A Cognitive-Augmented Mobility Program (CAMP): Combining Cognitive Strategy Training And Best Evidence Mobility Training To Optimize Long-Term Meaningful Living For People With Stroke

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RESEARCH PROTOCOL

1.0 OBJECTIVE

This project will combine best-evidence gait and mobility training with best evidence cognitive strategy training to produce a new cognitive-augmented mobility intervention that is expected to optimize long-term functional mobility outcomes for those living with stroke. More importantly, the new cognitive-augmented mobility program (CAMP) will address two crucial outcomes that do not occur with current approaches: 1. **Maintenance** of mobility gains after discharge from formal rehabilitation and 2. **Transfer** of skills learned in rehabilitation to real-world community living. This project will result in a new, fully defined intervention, and will provide effect size and cost estimates to design a future appropriately powered randomized controlled trial (RCT).

2.0 RATIONALE

After a stroke, two-thirds of survivors do not participate meaningfully in their communities.[1] Approximately half are dependent in activities of daily living;[1,2] most experience restrictions in physical exercise, housekeeping, and outdoor activities;[3] and they are significantly less active than age-matched controls.[4] While reasons for these poor outcomes are multi- factorial, dysfunctional gait is recognized as the most important factor associated with ongoing restrictions in activity and participation.[5] Two recent meta analyses concluded that physical rehabilitation interventions *do* improve function and mobility after a stroke, **but only during the intervention period**.[6,7] To have a sustained, meaningful impact on activity and community participation, two intervention outcomes are crucial: 1. Gains made during a formal rehabilitation program must be **maintained** after discharge to the community; and 2. The finite number of skills learned in a formal rehabilitation program must be **transferred** to new contexts and situations that the person encounters after discharge. Evidence suggests that current gait and mobility interventions do not usually impact maintenance and transfer of skills learned. Cognitive strategy training has demonstrated a large effect on skill transfer in people with stroke compared to dose-matched controls, and the large effect is maintained at follow-up.[8,9]

In an extensive meta-analysis, Veerbeek et al. concluded that several physiotherapy interventions are associated with statistically significant effects, but the magnitude of differences between treatment and control groups was small to moderate, improvements were restricted only to the intervention period, and changes were limited to those activities specifically trained in the intervention.[7] **Task-specific training** (TST) and **combined cardiorespiratory and strength exercises (CSE)** were identified among the most efficacious interventions. TST is training or therapy where patients practice specific functional motor tasks and receive feedback.[10] TST approaches, such as treadmill-based training, activity-based balance training, and functional activity-based circuit training showed significant positive effects on walking speed and distance and general physical activity, but not on health-related quality of life (HRQoL) or participation and only during the intervention phases.[7] **Cardiorespiratory and strength exercises** (CSE) are those that specifically target aerobic fitness and muscle strength. CSE approaches have largely similar benefits and limitations as TST.[7] While some CSE studies have shown an effect on aspects of HRQoL (see for example *Stroke*. 2005;36[8]:1764-1770), results are not maintained and whether there is a true effect is inconclusive.[11]

Cognitive strategy training approaches**,** such as Cognitive Orientation to daily Occupational Performance (CO-OP),[12] are performance-based approaches that teach clients to independently use **global cognitive strategies** to solve performance problems, supported by therapists' use of **guided discovery**. Global cognitive strategies provide a consciously applied problem-solving structure to support goal-directed learning, and include a self-evaluation component. Guided discovery is a means of providing instruction and feedback in which a knowledgeable therapist guides the client to self-discover solutions to functional problems through a process of questioning, hinting and cueing rather than more typically applied direct and explicit instruction.[13] When combined with TST of activities of daily living (largely upper-extremity-based), cognitive strategy training programs have a large and maintained effect compared to controls on transfer to untrained transfer goals[8,9,14] and functional independence[9] in people with stroke. Compared to controls, cognitive strategy training has also demonstrated an effect on apathy, self-efficacy, participation, aspects of HRQoL, cognitive flexibility and upper extremity function.[8,9,14-16] These positive results have been observed with an average 9 hours of treatment,[8] far less than the 20-75 hours estimated for pure TST approaches for similar effects, suggesting the approach may also be cost-effective.[17] Despite these successes, the effect on mobility has been small. In recent work focused on activities of daily living, participants in the cognitive strategy group reported an average 7 point change on the Stroke Impact Scale mobility domain, which is not considered to be clinically important.[15]

We postulate that using a global cognitive strategy together with therapist use of guided discovery teaches participants a simple and effective problem-solving framework that leads to success with their functional performance issues. Having success builds self-efficacy to re-learn skills, which then leads to motivation to practice independently in new contexts (leading to maintenance) and the confidence to attempt new skills as the need arises (leading to transfer). We further postulate that adding cognitive strategy training to best evidence task-specific gait and mobility training and CSE will ensure good mobility outcomes while simultaneously addressing the shortcomings related to maintenance and transfer of improvements. This project will answer four specific research questions:

1. Based on literature review and expert opinion, what best evidence components and processes should be included in a preliminary model for a new cognitive augmented mobility program (CAMP) for survivors of stroke?
2. Is CAMP feasible to implement with survivors of stroke who have been discharged from outpatient rehabilitation? Feasibility criteria include practicality (no adverse events, non-medical withdrawal rate <20%, attendance rate >80%), and acceptability to patients and therapists (satisfaction and intent to continue to use).
3. What is the estimated effect of CAMP post-intervention and at 1-month follow-up (maintenance) on gait speed, endurance, balance, activity and mobility self-efficacy, mobility goal attainment, mobility skill transfer, functional independence, HRQoL, and participation?
4. What is the preliminary estimated cost and cost effectiveness of CAMP?

3.0 METHODOLOGY

The Medical Research Council (MRC) in the United Kingdom established a framework for development and evaluation of complex interventions.[18] CAMP is a complex intervention in that it has several interacting components along with additional dimensions of complexity such as heterogeneity of patients, numerous and variable outcomes, and permits a significant degree of individual tailoring.[18] The MRC framework consists of *development*, *feasibility/pilot testing*, *evaluation*, and *implementation* stages. The current project will address the first two of these stages, ***intervention development*** and ***feasibility/pilot testing***.

3.1 Intervention Development

This stage consists of identifying the evidence base, identifying relevant theory, and intervention model development. Theoretical foundations for all intervention framework components (TST, CSE, cognitive strategy training) have been specified previously.[12,17,19,20] The theoretical justification for combining motor and cognitive domains in a single approach has been outlined;[12,21,22] and includes a substantial collection of neuroimaging data indicating that brain regions traditionally considered to be cognitive, such as the dorsolateral prefrontal area, are active during complex motor skill acquisition and when implementing motor tasks in presence of neuropathology.[22] Thus, we begin with model development using the following steps: literature review, preliminary CAMP model development by investigators, and refinement of the CAMP model for pilot testing.

Stroke rehabilitation literature was reviewed with an emphasis on meta-analyses and evidence-based practice guidelines. Clinical research coordinator KD and principal investigator SM use extracted information to develop a preliminary model for CAMP (described in the section below). The CAMP preliminary model will be reviewed by the studies co-investigators who have expertise in TST (JC), CSE (AT) , balance and mobility (EI), cognitive strategy training (EL) and the stroke health system (EL,JS). The final CAMP model will be decided by group consensus.

3.1.1 Preliminary CAMP Model Overview

CAMP will combine education, one-on-one cognitive strategy training, and a cardiovascular and strength-training program conducted within a group setting. It will be run as a group of up to 6 participants, facilitated by a physiotherapist (PT) and a physiotherapy assistant (PTA) or kinesiologist (KIN). It consists of 2 phases with a total of 19 sessions: Intervention

Preparation (3 sessions), Active Intervention (16 sessions), and Follow-Up (1 session).

3.1.1.1 Phase 1, Intervention Preparation: There will be two education sessions that will occur with the whole group. The first education session will introduce the rationale for CAMP, explaining the benefits of cognitive strategy training, task-specific training, and cardiorespiratory and strength training, and will be one hour long. The second education session will teach the global cognitive strategy that is used for self-directed problem solving, and will also be one hour long. In between the two education sessions there will be a one-on-one session with each participant and the PT to set individual functional mobility goals for the intervention that will also be one hour long. To minimize participant travel, some goal setting sessions will occur immediately after Education Session #1, and some will occur immediately before Education Session #2.

3.1.1.2 Phase 2, Active Intervention: The intervention sessions will consist of a 60-minute individualized exercise program (ExP), conducted within a group, twice per week for 8 weeks (16 sessions total), developed by a physiotherapist and overseen by a PTA or KIN; and a 30-minute goal practice (GP) session that will occur one-on-one with a licensed physiotherapist, once per week (8 sessions total). The one-on-one GP sessions will be adjacent to the ExP group sessions, so participants will only attend the CAMP program twice per week total, once for 90 minutes (30 minutes one-on-one and 60 minutes group) and once for 60 minutes (group only). Up to 6 participants will go through the CAMP program at a time.

During the **one-on-one GP** session the PT will implement the use of global cognitive strategies to teach the participants to consciously apply problem-solving skills to attain the goals they have set. The PT will use guided discovery to assist the participants to discover strategies to achieve their individual mobility goals.

Group ExP sessions will include a warm-up and cool-down, approximately 20 minutes of aerobic exercise individually prescribed (e.g. stationary bike, treadmill, or overground walking), and approximately 30 minutes of resistance and task-oriented training (e.g. heel raises, toe raises, squats, lunges, sit-to-stand, walk and carry tasks, reaching tasks, modified push ups, sit-ups/curls, bridging, etc). A physiotherapist will develop an ExP individualized for each participant following their goal-setting session and before Session #1. The ExP will be modified on an ongoing basis based on heart rate and input from the participant regarding his or her perception about the utility of the ExP towards goal achievement.

3.2 Feasibility/Pilot Testing

A single group pre-post design and 1-month follow-up with 12 participants will be employed for feasibility and pilot testing. Inclusion criteria are patients aged 18 years of age who are post stroke (ICD-10 codes 160-164), have completed outpatient therapy and who can walk a minimum of 3 metres with or without an aid. Those without mobility goals, with neurological diagnoses other than stroke, major psychiatric illness, and significant dementia (MoCA scores <21)[23] will be excluded. A research assistant not involved with delivering the intervention will conduct assessments, and will occur pre and post intervention and at a 1-month follow up. Feasibility will be determined by evaluating **practicality** (recruitment and withdrawal rates, adverse events, attendance), which will be evaluated by logs kept throughout the recruitment and intervention process , and **acceptability** (participant satisfaction and intent to continue use), which will be determined using a short Likert-type survey administered immediately post-intervention (Appendix A). Additionally, participant experiences with the CAMP program will be explored using a semi-structured interview that will be conducted at the 1-month follow-up assessment (See Appendix B for Interview Guide). The interviews will be audio recorded and transcribed verbatim and subsequently analyzed using directed content analysis (Hsieh & Shannon, 2005). Outcomes for pilot testing will include gait speed, endurance, balance, activity and mobility self-efficacy, goal performance and attainment, functional independence, participation and HRQoL. All outcome measures are described in detail in Appendix C. To estimate cost the number of visits, time spent with health professionals, hourly cost of health professionals, and equipment required will be considered. To estimate cost-effectiveness quality-adjusted life-year (QALY) gained will be estimated using SF-12 data collected (derived from the SF-36). Sf-12 data will be converted to a utility score using a validated algorithm. Data analysis for quantitative outcomes will be exploratory and descriptive; changes scores, confidence intervals and effect size estimates will be calculated for all outcomes, to plan for a future RCT.

3.3 Timeline

In the first 6 months (July 2016-December 2016), REB approval will be obtained, and the literature review, model development, and model refinement will be completed. Recruitment will begin in January 2017. Past experience suggests a recruitment rate of approximately 2 participants per month; up to 6 participants will be recruited from January 2017-March 2017 and will go through CAMP together in April and May 2017, with 2-month follow-up in July 2017. A second group of up to 6 participants will be recruited from April 2017- August 2017 and will go through CAMP in September and October 2017 , with 2-month follow-up occurring in December 2017. Analysis and manuscript preparation will occur in January and February 2018.

4.0 EXPECTED PROJECT OUTCOMES

The immediate outcome of this development work will be a fully defined novel gait and mobility intervention and effect size and cost estimates to design an appropriately powered RCT. Long-term outcomes may include improved functional mobility, community participation, and productivity for those living with the effects of stroke, decreased health system costs, and improved understanding of motor-cognition interactions. From a systems level the development of rehabilitation research capacity by engaging and educating therapists and scientists will build evidence for a more integrative approach to stroke rehabilitation and contribute to an overall shift in practice.

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APPENDICES

Appendix A: CAMP Satisfaction and Intent to Use Questionnaire

	Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
1. I am satisfied with the CAMP program	1	2	3	4	5
2. I will continue to use the skills I learned during the CAMP program	1	2	3	4	5

Appendix B: Pilot Testing Interview Guide

Opening Statement: Thanks once again for your participation in this study to develop a new program to help people who have had a stroke to relearn mobility skills and improve their fitness, called the Cognitive-Augmented Mobility Program (CAMP). This interview will help us to better understand your experiences with CAMP. In particular, we are interested in your experiences with making Goals and Plans and executing those Plans, your experiences with the program as a whole, whether or not you found it helpful to be involved with the development of your own Plan, whether or not you continued with an exercise program after CAMP ended, and if not, what were the reasons you did not. Findings from these interviews will be used to generate a better understanding of the perspective on this new program from those who are actually using it, and will help us to make the program better for other people in the future. Please feel free to be completely open. When we report on this interview, your name will not be used. Your name will not appear in any reports related to this project. You should feel free to speak your mind.

Do you have any questions before we begin?

If it's O.K. with you, I may take a few notes throughout the interview.

1. **Why did you want to participate in the CAMP research project?**

2. **Please describe your overall experience with the CAMP program.**
   Probes: Was there anything you particularly liked or disliked? Was it similar to other rehabilitation experiences you had? Why or why not?

3. **Can you tell me about setting mobility and fitness goals at the beginning of CAMP?**
   Probes: Can you tell me more about the goal-setting process? What goals did you set? Did you find it helpful to set goals? Were you able to implement your plan? Please elaborate.

4. **Can you tell me about the process of developing a plan to meet your goals?**
   Probes: How easy or difficult was it for you to develop plans? What sorts of things did you try? Which plans worked? Which plans didn't work?

5. **Were you able to implement your plans outside of CAMP, that is to say at home or in your community?**
   Probes: Can you tell me more about that? What worked or didn't work?

6. **CAMP began with an education component. Was the information you received helpful?**
   Probes: Was the information new to you? Did the information help with your goal setting? What would have been more helpful? Was the information presented in a helpful way? How

would you have preferred to receive the information?

7. **As part of the CAMP program, there was a time slot each week devoted to working on your personal mobility and fitness goals. Can you tell me about that?**
   Probes: Did you achieve your goals? Were the one-on-one goal-focused sessions helpful in achieving your goals? What could have been done differently?

8. **Another part of the CAMP program was working on exercises that were specific to you and your goals. Can you tell me about the exercise part of CAMP?**
   Probes: Did the exercises help you to achieve your goals? Were the exercises the right difficulty level? Could they have been easier or harder? Did you have input into changing the exercises when it was necessary to do so?

9. **After CAMP was over, were you able to continue with an exercise program or continue improving your walking and other mobility?**
   Probes: Why or why not? What helped you to continue making gains after the CAMP program? What were the barriers to making gains after the program ended? Have you sought other rehabilitation services since?

10. **Is the approach used in this program new to you? Have you used it before in a different setting?** Probes: Have you been involved in goal setting and planning your program before CAMP? Have you had to problem solve to improve your ability to complete a task before?

11. **Are you currently facing any challenges with day-to-day activities?**
   Probes: How are you managing these challenges? Did the CAMP program have any role in helping you to manage these challenges or other challenges?

12. **Is there anything else you would like to tell me about the CAMP program, either positive or negative?**

General Probes: Can you elaborate on that idea? Would you explain that further? I'm not sure I understand what you are saying. Is there anything else? Would you give me an example? Can you give me a specific example? Do you personally feel that way? Is that something you have experienced? Can you tell me more? Can you expand on your answer?

<u>Closing Statement:</u> Thank you for participating in this interview today. Your responses will help us to make CAMP better for others in the future.

Appendix C: Description of Outcome Measures

Instrument(s)	Description and Pyschometric Properties
	Gait speed
5 metre walk test (5 mWT)[a]	The 5 mWT is a measure of gait speed where participants are asked to walk a distance of 5 m including an additional 2 m to accelerate and 2 m to decelerate. The 5 mWT has high reliability and responsiveness in stroke.[a,b]
	Endurance
6-minute walk test (6MWT)[c]	The 6MWT is a widely used measure of walking endurance after stroke and has shown excellent reliability in stroke populations.[d-f]
	Balance
Berg Balance Scale (BBS)[g]	The BBS is a 14-item assessment of static balance and fall risk. In stroke populations, the BBS has excellent test-retest and interrater reliability and a minimally detectable change of 4.7.[h,i]
Mini BESTest[j]	The Mini BESTest is a 14 item assessment that uses a 3-level ordinal scale to assess dynamic balance. The Mini BESTest has excellent reliability and a cut-off score of 17.5 is used with people with chronic stroke.[k]
	Balance and mobility self-efficacy
Activity-specific Balance Confidence Scale (ABC)[l]	The ABC is a 16-item assessment that measures a participant's confidence to perform daily activities without falling. The ABS has excellent internal consistency[m] and adequate to excellent test-retest reliability.[n]
	Individualized mobility goal attainment
Canadian Occupational Performance Measure (COPM)[o]	The COPM is a semi-structured interview that focuses on identifying activities within performance domains that are important to the client The client and therapist then create goals for therapeutic interventions. The COPM has been validated for use with stroke patients.[p]
	Mobility skill transfer
Community Balance and Mobility Scale[q];	The CB&M measures balance and mobility in participants and is less susceptible to ceiling effects than other commonly used balance scales. Item(s) will not be trained during CAMP and will be assessed as a universal transfer item.
	Functional independence
Functional Independence Measure (FIM)[r]	The FIM is a reliable[s] 18-item measure that asks a rater to assess the amount of assistance a patient requires to complete ADL using a 7-level scale. The FIM has two subscales, motor and cognition.
	Health-related quality of life
Stroke Impact Scale (SIS)[t]	The SIS is a 59-item questionnaire about the perceived impact of stroke on function and everyday life. Each item is scored on a 5-point Likert scale related to the degree of difficulty the person with stroke is experiencing. psychometric properties of the instrument are well-defined.[t-v]
SF-36[w]	The RAND 36-Item Short Form Health Survey (SF-36) will be administered and SF-12 scores will be derived from SF-36 data. The SF-12 has been validated for use with participants with stroke[x] and the summary scores are strongly correlated with SF-36 summary scores in stroke populations.[y]
	Participation
SIS participation domain	See SIS description above.
Community Participation Indicators (CPI)[z]	The CPI is a self-report measure of community participation. The two enfranchisement factors importance of participation and control over participation are rated on a 5-point scale and scored using a Rasch-based key form. There is good evidence of validity and reliability.[z]

Note. References for table 1 are found in the Appendices

Appendix D: References For Outcome Measures

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