TeleRehabilitation with Aims to Improve Lower extremity recovery in community-dwelling individuals who have had a stroke: protocol for a multisite, parallel group, assessor-blinded, randomised attention-controlled trial

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ABSTRACT

Introduction Telerehabilitation is an accessible service delivery model that may support innovative lower extremity rehabilitation programmes that extend the stroke recovery continuum into the community. Unfortunately, there is limited evidence on the provision of exercises for lower extremity recovery after stroke delivered using telerehabilitation. In response, we developed the TeleRehabilitation with Aims to Improve Lower extremity recovery poststroke (TRAIL) programme, a 4-week progressive exercise and self-management intervention delivered synchronously using video-conferencing technology. Our primary hypothesis is that individual within 1-year poststroke who participate in TRAIL will experience significantly greater improvements in functional mobility than individuals in an attention-controlled education programme (EDUCATION).

Methods and analysis In this multisite, parallel group, assessor-blinded randomised attention-controlled trial, 96 community-living stroke survivors within 1-year poststroke will be recruited from five sites (Vancouver, Winnipeg, Toronto, London and Halifax, Canada) from the CanStroke Recovery Trials Platform which is a network of Canadian hospital sites that are affiliated with academic institutions to facilitate participant recruitment and quality trial practices. Participants will be randomised on a 1:1 basis to TRAIL or EDUCATION. Participants randomised to TRAIL will receive eight telehabilitation sessions where they will perform exercises and receive self-management support to improve lower extremity recovery from a TRAIL physical therapist. The primary outcome will be measured using the Timed Up and Go. Secondary outcomes include lower extremity muscle strength, functional balance, motor impairment, balance self-efficacy, health-related quality of life and health service use for our economic evaluation.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This randomised controlled trial studies the effect of TeleRehabilitation with Aims to Improve Lower extremity recovery (TRAIL) in community-dwelling individuals who have had a stroke, compared with an attention-controlled education programme.
⇒ In addition to examining the effect of TRAIL on lower extremity clinical outcomes, including functional mobility, strength and balance, our cost-utility analysis will examine the incremental costs and effects generated by using the TRAIL intervention compared with education.
⇒ This is a multisite national trial on the CanStroke Recovery Trials Platform.
⇒ Our volunteer sample may contribute to selection bias among participants, as the individuals who choose to participate may have greater interest to exercise and partake in rehabilitation programmes or have the necessary resources to participate in a virtual programme.
⇒ Study recruitment is primarily from larger hospitals affiliated with academic institutions which may limit the number of participants from rural and remote locations.

Measurements will be taken at baseline, immediately after the intervention, 3-month and 6-month postintervention.

Ethics and dissemination Ethics approval for this research has been obtained by all participating sites. All study participants will provide their informed consent prior to enrolling them in the study. Findings from this trial will be disseminated in peer-reviewed journals and presentations at international scientific meetings.

Trial registration number ClinicalTrials.gov, NCT04908241.
INTRODUCTION

Much has been done to improve survival rates after stroke and return individuals to independent community living. Longer-term care and rehabilitation after hospital discharge remain underdeveloped, with stroke survivors receiving minimal to no follow-up rehabilitation after returning to the community. Increasing demands on the limited service capacity of our healthcare system have led to suboptimal recovery of lower extremity function among individuals with stroke. This has resulted in greater disability and higher systemic costs.

Telerehabilitation is an accessible service delivery model that may be able to support innovative lower extremity rehabilitation programmes that extend the stroke recovery continuum into the community. Unfortunately, there is limited evidence on the provision of exercises for lower extremity recovery delivered using telerehabilitation, primarily due to the unique safety challenges. Exercise via physical rehabilitation is the gold standard for lower extremity recovery after stroke. A large body of literature indicates that lower extremity exercises delivered in-person and face-to-face improve independence, walking, mobility and balance in stroke survivors. Moreover, exercise improves psychosocial outcomes after stroke, such as self-efficacy related to balance and falls, participation in social and community activities, and quality of life. Typically, exercise programmes for lower-extremity recovery that focus on mobility and balance have been delivered in-person to manage safety issues and risks of falls. Thus, while telerehabilitation interventions have been used effectively for check-in sessions, education and counselling after stroke, there is minimal evidence on the use of telerehabilitation for lower extremity recovery poststroke.

In response, we developed the TeleRehabilitation with Aims to Improve Lower extremity recovery poststroke (TRAIL) programme. TRAIL is a 4-week progressive exercise and self-management intervention delivered synchronously using video-conferencing technology in a 2:1 participant to physical therapist ratio. In our single-group pre-post feasibility study (n=32), we observed high participant satisfaction with TRAIL, treatment fidelity and adherence, no serious adverse events or dropouts. We also observed positive trends in clinical outcomes, including mobility (Timed Up and Go (TUG)), lower extremity impairment (Fugl-Meyer Assessment) and strength (30s sit to stand), and balance confidence (Activity-specific Balance Confidence scale). In this paper, we report on the study protocol evaluating TRAIL in a phase 3, multisite randomised controlled trial. Our primary hypothesis is that individuals within 1-year poststroke who participate in TRAIL will experience greater improvements (p<0.05) in functional mobility of the lower extremity (measured using TUG) immediately following the intervention than individuals in an attention-controlled education programme (EDUCATION) focusing on stroke risk factor control. Our secondary hypotheses are that TRAIL participants will improve lower extremity muscle strength, functional balance, motor impairment, balance self-efficacy and reduce health service use compared with participants in EDUCATION over 3 and 6 months postintervention.

METHODS AND ANALYSIS

The reporting of this protocol follows the Standard Protocol Items: Recommendations for Intervention Trials guidelines. The study has received ethics from all participating sites and is registered with Clinical-Trials.gov (NCT04908241). Study recruitment started on 2 June 2021. As of 19 June 2023, we have recruited 42 participants.

Trial design

We will use a multisite, parallel group, assessor-blinded randomised attention-controlled trial to address our study hypotheses. Figure 1 provides an overview of trial procedures, outcomes and programmes.

Patient population

Volunteer participants will be recruited from five sites (Vancouver, Winnipeg, Toronto, London and Halifax, Canada) from the CanStroke Recovery Trials Platform which is a network of Canadian hospital sites that are affiliated with academic institutions to facilitate participant recruitment and quality trial practices. Individuals will be included if they: are at least 19 years of age and within 12 months poststroke (we have revised this criteria from our previous feasibility study from 18 months to 12 months to capture window of opportunity for neuroplasticity); have lower extremity hemiparesis; can walk at least 10 m; can tolerate 50 min of activity; and have cognitive-communicative ability to participate. Individuals will be excluded if they: are currently participating in formal in-patient or out-patient rehabilitation for lower extremity recovery; live in long-term care; have severe vision or hearing loss; have significant musculoskeletal or other neurological conditions; are not medically stable; or have comorbid conditions that influence their lower extremity function.

Randomisation

Stratified permuted block randomisation will occur with random block sizes of 4 and 6 stratified by sex (man or woman). Participants will be randomised (1:1 allocation) to either TRAIL or EDUCATION using a computer-generated sequence. Allocation concealment will be in place, and randomisation will be completed by a researcher not involved with recruitment, data collection or intervention delivery.

Interventions

Experimental

Participants randomised to TRAIL receive:

- Virtual Intake Session and Home Assessment: Prior to starting TRAIL, therapists will conduct a 30-min 1:1 session to meet with participants, confirm health
status and impairment level, ensure that the technology is functioning and that the home set-up is appropriate for the intervention.

Exercise: Participants will receive two synchronous telerehabilitation sessions (60–90 min) each week for 4 weeks, at ≤2:1 participant-to-therapist ratio. Each week has a specific focus for lower extremity rehabilitation: Week 1, building a base; Week 2, increasing repetitions; Week 3, building exercise tolerance; and Week 4, maximising repetitions. The protocol is standardised, but exercises are adaptable to accommodate individual abilities. Preparticipation

Exclusion criteria
- Current participation in formal in- or out-patient rehabilitation focusing on lower extremity training
- Living in long-term care
- Severe vision or hearing loss
- Significant musculoskeletal or other neurological conditions
- Not medically stable
- Presence of comorbidities that significantly impact lower extremity function

Figure 1 Trial flowchart.
checklists are completed prior to every session to verify participants’ health and well-being, ensure that technology is working and confirm emergency contact information.

- **Self-management support:** At the end of the second exercise session each week, the therapist and participants will work collaboratively to develop an independent exercise action plan to be completed before the first session of the next week. The self-managed plans include exercises selected from TRAIL, agreed on by the participant and therapist, that are safe to perform without therapist oversight. The aims of the exercise action plan are to: (1) add exercise volume without using programme resources (eg, therapist time) and (2) build capacity for self-management for long-term health and well-being after TRAIL has ended.

TRAIL therapists are registered physical therapists who have experience working with people with stroke. They will complete a 3-hour training curriculum on: (1) tele-rehabilitation; (2) exercise for lower-extremity recovery poststroke; (3) self-management support; (4) the TRAIL protocol, including training on the comprehensive safety protocol and (4) practice. Therapists also receive a comprehensive TRAIL Therapist Manual, Exercise Guide, videos and other resources, as well as the Participant Manual. Fidelity of TRAIL will be enhanced by our detailed protocols, close supervision, recording and auditing of TRAIL sessions, and monthly therapist meetings with the study research team for support, dialogue and information sharing.

**Attention control**

Participants randomised too EDUCATION receive:

- Two synchronous educational sessions (60–90 min) each week for 4 weeks with a trained educator at ≤2:1 participant-to-educator ratio, that controls for attention and expectancy of improvement resulting from TRAIL. EDUCATION has a specific focus on: Week 1, what is stroke; Week 2, what is self-management; Week 3, self-management for poststroke complications (eg, activities of daily living); and Week 4, self-management for secondary prevention (eg, blood pressure, diet and stress management).

- A manual that provides information about stroke, self-management, poststroke complication, stroke risk factors and secondary prevention, as well as homework.

Educators are professionals with experience working with individuals with stroke, knowledge of chronic disease self-management, and who have completed study-specific training on the EDUCATION programme. Similar to TRAIL, fidelity of EDUCATION will be enhanced by our detailed protocols, close supervision, auditing of EDUCATION sessions and monthly meetings with the study research team for support, dialogue and information sharing.

**Assessments**

Participants will be followed for 7 months. After receiving informed consent (online supplemental file 1), all outcome measures will be administered virtually at baseline (T1), the end of the 4-week intervention period (T2) to determine training-associated changes in outcomes; 3 months postintervention (T3) to evaluate retention of benefits; and 6 months postintervention (T4) to ensure a robust economic evaluation. We have established the safety, feasibility and test-retest reliability of the virtual outcomes assessments. During assessments, we may require a helper (eg, family and friend) to be present to help with set-up, safety and supervision. All assessors will be physical therapists who are not involved in administering TRAIL or EDUCATION, and blinded to group allocation. They will receive a 2-hour training workshop, comprehensive Assessor Manual, videos and other resources.

At T1, we will also collect demographic data including age, sex, details of stroke (type and location), gender-related factors such as gender identity, employment, partner status, living arrangements, caregiving, household roles, social support, independence and education, comorbidities (Functional Comorbidity Index), stroke severity (modified Rankin Scale), and NIH Stroke Severity Scale, and cognition (Montreal Cognitive Assessment-Short). At T2, we will also administer a user acceptability survey to assess participants’ attitudes, satisfaction. For participants who deviate from intervention protocols, we will continue with follow-up data collection on all study outcomes.

**Primary and secondary outcomes**

**Primary clinical outcome**

Our primary outcome is the between-group difference in functional mobility at postintervention, measured using the TUG. The time (seconds) to rise from a standard armchair, walk 3 m at a comfortable pace, turn and return to sitting in the chair is the primary outcome of the test. The test has excellent test-retest reliability (Intraclass Correlation Coefficient (ICC) = 0.96) and high convergent validity with the Berg Balance Scale (rho=0.70) and Community Balance and Mobility Scale (rho=0.75).

**Secondary clinical outcomes**

(1) Lower extremity strength will be assessed using a 30 s Sit-to-Stand test where participants begin by sitting in a standard chair with their arms crossed, and complete as many repetitions of sitting to standing as possible within 30 s. The number of completed repetitions is the primary outcome of this test. This measure has excellent test-retest reliability among older adults (r=0.89). (2) Functional balance is assessed using Functional Reach and Tandem Stand. Functional Reach assesses balance through maximum distance of forward reach (in cm) from a fixed base. It has been validated with walking speed, tandem walk and 1-footed stand, and has excellent test-retest reliability. We will also measure the ability to...
hold a tandem stance position (up to 10 s; alternate positions: semitandem or feet together).28 (3) Motor impairment is evaluated using a modified 12-item Fugl-Meyer Assessment which rates lower extremity impairment, coordination and speed on a three-point scale (0=cannot perform, 1=performs partially and 2=performs fully).29 The maximum score is 24, with higher scores indicating less impairment. (4) Balance self-efficacy is assessed using the 16-item Activities-specific Balance Confidence Scale, a self-report questionnaire that measures an individual’s self-efficacy in performing various activities without losing balance.30 Item responses range between 0 and 100, where a mean score is derived, with higher scores indicating higher balance self-efficacy. (5) Health-related quality of life is assessed using the 60-item Stroke Impact Scale.31 Participants rate the level of difficulty for strength, hand function, basic and instrumental activities of daily living, mobility, communication, emotion, memory and thinking, and participation on a five-point Likert scale. The scale has excellent concurrent validity with the Functional Independence Measure (r=0.83), Barthel Index (r=0.82) and the SF-36 (r=0.84).32

**Health economic outcomes**

Health resource use will be collected using a healthcare resource utilisation questionnaire.33 On a per participant basis, costs will be assigned using hospital costing models and the provincial guides to medical fees. Health-related quality of life will be evaluated using the EuroQol-5D-5 Level,34 a generic preference-based utility instrument comprises five domains related to health (mobility, self-care, usual activities, pain and anxiety/depression), each with five levels (1=no problems and 5=major problems); a health state utility value will be calculated from the scores on each of these five domains. Lower scores indicate poorer health-related quality of life; a score lower than zero indicates a health state considered worse than death. We will use Canadian conversion tariffs for transforming health state profiles into utility scores.35

**Feasibility indicators**

Data on process (recruitment rate, retention rate and perceived satisfaction), resources (treatment fidelity and adherence, blinding, randomisation, study criteria, participant and assessor burden), management (equipment and processing time) and scientific (safety) parameters will be collected throughout the study, beginning at baseline.36

**Data management and monitoring**

All participating sites will use REDCap to collect the study outcomes. Any adverse events related to the intervention will be reported by the study coordinators and followed up by the research steering committee (RSC). The RSC will perform day-to-day trial management and meet on a weekly basis and will provide overall supervision, monitor trial progress and advise on scientific credibility.

**Sample size estimate**

Based on our feasibility study with an SD of 9.6 s of the virtual/online TUG as our primary clinical outcome, we require a sample size of 74 participants to detect a clinically important difference of 5 s between groups, at a level of significance of 0.05 (two-sided), with 80% power (G*Power, V.3.1.9.7, Düsseldorf GER). To account for 20% attrition, we will recruit 93 participants, plus another 3 participants to ensure the 2:1 participant-to-therapist ratio for each of the TRAIL and EDUCATION groups, for a total of 96 participants (48 per study arm). Our previous work has found very low ICGs (<0.01) for walking and mobility outcomes across six Canadian stroke rehabilitation centres.30 Thus, clustering by site was not considered in the sample size calculation.

**Statistical analysis**

Means and SDs (continuous variables) and frequencies and proportions (categorical variables) will be used to summarise all variables at baseline.

**Clinical outcomes**

Intervention effects postintervention (T2) will be estimated using linear regression including baseline measures and the sex stratification variable as covariates. Linear mixed effects models will be used for the secondary endpoints (T3 and T4) with time by treatment group as an interaction term and ID as a random effect. Interaction of treatment group with baseline will also be explored. All analyses will be intention-to-treat. Analyses will be performed using R software (R Foundation, Vienna) with significance at 0.05.

**Health economic outcome**

Our cost-utility analysis will examine the incremental costs and effects generated by using the TRAIL intervention compared with EDUCATION. The outcome of the cost-utility analysis is the incremental cost-utility ratio (ICUR).39 The ICUR represents the difference between the mean costs of providing the intervention compared with the control divided by the difference in mean effectiveness, where the ICUR = Δ Cost/Δ Utility (eg, Δ Quality Adjusted Life Year (QALY)).39 The QALY is calculated based on the quality of life of a participant (ie, estimated from the EQ-5D-5L health state utility values) in a given health state and the time spent in that health state.

**Feasibility indicators**

Feasibility indicators will be treated as binary, with ‘success’ indicating that the indicator is sufficient with only small or no adaptations required and ‘revise’ indicating a need for changes prior to implementing TRAIL.

**Patient and public involvement**

An individual with lived experience of stroke (JM) is a member of our RSC, has advised on the development of TRAIL, this trial protocol and outcome measures, and meets weekly with the research team.

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ETHICS AND DISSEMINATION

Ethics approval for this research has been obtained by all participating sites (University of British Columbia Clinical Research Ethics Board (H21-01317); University of Manitoba Health Research Ethics Board (HS25245); Toronto and London via Clinical Trials Ontario (3786); and Nova Scotia Health Research Ethics Board (1027 411)). Prior to enrolling individuals into the study, a research coordinator will detail the study procedures to potential participants and answer any questions. After providing informed consent (online supplemental file 1), individuals will be enrolled into the study. This article describes protocol V.1.7. Any amendment to this protocol will be sent to the ethics committee for approval. Findings from this trial will be disseminated in peer-reviewed journals and presentations at international scientific meetings.

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Contributors BMS and AT conceived the study concept and design and will provide overall oversight of trial progress, data management and analyses, and knowledge translation. EB, RB, MB, JCD, JJE, AH, ELI, MM-L, JM, CP, SP, AS, RT and JY will contribute to the study protocol implementation, patient screening, and data acquisition and analyses. AS will provide statistical expertise. EW will handle the configuration of the database and data collection management. All authors provided critical review and approved the final version of this manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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Participant Information Letter and Consent Form

TeleRehabilitation with Aims to Improve Lower Extremity Recovery Post-Stroke (TRAIL-RCT): A Randomized Controlled Trial

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Funder: Canadian Institute of Health Research (CIHR)

Study Contact: Ms. Tzu-Hsuan Peng, Vancouver Study Coordinator
Email: trail.study@ubc.ca
1. Invitation

You are being invited to take part in this research study because your leg function has been affected by a stroke.

2. Background

A primary focus of stroke rehabilitation is learning how to manage stroke, and optimizing recovery of motor impairment, walking and balance. The rapid growth in Internet use and personal mobile devices like laptops and tablets has provided a variety of possibilities for stroke survivors to remotely access specialized rehabilitation from their homes and communities (i.e., telerehabilitation).

Research has shown that people with stroke view telerehabilitation to be as good as in-person rehabilitation, in terms of social interaction and satisfaction with the rehabilitation delivered by a therapist. Additionally, research has shown that people with stroke are interested in receiving rehabilitation services using mobile technologies like laptops and tablets. It is promising that stroke survivors are ready to use technology in self-directed ways and that many opportunities to research telerehabilitation to improve recovery after stroke exist.

Although the willingness to participate in telerehabilitation is encouraging, our understanding of whether exercise or education-based telerehabilitation are safe and possible and improves leg function is limited among people with stroke. Additionally, there have been no previous studies to examine the use of telerehabilitation in the first-year post-stroke when the potential for early brain recovery is greatest.

3. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. This consent form will inform you of the risks and benefits of this study. If you wish to participate, you will be asked to sign this form. If you decide to participate, you may still choose to withdraw from the study at any point without giving reason. If you choose not to participate, you will not lose the benefit of medical care, education, or other services to which you are entitled to, or are presently receiving. Please review the consent document carefully when deciding whether or not you wish to participate and sign this consent form, if you accept being a research participant. Please take time to read the following information carefully and discuss it with your with family, friends, and study team before you decide.

4. Who is conducting this study?

This study is being conducted by the members of the of Rehabilitation Research Program at GF Strong Rehabilitation Centre and the Centre for Chronic Disease Prevention and Management, both affiliated with the University of British Columbia (UBC), along with researchers from
5. What is the purpose of the study?

This study aims to examine the effects of a 4-week lower limb telerehabilitation program (Telerehabilitation with Aims to Improve Lower Extremity Recovery Post-Stroke (TRAIL), among people with stroke.

We will compare TRAIL to an education program for individuals with stroke (EDUCATION) on walking ability, balance, leg strength, quality of life, confidence in your abilities to balance while performing daily activities. We are also requesting access to some of your government compiled health records to examine the healthcare costs associated with your participation in the study.

6. Who can participate in this study?

You may be able to participate in this study if you:

• Are 19 year of age or older
• Are within 12 months of your most recent stroke
• Have weakness of the lower extremity due to your stroke
• Are able to walk 10m without physical assistance
• Are able to tolerate 50 minutes of activity (including rest breaks, as needed)
• Have a friend, or family member able to provide safety supervision and/or physical support during the baseline virtual evaluation sessions
• Have the ability to safely communicate with research team members
• Are able to provide informed consent

You are not eligible to participate if you:

• Are currently receiving in- or outpatient or community-based rehabilitation
• Live in long-term care
• Have severe vision or hearing loss
• Have other neurological conditions (e.g. Parkinson’s disease)
• Have other significant medical conditions (e.g. severe osteoarthritis) that significantly impact lower extremity function
• Have pain or other symptoms that significantly impact lower extremity function
• Have planned surgery that would preclude or affect participation in the protocol

7. What does the study involve?

A total of 96 participants will be recruited across six sites in Canada, including: Vancouver, Kelowna, Winnipeg, Toronto, London, and Halifax. Half of the participants (i.e., 48 participants)
Faculty of Medicine

will be randomized into the TRAIL program, and 48 participants will be randomized into the EDUCATION program.

If you agree to participate in this study, you will be asked to attend: i) a technology set-up orientation; ii) two virtual baseline assessment sessions that will be conducted remotely using the video-conferencing platform; iii) a virtual intake session; iv) either the 4-week TRAIL or EDUCATION telerehabilitation program; and v) three follow-up virtual assessment sessions.

With your consent, we will ask to link the data collected by the researcher about you during the duration of your time in the study to some of your health records from the date that you completed your baseline assessments to 6-months after you’ve completed the study from the agencies described below. This process is called “data linkage” (please see the next section for more information about data linkage). If you allow us and if these agencies give us approval, we will link the data collected about you during the duration of the study period to the following data sources to help us answer our research questions:

a. **Population Data BC:** We will request information from the Statistics Canada Income Band file, which contains information about average incomes associated with Postal Codes. Data requested will be from the date that you completed your baseline assessments to 6-months after you’ve completed the study.

**How will “data linkage” happen?**

In order to link the responses that you provide in your survey to the information about you that we request from the agencies described above, we will follow strict guidelines designed to maximize the privacy and security of the information about you used in the study. The data linkage process will be completed by Population Data BC (PopData). PopData is a multi-university organization dedicated to data access, protection and privacy of research data. PopData acts as a trusted third party for data linkage.

Data linkage for this study will include the following procedures:

- We will ask you for your Personal Health Number and provide it to PopData so that they can identify your records that we request from the agencies listed above.
- PopData will use your Personal Health Number to communicate with the agencies listed above and to identify the records that were requested and approved in this study. PopData will not use your information in any way other than as authorized by this consent form.
- Before providing your agency health records to the research team, PopData will replace your Personal Health Number with a randomly assigned number known as Study IDs that is specific to the project. **This way, the researcher will not be able to connect your responses and records to the information that was used to identify you as part of the linkage process** (i.e., your Personal Health Number)
Where will my PHN information be stored and analyzed?

Your study information will be stored in two different places as described below:

- **Location 1 (UBC RedCap)**: The information collected by the research team will be stored separately from any other data on a password-protected database called RedCap (e.g., your Personal Health Number will be stored separately from your survey responses).

- **Location 2 (PopData)**: As explained, we will provide your Personal Health Number to PopData so that they can undertake the data linkage process. The research team will usually access and analyze the linked study data (including your survey responses and your requested and approved agency records) on Population Data BC’s Secure Research Environment (SRE), unless otherwise approved. Information is stored on the SRE in accordance with strict government security standards. The SRE is a secure central server accessible only via an encrypted Virtual Private Network (VPN) through a firewall.

**Technology Set-Up Orientation**

This orientation session will provide you with information about the video-conferencing platform we will use for data collection and for delivery of the TRAIL and EDUCATION programs. We will review basic features of the online platform with you to ensure that you are familiar with the platform prior to starting your program. During this session, you will be given the schedule (days/times) of your telerehabilitation program. This orientation session will take approximately 30 minutes to complete.

**Virtual Assessment Sessions**

- You will be asked to attend virtual assessment sessions (each lasting approximately 70-80 minutes), with a trained therapist. Before starting the telerehab programs, you will have two assessment sessions, where at the first baseline session, we will ask you questions about your age, sex and gender, living arrangements, ethnicity, education level, your stroke, and your medical history. We will also perform an assessment of thinking and memory.

- At the second baseline session, we will assess your walking ability, leg strength, balance, quality of life, confidence with your ability to balance while performing daily activities, and usage of healthcare resources.

After the end of the telerehabilitation programs, we will repeat these assessments again, and you will also be asked to complete a satisfaction exit survey. The follow-up session will take approximately 90 minutes to complete.
If you do not have a helper for the two baseline visits, you will be provided the opportunity to come into the GF Strong Rehabilitation Centre for your assessments. Your assessments will be overseen by a study staff member and you will be compensated for the costs of transportation.

The assessor and therapists that you work with over the course of the study may suggest that the presence of a helper at your follow-up assessment visits may not be needed. If you are randomly assigned to the TRAIL program, this decision will be based on the assessor’s clinical judgment from the initial assessment from the baseline visits, but also on the TRAIL therapist’s observations with having overseen your exercises over the previous 4 weeks (2x/week). If you are assigned to the EDUCATION program, the decision on the need of having a helper present at follow-up visits will be based on the assessor’s initial clinical judgment from your baseline assessments. This decision will be communicated to you by the site coordinator at each of your follow-up visits.

By signing this consent waiver, you are acknowledging that this decision to have a helper present at your follow-up visits will be based on the clinical judgements of the study therapists, and your own informed decision will be also taken into account. If the therapist believes that a helper should be present, please know that this decision is based on the priority to keep you safe and prevent the risk of injuring yourself.

The following points will be taken into consideration when determining whether a helper is needed at any of your follow-up visits:

- Have you experienced any significant changes in health status or functional status since your last assessment visit?
- Were there any safety issues noted by assessor during assessments or virtual sessions, such as balance issues?
- How much assistance did you receive from a helper with room set up at your baseline assessment?
- Did you have any issues with setting up your technological device, adjusting your camera views, and/or managing Zoom?
- Will your confidence in your abilities to maintain balance during the assessments change if a helper isn’t present?
- Do you have to make special arrangements to have a helper present with you during the assessments?

We may also seek your permission to access your medical charts through your current therapist to obtain more details about your stroke, clinical outcome measures, and functional ability that can be shared with your therapist to better support you throughout your 4-week program. This information will solely be used for telerehabilitation.

**Virtual Intake Session**

After completing the baseline evaluation, you will meet with your telerehabilitation therapist individually in a 30-minute video-conference that will serve as a virtual intake and orientation session and home assessment. At this ‘virtual orientation’, you will be provided with an overview...
of the manual of the telerehabilitation program that will be administered. During this time, we will provide instructions on how to set up the video-conferencing system at home on your preferred device, the schedule (days & times) of your telerehabilitation sessions, and next steps. The therapist will also answer any questions you might have and remind you of your first session.

**Group Allocation**

After your baseline evaluation, you will be assigned to one of 2 programs: the TRAIL program or EDUCATION program. Your allocation to either the TRAIL or EDUCATION program will be determined by chance, after the completion of your second baseline session. You will have a 50-50 chance (like the flip of a coin), of being assigned to either program, but not both. Both programs are 4 weeks long and led by a trained health professional.

**TRAIL Program**

The TRAIL program is comprised of evidence-based exercises and self-management techniques that harness the expertise of clinical therapists and the motivation of stroke survivors, such as yourself. The TRAIL program will be delivered in a group format with a maximum of two participants for one therapist. Each grouping will receive 2 x 60-90-minute telerehabilitation sessions per week with a physical therapist trained in telerehabilitation. You will also be asked to complete at least one additional independent self-managed exercise session each week. The self-management exercises will replicate those performed with your therapist, and will take approximately 60-90 minutes to complete. The self-managed exercise sessions consist of exercises that have been decided on together between the therapist and participant. This provides the participants the opportunity to build confidence and capacity in self-management and facilitates transition to independent exercise after the study is over.

**TRAIL has a specific focus on:**

**Week 1** Building a base → 8 exercises, 10-15 repetitions x 2-3 sets

**Week 2** Increasing repetitions → 8 exercises, 15-20 repetitions x 3 sets

**Week 3** Building exercise tolerance → 10 exercises, 15-20 repetitions x 3 sets

**Week 4** Maximizing repetitions → 10 exercises, 30 seconds as many reps as possible x 2 sets

**EDUCATION Program**

EDUCATION therapists are professionals who have experience working with individuals with stroke, knowledge of chronic disease self-management (e.g. physical or occupational therapists, nurses, kinesiologists), and who have completed study-specific training on the EDUCATION program. The EDUCATION program will also be delivered in a group format with a maximum of two participants for one therapist. Each grouping will receive 2 x 60-90minutes educational telerehabilitation sessions per week with a physical therapist. You will receive an education manual that provides information about stroke, self-management, post-stroke complications, and management of stroke risk factors for secondary prevention. In addition to your biweekly education sessions with a trained therapist, you will be asked to complete homework that is designed to help put your newly acquired knowledge to use, through the development of self-management action plans. The homework will also include multiple choice style questions to...
help reinforce the content covered from the previous lesson. Your responses to the homework questions will be discussed with your therapist at the beginning of each session. The discussion of homework material will take approximately 20 minutes to complete.

**EDUCATION has a specific focus on:**

- **Week 1** What is stroke (e.g., understanding of the brain, types of strokes, and how stroke affects function); and introduction to self-management;
- **Week 2** What is self-management;
- **Week 3** Self-management for post-stroke complications (e.g., activities of daily living);
- **Week 4** Self-management for secondary prevention (e.g., blood pressure, medication, diet, stress management).

**Time Commitment for Study**

The total time commitment for the study is as follows:

<table>
<thead>
<tr>
<th></th>
<th>Time Commitment</th>
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<tbody>
<tr>
<td>1. Screening &amp; Consent</td>
<td>30 mins = 0.5 hours</td>
</tr>
<tr>
<td>2. Technology Set-Up Orientation</td>
<td>30 mins = 0.5 hours</td>
</tr>
<tr>
<td>3. Baseline Virtual Evaluation Part 1</td>
<td>~70 mins = ~1.0 hours</td>
</tr>
<tr>
<td>4. Intake Session and Home Assessment</td>
<td>30 mins = 0.5 hours</td>
</tr>
<tr>
<td>5. 4-week TRAIL or EDUCATION Program</td>
<td>8 x 60-90 mins = 8-12 hours</td>
</tr>
<tr>
<td>6. Self-Managed Exercise Sessions or Written Homework</td>
<td>4 x 60-90 mins = 4-6 hours</td>
</tr>
<tr>
<td>7. Post-Program Follow-Up 1 Virtual Evaluation (4 weeks after baseline)</td>
<td>90 mins = 1.5 hours</td>
</tr>
<tr>
<td>8. Post-Program Follow-Up 2 Virtual Evaluation (3 months after baseline)</td>
<td>90 mins = 1.5 hours</td>
</tr>
<tr>
<td>9. Post-Program Follow-Up 3 Virtual Evaluation &amp; Exit Survey (6 months after baseline)</td>
<td>90 mins = 1.5 hours</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>Minimum of ~20.5 – 26 hours</strong></td>
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</table>

*Participants allocated to TRAIL will be asked to complete at least 1 self-management session per week during the program. The anticipated time commitment for homework in the EDUCATION group is 1-2 hours per week.

8. **What are the potential benefits of participating?**

There is a chance that you may experience improvements to your lower limb function and the amount you use your lower limbs. You may also experience improved health status and confidence performing daily activities. You may also benefit from gaining knowledge on your stroke and acquire self-management strategies for secondary stroke prevention. As well, the information that we gather will increase our understanding about the safety and effects of using telerehabilitation for leg recovery after stroke. Findings from this study will help inform clinical practice and future larger-scaled trials.

9. **What are the possible harms and discomforts?**
Occasionally, answering questions about feelings and experiences may make participants feel uncomfortable. Subjects are not required to answer all of the questions and may skip any that make them feel uncomfortable.

One questionnaire includes questions about thinking about death or feelings of worthlessness. The researcher may need to tell someone if you talk about harming yourself. If you tell research staff that you are thinking about death or if you answer “Yes” to questions about thinking of death or persistent feelings of worthlessness, the researcher may ask you more questions about your thoughts. They may give you names and contact information for places you can call for help, or help you to call your doctor, a relative, or therapist. The researcher may also help you to get to a medical facility for your safety.

There is a chance you may feel tired or experience muscle soreness from the assessment session or after completing the telerehabilitation exercises, for those completing the TRAIL program. The soreness should subside with rest and you should not feel deeply tired or remain fatigued the next day. All TRAIL sessions will be supervised by a registered physical therapist to ensure your safety, and activities can be modified according to your condition to reduce the risk of falls and injury.

There is a small risk that you might fall during the virtual assessment sessions. All assessment sessions will be conducted by a trained physical therapist who will monitor your movements carefully and may choose to leave out any assessments that are not deemed to be safe. We also require that you have another person present with you during the virtual assessment sessions who is able to provide safety supervision and physical assistance if needed. You may feel uncomfortable answering questions about your general well-being during the measurement session. You do not have to answer any question that makes you feel uncomfortable.

As the video-conferencing platform (i.e., Zoom) will be used for the online interview, several security measures will be put in place to maintain the confidentiality of participants to ensure that the data is being collected in a secure manner:

- Personalized Zoom links for each individual to avoid unwanted participants
- Restrict screensharing to just to the host to prevent random individuals to takeover
- Lock the meeting after it has started so no new participants can join
- Introduce the waiting room feature to allow only the 2 participants and therapist into the main Zoom room
- Include a password to gain access to the meeting room

With regards to the information collected related to your medical records (i.e., Health Records Data Linkage), once data collected by the study team has been linked to your agency health records, the risk of identifying you is small. No identifiers (e.g. PHN) will be released to the study team without your consent. Records linked will be identified only using a unique study IDs.

TRAIL-RCT Informed Consent Form | V2.8 | February 8, 2023
10. What if new information becomes available that may affect my decision to participate?

You will be advised of any new information that becomes available that may affect your willingness to remain in this study. You may be invited to sign an amended consent form to indicate your continued consent to participate in the study.

11. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information already collected. You have the right to request the destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note, however, that there may be exceptions where the data will not be able to be withdrawn – for example, where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let the study team know.

You may withdraw at any time without any impact to your medical care and may choose between two types of withdrawal:

a) Withdraw but allow the research team to retain data already collected about you. No additional data will be collected about you.

b) Withdraw and request all data already collected about you be destroyed. No additional data will be collected about you.

If you choose to withdraw all your data AFTER your data has been de-identified and merged with data from the other providers noted above, then the research team will inform PopData of your withdrawal. PopData will then give the research team information about you that would allow the research team to identify all your records (including those from the agencies noted in this consent) in the combined data. The research team will then remove the data collected by them within the combined data.

12. How will my participation be kept confidential?

Your confidentiality will be respected. However, research, health, or other records identifying you may be inspected with the study assessor or their designate by representatives of Dr. Brodie Sakakibara, or UBC Clinical Research Ethics Board, for the purpose of monitoring the research. No information or records that reveal your identity will be released, published, or removed without your consent, unless required by law.
You will be given a unique participant number as a participant in this study. This number will not include any personal information that could identify you (e.g., Personal Health Number, SIN, etc.). Only this participant number will be used on any research-related information collected about you during the study (called de-identified data) so your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

The videoconferencing program used to administer the telerehabilitation will be UBC-licensed Zoom©. Although no personal identifiers or data will be collected or stored for research, Zoom© automatically collects passive data from all users of the program including “host information,” “usage information, and “user-generated information” as explained in https://zoom.us/privacy which are stored on data servers in Canada. To receive the telerehabilitation program you will be required to use the Zoom video-conferencing platform. We will email you a link to access the Zoom platform for each telerehabilitation program. As such, Zoom will have knowledge of your email address.

All documents will be kept in a locked filing cabinet in the Centre for Chronic Disease Prevention and Management at the UBC Southern Medical Program, Okanagan Campus. Electronic files will be encrypted and saved on a password protected server in the Department of Occupational Science and Occupational Therapy, which only the Principal Investigator, Co-Investigators, and the study coordinator have access to the files. In addition, your data will be stored on UBC REDCap, which is a secure web platform that runs on servers located in Vancouver, BC at the UBC University Data Centre. Access to data on UBC REDCap will also be restricted to the study investigators and coordinator.

The health information discussed during the telerehabilitation session may be made known to the other participant in your group telerehabilitation session. While all participants are encouraged to refrain from disclosing the contents of the discussion outside of the group telerehabilitation sessions, we cannot control what other participants do with the discussion discussed.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure your privacy is respected. You also have the legal right of access to the information about you that has been provided to the funder and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available upon request to the study team.

Your de-identified research data may be made publicly available at the time of publication. This data could include demographic and medical information. Identifying information (i.e., name, birth date) is never included. This improves transparency of research and allows others to access the data. This should not increase your risk, but it does mean that other researchers may analyze the data for different reasons. Once data is publicly available, you will not be able to withdraw...
your data. While the risk of being identified through public data cannot be completely eliminated, it currently appears to be low.

In the health care linkage portion of the study, the identifier list described above will be sent to PopData via a secure file transfer program. The data collected by the researchers about you that are identified only by a unique study ID will be sent in a separate file to PopData, also using a secure file transfer program. PopData will link the data collected by researchers to your health records and replace all identifiers including the old study ID with a new final study ID created by PopData in order to protect your identity. At this point, all information about you will only be identified by the new final study ID. The linked data about you and the final study ID will be stored and accessed by the research team on the Secure Research Environment at PopData. We will follow strict guidelines designed to maximize the privacy and security of your information, which are described in more detail in the "How will data linkage happen?" and "Where will my information be stored and analyzed?" sections.

13. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights. You do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan. If you have any concerns, please contact Dr. Brodie Sakakibara (Principal Investigator) at (250) 807-8505 or by email at brodie.sakakibara@ubc.ca for further information.

14. What will the study cost me, and will I be compensated for my time?

In order to offset some of the costs of your time to participate in the virtual evaluation sessions, you will receive an honorarium in the amount of $25.00 for the two baseline sessions and post-intervention follow-up sessions (1-, 3-, and 6-months; 3 total), for a total of $100.00. To participate in this study, you will require an internet connection. Some internet service plans have limited use per month. If you have a limited use internet service plan, and you exceed your monthly usage, you will be responsible for any additional charges by your service provider.

15. What do I do if I have questions about the study during my participation?

If you have questions or want more information at any time about this study before or during participation, or if you experience any adverse effects, you can contact the Principal Investigator, Dr. Brodie Sakakibara at brodie.sakakibara@ubc.ca or the study contact, Tzu-Hsuan Peng, at trail.study@ubc.ca or by phone at 250-807-8505.

16. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the ...
17. Notification of study results

__________  I want to be notified when study results are available
Informed Consent

Telerehabilitation with Aims to Improve Lower Extremity Recovery Post-Stroke
(TRAIL-RCT): A Randomized Controlled Trial

UBC Site Principal Investigator:
- Dr. Brodie Sakakibara, PhD, UBC Department of Occupational Science & Occupational Therapy, Centre for Chronic Disease Prevention and Management, Southern Medical Program, 1088 Discovery Ave, Kelowna, B.C., V1V 1V7

Funder: Canadian Institutes of Health Research (CIHR)

Contact: Ms. Tzu-Hsuan Peng, Vancouver Study Coordinator
Email: trail.study@ubc.ca

Participant Consent
My signature on this consent form means:
- I have read and understood the information in this consent form
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary and I can refuse to participate or to withdraw from this study at any time, and this will not change the quality of care I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I authorize my telerehabilitation therapist to access my health records either through my previous therapist or directly accessing the electronic medical record system
- I understand that the health information that I discuss during a telerehabilitation session may be made known to the other participant
- I have been told that I will receive a signed and dated copy of this consent form for my own records
- I have read this form and I freely consent to participate in this study.

[Initial] Yes, I would like to be contacted for future studies

Clinical Trial (Telerehabilitation program) - I consent to participate in this study

____________________  __________________________  ______________________
Signature of Participant  Printed Name  Date

____________________  __________________________  ______________________
Signature of Person Obtaining Consent  Printed Name  Study Role  Date

Health Records Data Linkage - I consent to participate in this study.
# Informed Consent Form

**Faculty of Medicine**

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<tr>
<th>Participant’s Signature</th>
<th>Printed name</th>
<th>Date</th>
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Telerehabilitation with Aims to Improve Lower Extremity Recovery Post-Stroke (TRAIL-RCT): A Randomized Controlled Trial

Request to Access Medical Records through Population BC Database

Name: _______________________________________
DOB: _______________________________________
PHN: _______________________________________

What is Population BC?

Population BC is a database that was made for researchers to be able to access information on person-specific healthcare services usage. Researchers may only access your personal medical data through a comprehensive application process through Population BC. In order to be able to access your data, we will need to know your Personal Health Identification Number (PHN).

Authorization to Release Information

I, ____________________________________________, hereby consent to having any information regarding any medical attention conducted during my participation in the above named study accessed through the Population BC database. Only approved members of the study team will have access to the secure and confidently database. Transfer of these records will not compromise my confidentiality.

Signature: _________________________________
Principal Investigator or Study Representative: ___________________________
Date: ________________________________