Access Committee, if such a committee is established by the coordinating institution.

## 11. STUDY STRENGTHS AND LIMITATIONS

We have adopted an 'integrated knowledge translation' approach, whereby knowledge users (rehabilitation managers and physiotherapists) have been involved in the study from conception. The interventions are being implemented as part of routine care at each site. This also helps to increase the likelihood that the interventions will continue as part of routine care beyond the end of the study, compared to implementing the interventions for study participants only.

The novel 'stepped wedge' trial design is appropriate for evaluating the group-based PROPEL intervention as it is 'rolled out' as part of routine practice to each site.[27] However, it is possible that factors that change over time will influence the study results. For example, stroke rehabilitation delivery in Ontario is supported by the Ministry of Health and Long-Term Care through the Ontario Health Insurance Program. During the course of the study, it is possible that the Ministry will dictate changes to care delivery, such as changes to lengths of stay. However, 'vertical' comparisons between sites can be made at any point in time to account for such secular trends.[52 55] An alternative approach would be to have some sites start with the PROPEL intervention and transition to GAE; however, there would be a risk of contamination as staff administering the GAE would have been trained in PROPEL, which might influence how they treat their patients.[26 56]

Participants in the PROPEL phase will have one extra hour per week of interaction with the PT and with other participants in the group. It is possible that this extra attention/interaction alone, rather than the content of the PROPEL discussions, will influence the study results. We opted to not add an attention control activity to the GAE phase (e.g., group discussion on a topic unrelated to physical activity) based on feedback from stakeholders. We designed the GAE phase to resemble clinical practice as closely as possible, while still maintaining controls and standardization necessary for a research study. An unrelated discussion group would be contrived for the purpose of the study and would not reflect clinical practice.

This large multi-site trial will determine if a simple clinical intervention, delivered during stroke rehabilitation, can increase participation in physical activity after discharge. 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 (i.e., 6 months post-intervention). If the study results are positive, 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.

## 12. 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, Bayley M, Richardson D, McIlroy WE, 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, Eng JJ, Franklin BA, Mortag Johnson C, 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, Fraser JE, Mileris R, Howe J, 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, Bell RC, Croteau KA, De Bourdeaudhuij I, 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. *Systematic Reviews* 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, van der Woude LHV, Vollenbroek-Hutten MMR, van Harten WH, et al. Successfully improving physical activity behavior after rehabilitation. *American Journal of Health Promotion* 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, Inness EL, Middleton L, Biasin L, 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, Franklin BA, Lamonte MJ, Lee I-M, 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. Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982;14(5):377-381.

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

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

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

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

34. 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.

35. Resnick B, Michael K, Shaughnessy M, Nahm ES, Kobunek S, Sorkin J, 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. Klassen TD, Simpson LA, Lim SB, Louie DR, Parappilly B, Sakakibara BM, et al. "Stepping up" activity poststroke: ankle-positioned accelerometer can accurately record steps during slow walking. *Phys Ther* 2016;96(3):355-360.

37. 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.

38. 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.

39. 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.

40. Barriers to Being Active Quiz: Centers for Disease Control and Prevention.

41. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Nutrition and Physical Activity. *Promoting physical activity: a guide for community action*. Champaign, Illinois: Human Kinetics, 1999.

42. Sawchuck CN, Russo JE, Bogart A, Charles S, Goldberg J, Forquera R, et al. Barriers and facilitators to walking and physical activity among American Indian elders. *Prevn Chronic Dis* 2011;8(3):A63.

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

44. Gowland C, Stratford P, Ward M, Moreland J, Torresin W, Van Hullenaar S, et al. Measuring physical impairment and disability with the Chedoke-McMaster Stroke Assessment. *Stroke* 1993;24:58-63.

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

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

47. Raina P, Wolfson C, Kirkland S. Canadian Longitudinal Study on Aging (CLSA) Protocol, 2013.

48. 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.

49. Brown C, Fraser JE, Inness EL, Wong J, Middleton LE, Poon V, 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. 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.

52. Davey C, Hargreaves J, Thompson JA, Copas AJ, Beard E, Lewis JJ, 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.

53. Hebert D, Lindsay MP, McIntyre A, Kirton A, Rumney PG, Bagg S, 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, Billinger S, Hafer-Macko C, Suskin N, et al. Aerobic exercise recommendations to optimize best bractices in care after stroke, 2012.

55. Hargreaves JR, Prost A, Fielding KL, Copas AJ. How important is randomisation in a stepped wedge trial? *Trials* 2015;16:359.

56. Beard E, Lewis JJ, Copas A, Davey C, Osrin D, Baio G, et al. Stepped wedge randomised controlled trials: systematic review of studies published between 2010 and 2014. *Trials* 2015;16(353).

## 13. TABLES

**Table 1: Overview of data collection time points.**

| | Study enrolment | 1-month post-discharge | 4-months post-discharge | 6-months post-discharge |
|---|---|---|---|---|
| ***Cohort descriptors*** | | | | |
| Chart review form | RA-CR | | | |
| NIH-SS | RA-P | | | |
| CMSA | RA/PT-CR/P | | | |
| MOCA | RA-P | | | |
| Baseline questionnaire | RA-P | | | |
| 6-month follow-up questionnaire | | | | RA-P |
| Schmidt questionnaire | RA-P | | | |
| ***Primary outcomes*** | | | | |
| FitBit activity monitoring* | | RA-P | RA-P | RA-P |
| FitBit heart rate data* | | RA-P | RA-P | RA-P |
| PASIPD** | | RA-P | RA-P | RA-P |
| ***Secondary outcomes*** | | | | |
| SSEE | RA-P | | | |
| SOEE | RA-P | | | |
| BBAQ | | RA-P | | |

Outcomes: BBAQ=Barriers to Being Active Quiz; CMSA=Chedoke-McMaster Stroke Assessment; MOCA=Montreal Cognitive Assessment; NIH-SS=National Institutes of Health Stroke Scale; PASIPD=Physical Activity Scale for Individuals with Physical Disabilities; SOEE=Short Outcome Expectations for Exercise scale; SSEE=Short Self-Efficacy for Exercise scale.

Data collection: PT-CR=data collected by the physiotherapist by chart review; PT-P=data collected by the physiotherapist directly from the participant; RA-CR=data collected by the research assistant from chart review; RA-P=data collected by research assistant directly from the participant.

*Activity and heart rate monitoring for 7 days continuously

**PASIPD questionnaire should be done at the end of the 7-day activity/heart rate monitoring period.

## 14. FIGURE CAPTIONS

**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.

**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.

| | 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.

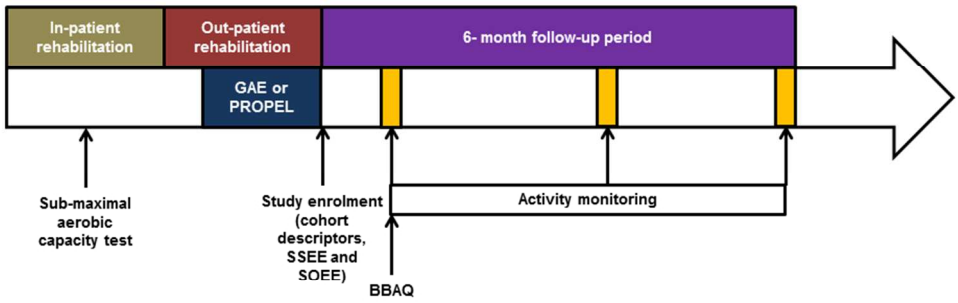


Figure 2: Hypothetical timeline for one participant. The exact timing of in- and out-patient rehabilitation will vary for each participant. The sub-maximal aerobic capacity test is completed during in-patient rehabilitation. After this point the participant could participate in individual or open-group 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.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | 3-5 |
| Protocol version | 3 | Date and version identifier | 1 |
| Funding | 4 | Sources and types of financial, material, and other support | 1-2 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 |
| | 5b | Name and contact information for the trial sponsor | 3 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 1-2 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | N/A |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 8-9 |
| | 6b | Explanation for choice of comparators | 8 |
| Objectives | 7 | Specific objectives or hypotheses | 9 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 9-10 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 10 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 11-12 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 12-14 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 12-14 |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | N/A |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | N/A |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 14-17 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Figure 2 |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 17 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 18 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 18-19 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 18-19 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 18-19 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 19 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 19 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 19-20 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 20 |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 20-21 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 21 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 21 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 21 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | N/A |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 22 |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 22-24 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 22-24 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 24 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 24-25 |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 25 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | N/A |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 25-26 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 26 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 26 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | 26 |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 26-27 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 27 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 27 |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Appendix |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | N/A |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

# CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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

**Principal investigator**
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**Funding**
This study is funded by the Canadian Institutes of Health Research

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## Introduction

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

## Background and purpose

Research shows that physical exercise is good for people with stroke. However, many people with stroke do not perform enough exercise. The purpose of this study is to see if a fitness program delivered during rehabilitation helps people with stroke to be more physically active *after* leaving the rehabilitation hospital. You are being asked to participate in this study because you completed this fitness program during your rehabilitation stay at the Toronto Rehabilitation Institute.

## Study visits and procedures

If you agree to participate in this study, we will measure how much physical activity you do over the 6-months after you finish out-patient rehabilitation at the Toronto Rehabilitation Institute. We will do this by asking you to wear an activity monitor on your wrist for three 1-week periods: 1-month, 4-months, and 6-months after you finish rehabilitation. The activity monitor looks like a watch and counts how many steps you take during the day. It also measures how fast your heart is beating. We will mail the activity monitor to you and ask you to return it in a postage-paid envelope. You can remove the activity monitor before you go to bed. You should remove the activity monitor before bathing/showing, if you go swimming, if it becomes uncomfortable to wear, or if you are requested to do so for any medical care.

**Wrist activity monitor**

| Time | Time commitment | Tests and procedures | Location |
|---|---|---|---|
| Around the time of discharge from the hospital | ~30 minutes | Tests of leg function, and memory<br>Questionnaires about previous exercise habits and how you feel about exercise | Toronto Rehab |
| 1-month post-discharge | ~30 minutes | Activity monitoring<br>Questionnaire about your physical activities | Your home (telephone call) |
| 4-months post-discharge | ~30 minutes | | |
| 6-months post-discharge | ~30 minutes | | |

Some types of exercise might not be recorded by the activity monitor; for example, if you go swimming or do exercises where you don't walk around a lot (like seated exercises at home). For this reason, we will also ask you to complete a questionnaire about your physical activities. A research assistant will call you to ask you to complete this questionnaire three times: 1-month, 4-months, and 6-months after you finish rehabilitation. The questionnaire will take about 10-15 minutes to complete. At these time points, the research assistant will also ask you if there have been any changes to your health since he last spoke to you.

With your permission we will obtain information from your clinical chart such as your age, gender, height, weight, information about your stroke and the effects it has had

on you, and information about your medical conditions and medications. You do not have to do anything extra for this chart review. Before you are discharged from the rehabilitation hospital, we will also measure your leg function, and you memory and will ask you some questions about yourself, your previous exercise habits, and how you feel about exercise. It will take about 30 minutes to perform these measures; we will schedule the testing at a time that is convenient for you. This information is necessary in order to describe the group of people who are participating in this study.

**Potential harms, discomforts and inconveniences**

There is some extra time involved with participating in this study. You might find this a burden. We think it will take about 3 hours to complete all of the parts of this study. This time commitment will be spread out over 6 months. You might find that it is a burden to wear the activity monitor every day for three 1-week periods or to mail the activity monitors back to us.

There is a small chance that you will feel uncomfortable answering some of the questions related to the study. You are free to choose not to answer any question.

There is a small chance you will develop a skin irritation from wearing the activity monitor. Removing the activity monitor at night might help to prevent this from happening. If you do develop a skin irritation on your wrist, remove the activity monitor and call the research assistant to let him know.

**Potential benefits**

You will not directly benefit from being in this study. Information learned from this study may give us more information about how to increase participation in exercise in people with stroke after they leave rehabilitation. These results could be used to benefit other people with stroke in the future.

**Reminders and responsibilities**

It is important to remember the following things during the study:

- Tell the study staff your health history and medications as accurately as possible. This will help to prevent any harm to you.
- Ask the study staff about anything that worries you.
- Tell the study staff if anything about your health has changed.
- Wear the activity monitors every day for a week on three different occasions, and return them to us in the postage-paid envelope.

## Confidentiality

*Personal Health Information*

If you agree to join this study, the research team will collect your personal health information. Personal health information is any information that could identify you and includes your:

- name,
- age,
- telephone number, and
- existing medical records, including types, dates and results of medical tests or procedures.

Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines.

The research team will keep any personal health information about you in a secure and confidential location for 10 years. A list linking your study number with your name will be kept by the research team in a secure place, separate from your study file.

*Study information that does not identify you*

This is a multi-site study; Sunnybrook Research Institute is the lead site for this study. Some study information will be sent outside of the hospital to Sunnybrook Research Institute. Any information that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you.

All information collected during this study, including your personal health information, will be kept confidential. Information from the activity monitors will be stored on the manufacturer's web servers; however, this information will be completely anonymous and will not be associated with any information that could identify you. Your personal health information will not be shared with anyone outside of the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

## Voluntary participation

You are encouraged to ask any questions that you may have about this study. If you do not wish to participate in this study, it will not affect any treatment that you receive at Toronto Rehabilitation Institute – UHN, either now or in the future.

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. We will give you any new information that is learned during the study that might affect your decision to stay in the study.

**Withdrawal from study**
If you chose to participate initially but wish to withdraw at a later date, for any reason, it will not affect the current or future care that you receive at Toronto Rehabilitation Institute – UHN. If you decide to withdraw from the study, the information that was collected before you leave the study will still be used in order to help answer the research question. No new information will be collected without your permission.

**Costs and reimbursement**
Participation in this study will not involve any additional costs to you. You will receive a $30 gift card after completing all parts of the study as a token of our appreciation for your participation.

**Rights as a participant**
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**Conflict of interest**
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

**Questions about the study**
If you have any questions, concerns or would like to speak to the study team for any reason, please call the Principal Investigator Avril Mansfield at 416-597-3422 extension 7831. **If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849**. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.
You will be given a copy of this form.

## Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

In some cases when we are unable to contact you directly, may we leave a voice message (if applicable)? No personal health information will be included in the voice message.

❑ Yes_____(initials) ❑ No_____(initials)

If we have been unable to contact you after repeated attempts by telephone or mail, may we contact a friend or family member? We will ask for your friend or family member's contact information in a separate document. We will not share any of your personal health information with your friend or family member.

❑ Yes_____(initials) ❑ No_____(initials)

| _____ | _____ | _____ |
|---|---|---|
| Study participant's name | Signature | Date |

My signature means that I have explained the study to the participant named above. I have answered all questions.

| _____ | _____ | _____ |
|---|---|---|
| Name of person obtaining consent | Signature | Date |

**Was the participant assisted during the consent process? ❑YES ❑NO**
If **YES**, please check the relevant box and complete the signature space below:

❑The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

| _____ | _____ | _____ |
|---|---|---|
| Name of witness | Signature | Date |

_____
Relationship to participant