



Feasibility and preliminary effects of an integrated hospital-to-home transitional care intervention for older adults with stroke and multimorbidity: A study protocol

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Abstract

Background: Stroke is a major life-altering event and the leading cause of death and disability in Canada. Most older adults who have suffered a stroke will return home and require ongoing rehabilitation in the community. Transitioning from hospital to home is reportedly very stressful and challenging, particularly if stroke survivors have multiple chronic conditions. New interventions are needed to improve the quality of transitions from hospital to home for this vulnerable population.

Objectives: The primary objective of this study is to examine the feasibility of implementing a new 6-month transitional care intervention supported by a web-based app. The secondary objective is to explore its preliminary effects.

Design: A single arm, pre/post, pragmatic feasibility study of 20–40 participants in Ontario, Canada. Participants will be community-dwelling older adults (≥ 55 years) with a confirmed stroke diagnosis, ≥ 2 co-morbid conditions, and referred to a hospital-based outpatient stroke rehabilitation centre. The 6-month transitional care intervention will be delivered by an interprofessional (IP) team and involve care coordination/system navigation, self-management education and support, home visits, telephone contacts, IP team meetings and a web-based app. Primary evaluation of the intervention will be based on feasibility outcomes (e.g. acceptability, fidelity). Preliminary intervention effects will be based on 6-month changes in health outcomes, patient experience, provider experience and cost.

Conclusions: Information on the feasibility and preliminary effects of this newly-developed intervention will be used to optimize the design and methods for a future pragmatic trial to test the effectiveness and implementation of the intervention in other contexts and settings.

Keywords

Older adults, integrated care, transitional care, stroke rehabilitation, mobile apps

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Introduction

Background and rationale

The provision of quality transitional care is important for all patients, as it helps to ensure that their care needs are met when they move between healthcare providers and across care settings.¹ Transitional care is described as a set of actions designed to ensure the continuity and coordination of healthcare when patients transfer across care settings and between providers.^{2,3} By necessity, transitional care involves several providers within and among disciplines and settings, all sharing the responsibility of care for one individual.⁴ Older adults (≥ 65 years) with stroke; 92% with at least two co-morbid conditions and 75% with three or more,⁵ tend to have high levels of ongoing care and frequently transition between providers and across care settings, such as hospitals, primary care, home care and specialists.^{3,6} Older adults and their caregivers are often the only common denominator across the care continuum and as a result, often assume major responsibility in the planning, coordination and management of information and care during transitions between providers and care settings.⁷⁻⁹

Stroke patients represent a vulnerable population who are susceptible to adverse events as a result of a poorly designed healthcare systems. Problems associated with hospital-to-home transitional care for older adults with stroke, particularly those with multimorbidity and functional difficulty, include (i) poor communication between patients and healthcare providers, (ii) inadequate follow-up care following discharge from hospital,⁶ (iii) problems with continuity of care between inpatient and community-based services,¹⁰ (iv) lack of knowledge about available community services and supports,⁷ (v) limited access to health and social services post-discharge, (vi) difficulties accessing services due to lack of transportation, (vii) limited finances, (viii) geographical locations and long wait times for appointments,¹⁰ (ix) lack of involvement in decisions regarding their care, and (x) a lack of confidence regarding their ability to self-manage in the community.^{6,7,11} Stroke survivors frequently report that they are unprepared to self-manage, forced to navigate a constantly shifting landscape of providers and sites, in receipt of conflicting advice regarding co-morbidity management, uninformed about what they can realistically expect in the future, experience difficulties accessing services, not consulted for input into their care¹² and unable to participate in life in ways that they find fulfilling.^{3,6} The resulting fragmentation in care leads to many under-detected and unmet needs for older adults with stroke and multimorbidity and their caregivers.

Problems associated with transitional care are linked to adverse outcomes, including increased rates of unnecessary hospital readmissions, increased healthcare costs, reduced quality of life, reduced patient satisfaction and safety (e.g.

medication errors, including dangerous drug interactions and duplications, poor medication adherence, falls), and increased burden on family caregivers.^{7,13} Readmission rates of up to 37% have been reported for this population for any cause (including stroke) within 1 year following stroke.^{14,15} The magnitude of this problem is expected to increase considerably with the predicted increase in the population of older adults, and the associated increase in stroke and multimorbidity. The proportion of individuals who survive a stroke has increased by 113% among older adults between 1990 and 2010,¹⁶ meaning that the number of people living with the longer-term effects of stroke is on the rise. The costs of healthcare associated with stroke are staggering. Stroke patients are one of the highest users of healthcare services.¹⁷ Canadians spend a total of 3 million days per year in hospital because of the physical disability associated with stroke. The cost to the Canadian economy is significant with CDN dollars 3.6 billion spent annually in hospital and physician services, lost wages and decreased productivity.¹⁸ New patient-centred models of care that complement standard stroke care are urgently needed to mitigate the risk of negative outcomes resulting from poor care transitions in this complex population.

Transitional care interventions have emerged as a potential solution to addressing fragmented care and preventing adverse outcomes in community-living older adults with complex care needs transitioning from hospital to home.^{1,11,19,20} Transitional care can be considered as part of integrated care, which occurs over a longer duration of care episodes.^{11,21} Integrated care aims to bring together 'services, providers, and organizations from across the continuum to work together jointly so that their services are complementary to one another, are coordinated with each other, and are a seamless unified system, with continuity for the client'.²² Integrated care has the potential to positively improve patient, provider and system outcomes by improving the quality of care and decreasing the cost of use of acute healthcare services.²³ Older adults with stroke and multimorbidity particularly benefit from integrated care because their needs are complex, continuously changing, and they typically require a range of health and social services over a long time frame.²⁴ The goal of transitional care is to facilitate and support seamless transitions across the continuum of care, and to achieve and maintain optimal adaptation, outcomes and quality of life for patients, families and caregivers following a stroke.³ Best practice guidelines in transitional stroke care include support, education and skills training for patients, families and caregivers; effective discharge planning; interprofessional (IP) communication; adaptations to resume activities of daily living; if needed, transition to long-term care.³ Although transitional care interventions have been linked to several positive outcomes, such as lower use of hospitalization and lower costs, the effectiveness of these interventions for older adults with stroke and multimorbidity are undetermined.²⁵

At the centre of any transitional care intervention, the patient's needs, goals, preferences and values should be considered. A person-centred approach should consider these elements of the older adult with stroke while at the same time integrating the caregiver as an essential partner in care whose needs and preferences also should be considered.²⁶ Recent stroke best practice recommendations suggest that effective transitional care interventions for older adults with stroke include an engaged patient and caregiver, with ongoing support by an IP team of providers with expertise in stroke care who use a chronic disease management or self-management approach and engage in integrated care planning and service delivery.^{2,3,6} More specifically, the core elements of successful transitional care interventions include (i) care coordination and system navigation^{3,7,27}; (ii) patient and caregiver education about self-management to strengthen health literacy² and develop knowledge and skills to independently manage their care; (iii) education about available community services and supports⁷; (iv) reconciliation of medications at key transition points; (v) preparation of patients for care transitions; (vi) development of a patient-centred, culturally appropriate and evidence-informed care plan for follow-up; (vii) formalized processes for communication among providers, patients and their caregivers about the plan of care within and across care settings (e.g. hospital and community-based services); (viii) ongoing assessment and follow-up using validated screening instruments; and (ix) ongoing support and access to rehabilitation services to optimize community reintegration.^{3,28–31}

Early supported discharge (ESD) interventions have received the most attention as a transitional care strategy designed to accelerate the transition from hospital to home through the provision of rehabilitation therapies delivered by an IP team in the community in the early discharge phase (<3 months) following stroke.³² Randomized controlled trials (RCTs) and meta-analyses have shown that ESD interventions are effective in reducing the length of hospital stay (on average by 8 days),^{33–35} increasing physical health and independence,^{36–40} reducing the risk of death or dependency by 6 patients per 100 treated,³⁴ decreasing caregiver strain,^{41,42} increasing the level of community reintegration³⁶ and improving patient satisfaction for selected mild-to-moderately disabled stroke survivors.^{34,43} Limited evidence from RCTs or meta-analyses exists, however on how to optimize transitions in care following stroke. Existing best practice guidelines for managing transitions in care following stroke in Canada are largely built upon emerging evidence in other forms – observational quantitative or qualitative studies, or a consensus of clinical expertise.³ This limited evidence base for interventions to manage transitions in care is based largely on studies that have (i) excluded older adults with comorbidities or do not report how many patients with comorbidities were excluded or sampled; (ii) focused solely on the management of stroke, not on other co-morbidities;

(iii) focused on functional outcomes with less attention to promoting self-management or addressing the broader determinants of health; (iv) provided limited information on implementation of the interventions; and/or (v) provided limited attention to other indicators of transitional care quality, such as cost, safety, equity and person- and family-centred care.^{6,11,44–46}

To whom, then, are the results generalizable? Meaningful research to identify optimal transitional care models requires a shift from a reductionist single-condition paradigm to a model that embraces complexity and considers the complex interaction of multimorbidity with stroke, the broader determinants of health (e.g. social, economic, environmental) and healthcare system factors. The sole focus of transitional care interventions on the management of stroke may be impractical or harmful, and lead to increase in healthcare costs and use that are already shown to be associated with multimorbidity.^{5,46,47} It is well established that chronic disease is not just about the disease but intersects with the broader social determinants of health (e.g. income, social connectedness). An estimated 75% of the factors that influence health and health outcomes lie outside the healthcare system.^{48,49} Older adults are increasingly expected to self-manage their care at home following discharge as well as navigate complex health and social care systems.^{11,50} Promotion of self-management support including problem-solving, decision-making and goal-setting has been shown to improve patient outcomes following stroke.⁵¹ Implementation of new models of transitional care must be evaluated to determine the factors that facilitate or impede the integration of the intervention into usual care practice.

Overall, the literature suggests that there is a need for further research to improve understanding and evidence for how to best provide quality transitional care for older adults with stroke and multimorbidity transitioning from hospital to home. We designed a new hospital-to-home transitional care intervention to provide an interdisciplinary and integrated strategy for older adults with stroke and multimorbidity. This intervention was designed to improve Quadruple Aim outcomes⁵² (health outcomes, patient experience, provider experience, cost) by addressing gaps in transitional care for this complex and underserved population.

Objectives

The *primary objective* of the study is to examine the *feasibility* of implementing the transitional care intervention. The *secondary objectives* are to (i) explore the preliminary effects of the intervention based on changes over 6 months in health outcomes, patient experience, provider experience and costs of use of health and social services; (ii) evaluate the feasibility of the study methods; and (iii) determine the most appropriate primary outcome measure for a future

RCT to test the effectiveness of the intervention in other contexts and settings.

Methods

This study protocol follows the reporting standards developed by the SPIRIT (Standardized Protocol Items: Recommendations for Interventional Trials) statement⁵³ and the CONSORT extension for feasibility studies.⁵⁴

Study design

The study will be a single arm, pre-test/post-test pragmatic feasibility study to examine feasibility and preliminary effects. Preliminary intervention effects will be examined at 6 months, which is supported by our previous research.⁴⁴ The study will combine a quantitative evaluation of the preliminary effects of the intervention with a qualitative and quantitative evaluation of feasibility. Overall, the study design will provide in-depth feedback on feasibility while at the same time provide sufficient information to study preliminary effects.

Study setting

This is a collaborative project between the Aging, Community and Health Research Unit (ACHRU) at McMaster University (Hamilton, Ontario, Canada) and an outpatient stroke rehabilitation centre within a large urban community hospital in south central Ontario. The centre is in a large city (Hamilton population: 536,917) where older adults (≥ 65 years) represent 17.3% of the total population.⁵⁵ The goal of the ACHRU is to promote optimal aging at home for older adults with multimorbidity and to support their family/friend caregivers. To achieve this end, the ACHRU research program co-designs, implements and evaluates innovative community-based interventions, and assesses the potential for scale-up of these interventions to improve Quadruple Aim outcomes.^{56,57}

Eligibility criteria

We will use a convenience sample of consecutive patients who have been referred to the outpatient stroke rehabilitation centre and reside in the catchment area. Study participants will be included if they meet the following inclusion criteria: (i) are an older adult (≥ 55 years), (ii) have a confirmed diagnosis of stroke (first ever or recurrent) within the past 12 months at the time of enrolment, (iii) have ≥ 2 co-morbid conditions, (iv) were referred to outpatient stroke rehabilitation services, (v) are community-dwelling (not in long-term care), (vi) are mentally competent to give informed consent (or via a substitute decision maker), (vii) are not planning to move away from the community within 6 months of study enrolment, and (viii) are competent in English (or with an interpreter available).

Providers will be eligible for study inclusion if they are (i) a registered health professional who is a member of the intervention team made up of an occupational therapist (OT), physiotherapist (PT), registered nurse (RN), social worker (SW), or speech language pathologist (SLP); and (ii) a health professional at the hospital-based outpatient stroke rehabilitation centre at the study location. The managers on the intervention team will also be eligible.

Intervention

This feasibility study is pragmatic, which means that the intervention will be implemented under real-world conditions, including reliance on existing staff at the participating site to deliver the intervention. The intervention was designed to complement usual stroke care provided by the outpatient stroke rehabilitation centre. The usual stroke care practices include (i) routine outpatient clinic visits with an OT, PT and/or SLP; (ii) a focus by these providers on functional goals for recovery; and (iii) provision of information and referral to community agencies over an average of 3 months. Providers delivering the intervention will also be responsible for usual care for patients not enrolled in the feasibility study. Therefore, there will be no restrictions placed on the providers regarding their normal provision of stroke care.

The intervention protocol was developed by triangulating several resources. The intervention protocol was developed using (i) guidelines for developing complex interventions⁵⁸; (ii) results from a previous pilot study⁴⁴; (iii) best practices for stroke rehabilitation³; (iv) best practices for the management of multimorbidity⁵⁹; (v) best practice and empirical evidence related to stroke and transitional care^{3,7,9} and integrated care for older adults,^{2,3,7,28-31}; and (vi) qualitative interviews with healthcare providers, older adults and their family caregivers. It was designed to address identified gaps in hospital-to-home transitional care for this population as described earlier. Our previous RCT that examined the effectiveness of an IP team approach to stroke rehabilitation in home care served as a strong base for the design of the intervention.⁴⁴ In the pilot, 77% of the 101 participants who were older adults with stroke referred to home care services, had at least one hospital admission in the 6 months prior to baseline. Additionally, the three main intervention components (regular home visits and telephone contacts, care coordination/system navigation, IP case conferences) in this RCT are consistent with those featured in systematic reviews of effective care transition interventions, particularly for complex populations.^{3,11,60} Recent systematic reviews suggest that 6 months is a typical duration for a care transition intervention, and effects may be more responsive to intensity rather than duration, given that high-intensity care transition interventions were found to be effective regardless of duration.⁶⁰

This 6-month transitional care intervention is complex and consists of four main intervention components, described below, including (i) home visits or telephone calls by an IP team from the hospital-based outpatient rehabilitation centre, (ii) monthly case conferences where the providers discuss individual patients (iii) care coordination/system navigation by the OT, and (iv) our web-based app ‘My Stroke Team (MyST)’.

Home visits and telephone contacts. A key component of the intervention is holistic, person-centred care, facilitated by proactively providing home visits to more fully understand the participant’s context. Home visits are not normally included in usual services at the majority of outpatient stroke rehabilitation centres in Ontario. Each participant will be offered a maximum of 6 monthly in-home visits supported by telephone follow-up calls by a member of the IP team (i.e. OT, RN, PT, SLP or SW). The maximum number of visits were based on the literature on care transition interventions.^{44,60} The IP team’s main activities during the home visits will include (i) comprehensive health assessment using standardized screening tools as outlined in Table 1, (ii) medication review and reconciliation, (iii) self-management education and support using strengths-based practice,^{70–72} (iv) integrating best practices into care plans to prevent and manage stroke and multimorbidity, (v) facilitating timely primary care and specialist follow-up, (vi) identifying and linking participants to relevant community services, and (vii) providing caregiver support. Participants will be able to decline any number of home visits, and all participants will continue to have access to the services normally offered by the outpatient stroke rehabilitation centre. Strengths-based practice will be used because of its positive impact on self-efficacy, self-management and consequently quality of life.⁴⁴ The intervention is also grounded in Bandura’s Social Cognitive Theory,⁷³ which recognizes the central role of self-efficacy in changing self-management behaviour. For example, key sources of self-efficacy (e.g. social modelling, mastery) will be the focus of the home visits and telephone calls. The intervention will address the full range of stroke self-management activities within the context of multimorbidity but will be inherently flexible so that it can be shaped by participants and tailored to their needs. Self-management support in the context of stroke involves empowering individuals with the skills to (1) manage medical tasks, for example, secondary stroke prevention; (2) maintain or change behaviours or life roles, for example, perform activities of daily living; and (3) deal with the emotional consequences of stroke, for example, anxiety and post-stroke depression.⁵¹ Figure 1 displays the main activities that will be carried out during and between the home visits or telephone calls with participants.

Monthly IP case conferences. The intervention emphasizes communication and collaboration among the IP team and with providers across care settings. The IP team will meet monthly for a case conference to identify patient-identified goals and develop a person-centred and evidence-based plan of care for each participant. Case conferences are not normally included in usual outpatient rehabilitation services at the study centre. Case conferences will provide an opportunity to share observations about participants’ strengths and challenges, identify patient-centred goals related to stroke rehabilitation and identify needs for other health professionals or community services.

Care coordination/system navigation. Care coordination is not normally included in usual outpatient stroke rehabilitation services.^{3,10} The OT will function as a care coordinator and system navigator and provide leadership to the IP team in devising a comprehensive care plan for the older adult participants. The OT will assist with system navigation, linking/referring patients to home and community-based health and social services and supports, and facilitating communication among the patient, family and team to ensure a holistic approach to care including consideration of the social determinants of health. The OT Care Coordinator will facilitate clinic–community connections by building working relationships with key health and social service providers and agencies. Related to this, the OT will follow-up after referrals have been made to ensure that participants can access services and advocate for them. This includes problem-solving to address any barriers to accessing health and social services, such as lack of transportation or low income.

Web-based app. IP team communication and coordination will also be supported by our web-based app, ‘My Stroke Team (MyST)’. MyST was developed using a user-centred design approach with substantial end-user and stakeholder involvement, and usability testing involving the ‘think-aloud’ method.⁷⁴ End users primarily involved providers. MyST includes a patient profile and space that can be viewed by the IP team and patient/caregiver. However, only providers will be able to add content or communicate through MyST in the outpatient setting as well as during the home visit. MyST is an add-on technological tool that does not replace providers’ usual practice, and will provide a secure space for (i) detailed personal information of the patient; (ii) documenting and sharing: information about the home visits, case conference records, standardized screening tool scores, client goals and follow-up items; (iii) posting ‘alerts’ for individuals or the team; and (iv) accessing resource links (e.g. stroke best practice guidelines, stroke educational materials, community resources). There is emerging evidence to suggest that e-health applications supporting an IP transitional care intervention could help create more integrated and effective systems of care for older adults.⁷⁵

Table 1. Fidelity scale.

Intervention components	Data source
Staffing and supervision	
IP team members (OT, PT, RN, SLP, SW) received standardized training	Attendance record
IP team members meet with investigators monthly	Attendance record Meeting minutes
Delivery of key components of intervention	
Monthly in-home visits by at least one member of the IP team for 6 months	MyST home visit record Home visit tracking record kept by Care Coordinator
Monthly IP case conferences over the study intervention period	MyST team meeting record
Activities during and between the home visits and telephone calls	
Use of standardized screening tools:	Standardized assessment forms in MyST
<ul style="list-style-type: none"> • Level of function monitored using the Stroke Safety Checklist⁶¹ • Depressive symptoms monitored using the Patient Health Questionnaire-2 item screener⁶² • Depressive symptoms monitored using the Centre for Epidemiological Studies in Depression Scale⁶³ • Cognitive status monitored using the Montreal Cognitive Assessment⁶⁴ • Presence of delirium monitored using the Confusion Assessment Method⁶⁵ • Fall risk monitored using the 2-question fall screener⁶⁶ • Fall risk monitored using the Performance-Oriented Mobility Assessment Tool⁶⁷ • Level of community reintegration monitored using the Reintegration to Normal Living Index⁶⁸ • Caregiver stress monitored using the Modified Caregiver Strain Index⁶⁹ 	
Medication review and reconciliation	
Self-management education and support using strengths-based practice	
Caregiver engagement and support	
Use of evidence-based guidelines to prevent and manage stroke and other co-morbidities	Number of links to evidence-based guidelines in MyST
Identification of patient-centred goals	Number of goals created and completed in MyST record
Single, patient-centred IP care plan	Individual goals assigned to IP team members in MyST
Referral to health and social service organizations	Number of links to community-based services in MyST Monthly research meeting minutes Focus group data

IP: interprofessional; OT: occupational therapist; PT: physiotherapist; RN: registered nurse; SW: social worker; SLP: speech language pathologist; MyST: My Stroke Team.

The feasibility of implementing the intervention will also involve assessing both the utilization and usability of MyST. Utilization of MyST will be evaluated based on data from the audit warehouse within MyST. Utilization, in contrast to usability, is the extent to which something is used regardless of the ease or complexity of using it. These data will allow for early and ongoing monitoring of use to understand how MyST is being used and monitor its uptake and acceptability over time. Usability of MyST will be evaluated based on data from focus groups with providers and interviews with managers.

Fidelity and adherence strategies. The delivery of the intervention will be supported by a well-developed infrastructure that will enable the clinic to make needed system improvements and deliver high-quality patient-centred

care. Key elements of the infrastructure are consistent with key features of integrated care for older adults and high-performing primary care practices.^{21,76} These include (i) engaged leadership that understands and visibly supports changes in practice, (ii) use of a person-centred approach to care, (iii) use of team-based care, (iv) expanded responsibilities of staff, (v) training and support for providers implementing the intervention, (vi) the addition of an RN and a SW to the usual outpatient rehabilitation team of providers (OT, PT and SLP), (vii) change in workflows and systems, and (viii) use of MyST to support communication and coordination of care among the IP team.

The intervention will be implemented using a multi-pronged approach. First, the investigators will hold a 1½-day training workshop with the IP team (RN, OT, PT, SLP,

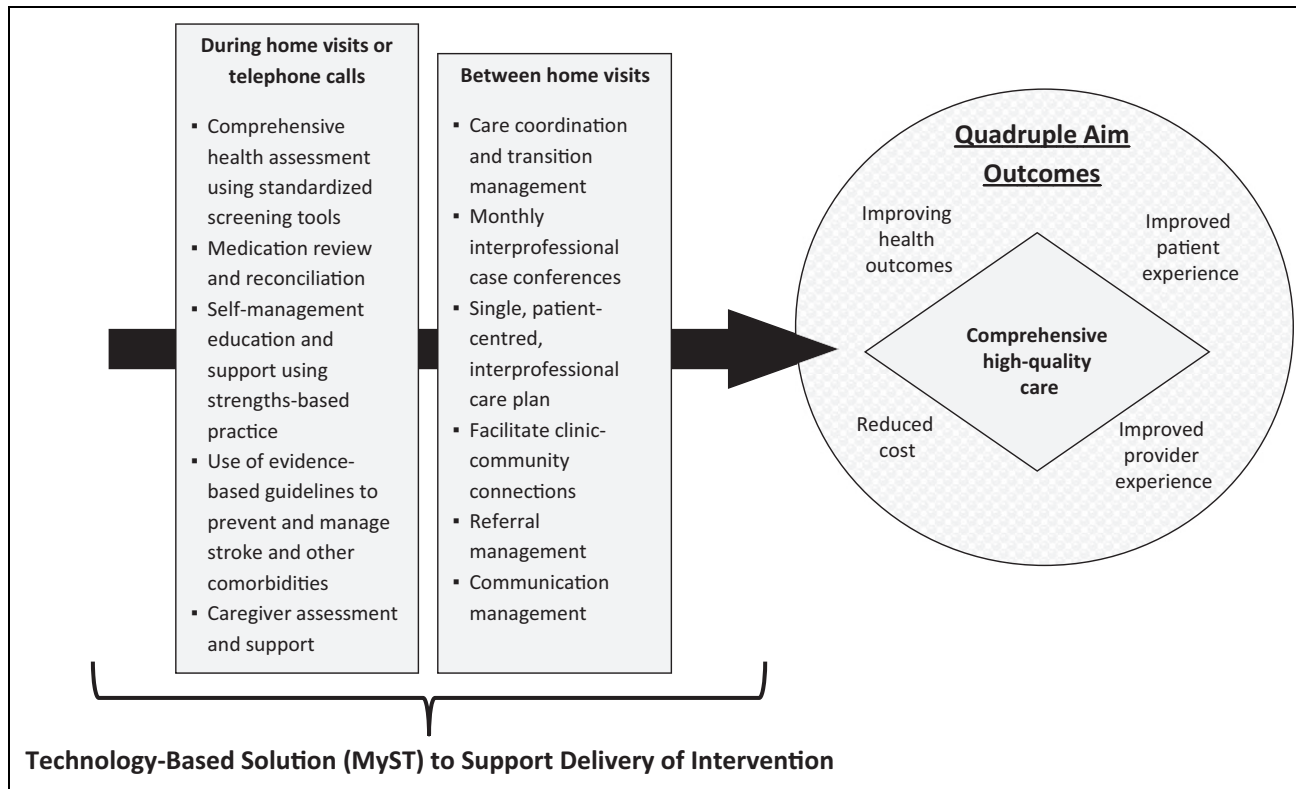


Figure 1. Integrated transitional care intervention.

SW) to convey key intervention activities, research study procedures, technology use and underlying theories (Figure 2). To support intervention fidelity, a standardized manual was developed that includes key content pertaining to all aspects of the intervention. Training will be adapted to the needs of the providers including hands-on training on the use of the MyST app. Monthly outreach meetings will be conducted to enable the investigators and/or the research coordinator (RC) to meet with the IP team to monitor intervention implementation and discuss any challenges.

Timing of the intervention. The timing of the intervention is shown in Figure 2. The intervention will take place over a 6-month period. The frequency and timing of the home visits and phone calls will be flexible and will be based on individual participant needs and preferences. Therefore, patients could have up to six home visits which may include phone calls but only up to a maximum of six for any combination of them (i.e. total number of home visits [max: six]: number of home visits plus number of phone calls). Fixed intervention components are the monthly IP team case conferences among providers and the care coordination/system navigation. The flexible and fixed nature of intervention components as depicted in Figure 2 are aligned with the pragmatic nature of the feasibility study. MyST, the web-based app, is a fixed component that will support coordination, IP team, communication and information sharing among the IP team.

Participant recruitment

A trained recruiter employed by the outpatient stroke rehabilitation centre will identify potential participants who meet the inclusion criteria as determined from review of the existing medical records. The recruiter will telephone potentially eligible participants to obtain their verbal consent to be contacted by a research assistant (RA) to conduct an in-home interview. During the in-home interview, the RA will obtain written informed consent from the patient and complete the time 1 (baseline) questionnaire. To validate the informed consent of potential participants prior to finalizing enrolment and for continuing participation in the study, participants will be required to complete the Short Portable Mental Status Questionnaire (SPMSQ).⁷⁸ Patients will need to score >5 on the SPMSQ to validate their informed consent or else will be required to have a substitute decision maker to provide consent and complete the baseline (and follow-up) questionnaires on their behalf.

Outcome measures

Table 2 provides a summary of the outcomes, variables, measures and methods of analyses organized by the Quadruple Aim outcomes.

Feasibility outcomes

Feasibility of the intervention. Assessment of feasibility includes perceptions of the appropriateness and

Key Activities	Elements
Training for Interventionists	A
Training for Research Assistants	B
Participant Recruitment	C
Baseline Data Collection (T1)	D
Intervention begins	E
<i>1 month</i>	HV PC IP CC MYST
<i>2 months</i>	HV PC IP CC MYST
<i>3 months</i>	HV PC IP CC MYST
<i>4 months</i>	HV PC IP CC MYST
Feasibility Data Collection	F
<i>5 months</i>	HV PC IP CC MYST
<i>6 months</i>	HV PC IP CC MYST
Intervention ends	G
Six Month Data Collection (T2)	H
Feasibility Data Collection	I J K

- A Completion of a training program for interprofessional (IP) team of interventionists: Registered Nurse (RN), Occupational Therapist (OT), Physiotherapist (PT), Speech Language Pathologist (SLP), and Social Worker (SW).
- B Completion of training program for Research Assistants.
- C Recruitment of potential study participants at study site by trained recruiters.
- D Completion of informed consent by patient and completion of baseline (T1) pre-test questionnaires via in-person interview at the patient's home by the Research Assistant.
- E The IP team of interventionists deliver the intervention: monthly in-home visits, monthly IP case conferences, use of MyST app, care coordination/system navigation.
- HV Home visits will be offered (up to 6). Main activities include: 1) comprehensive health assessment using standardized screening tools, 2) medication review & reconciliation, 3) self-management education and support using strengths-based practice, 4) integrating best practices into care plans to prevent and manage stroke and multimorbidity, 5) facilitating timely primary care and specialist follow-up, 6) identifying and linking participants to relevant community services, 7) identifying and linking to community services, 8) providing caregiver support.
- PC Structured telephone follow-up calls by an IP team member; in addition to home visits or in place of a home visit.
- IP Monthly interprofessional case conferences, effective communication and collaboration among the interprofessional team, goal setting, development of a patient-centred and evidence-based care plan for each patient.
- CC Care coordination/system navigation led by the OT. Main activities include: team leadership, development of comprehensive care plan, linking/referring patients to home and community services, promoting effective communication across patients, family members, and IP team, and address system barriers.
- MYST Provide timely communication among the IP team, promote coordination of care, use of best practices and person-centred care.
- F Feasibility assessment of the intervention and MyST at 3 and 9 months following the initiation of the intervention via focus groups and review of research team meeting minutes for interventionists and managers. Assessment of collaboration and MyST usability among interventionists via self-administered questionnaires.
- G Following completion of the 6-month intervention, all required documentation sent to the researchers by the interventionists.
- H Completion of 6-month (T2) post-test questionnaires via in-person interview at the patient's home by the Research Assistant.
- I Data on utilization of MyST obtained from host site.
- J Feasibility assessment of study methods (e.g. retention rate), intervention implementation (e.g. barriers, facilitators) and MyST (e.g. ease of use) via log records and focus groups and review of outreach meeting minutes with interventionists and managers. Assessment of collaboration and usability of MyST among interventionists via self-administered questionnaires.
- K Assessment of patient experience with the intervention (e.g. perceived benefits) via semi-structured interviews with selected study participants.

Figure 2. Timeline. Squares represent fixed elements. Circles represent activities that are flexible. Measurement times are bolded. (Adapted from Perera et al.⁷⁷)

Table 2. Summary of outcomes, variables, measures and method of analysis.

Outcome	Variable	Assessment tool/data source	Measure/scoring	Timing of data collection	Methods of analysis
Trial design					
Feasibility of study methods	Eligibility rate	Research activity log	% patients screened who were eligible	T1	Calculated as the number of patients screened/number of patients eligible × 100%
	Recruitment rate	Research activity log	% eligible patients enrolled in the study	T1	Calculated as the number of enrolled patients/number of eligible patients × 100%
	Retention rate	Research activity log	% patients who complete the 6-month intervention	T2	Calculated as the number of patients who complete the 6-month intervention/number of patients enrolled in the 6-month intervention × 100%
	Adequacy of data and data collection	Feedback from assessors: – Interview length – Clarity and acceptability of interview questions – Applicability of interview questions – Ease of data collection – Data quality missing or inconsistent responses	Themes identified relating to issues of data collection or analysis	T1, T2	Themes identified relating to issues of data collection or analysis
Feasibility of the intervention – Core components	Fidelity to the intervention	– Visit record – Monthly team meeting record – Fidelity checklist	– Number of home visits by each member of the IP team – Number of times each patient is discussed at a case conference – Number of case conference meeting notes	T2	Means, medians, SDs, range; per cent and frequencies for categories
	Engagement rate	Intervention record	% patients engaged in the intervention, mean engagement rate	T2	Calculated as the number of patients who had one or more home visits or phone calls over 6 months/total number of patients × 100% Mean engagement rate calculated as the total number of home visits or phone calls over 6 months/total number of patients.

(continued)

Table 2. (continued)

Outcome	Variable	Assessment tool/data source	Measure/scoring	Timing of data collection	Methods of analysis
Feasibility of the intervention – Providers' and managers' perceptions/experience with the intervention	Feedback on: – Appropriateness – Benefits – Convenience of implementing – Perceived impact – Barriers/facilitators – Implementation processes	– Feedback from focus groups with providers and interviews with managers – Review of meeting minutes from outreach meetings with the researchers, providers and managers	– Themes identified relating to providers' and managers' perceptions/experience with the intervention – Normative Process Theory ^a : • Coherence • Cognitive participations • Collection action • Reflexive monitoring	3 and 9 months following initiation of the intervention	– Content analysis for themes identified relating to providers' and managers' perceptions/experience with the intervention – Content analysis for themes that support: • Coherence • Cognitive participations • Collection action • Reflexive monitoring
Feasibility of the intervention – MyST	Utilization/use	MyST audit log	– Number of team meeting records completed per patient – Number of hits on links to best practices, community health and social services resources and patient education materials – Number of medication reviews per patient – Number of home visit checklists completed per patient – Number of survey tools completed per patient – Number of goals created, achieved, not completed categorized by dimension of community reintegration – Number of safety checklists completed per patient	Monthly for the duration of the intervention period	Means, medians, SDs, range
	Usability/ease of use	– Feedback from focus groups with providers and managers – SUS, based on responses to a self-administered survey to providers	– Themes identified relating to providers' and managers' perceptions/experience with MyST – SUS total score (0–100); scores >70 are considered satisfactory in terms of usability	3 and 9 months following initiation of the intervention	– Content analysis for themes identified relating to providers' and managers' perceptions/experience with MyST – Proportion of providers and managers scoring MyST below a SUS of 70

(continued)

Table 2. (continued)

Outcome	Variable (based on Quadruple Aim)	Assessment tool/data source	Measure/scoring	Timing of data collection	Methods of analysis
Provider experience among collaborators	Change in collaborative practice	CPAT	Average score for eight domains	3 and 9 months following initiation of the intervention.	Means, medians, SDs, range for each domain
Feasibility of the Intervention – Providers' and Managers' perceptions/experience with the intervention	Feedback on: – Appropriateness – Benefits – Convenience of implementing – Perceived impact – Barriers/facilitators – Implementation processes	– Feedback from focus groups and monthly outreach meetings with providers and managers	– Themes identified relating to providers' and managers' perceptions/experience with the intervention – Normative Process Theory: • Coherence • Cognitive participations • Collection action • Reflexive monitoring	3 and 9 months following initiation of the intervention.	– Content analysis for themes identified relating to providers' and managers' perceptions/experience with the intervention – Content analysis for themes that support: • Coherence • Cognitive participations • Collection action • Reflexive monitoring
Feasibility of the intervention – MyST	Usability/ease of use	– SUS, based on responses to a self-administered survey to providers	– SUS total score (0–100); scores >70 are considered satisfactory in terms of usability	T1, T2	–Proportion of providers and managers scoring MyST below a SUS of 70
Patient experience (based on Quadruple Aim)					
Feasibility of the Intervention – Patients' perception/experience with the intervention	Feedback on: – Perceived benefits – Suggested changes – Likes/dislikes – Barriers/facilitators	Patient responses from semi-structured interviews	Themes identified relating to patients' perception/experience with the intervention	Following T2 interview and completion of 6-month intervention	Content analysis for themes identified relating to patients' perception/experience with the intervention
Patient health outcomes (based on Quadruple Aim)					
Cognition	Cognitive status	SPMSQ	≥ 5 suggests patient has normal cognitive function	T1, T2	Calculated as a binary score (<5 vs. ≥5) for an individual patient
Demographic and stroke-related characteristics	Age, gender, education, household income, marital status, ethnicity, accommodation, living arrangement, employment, informal support, technology use and comfort, co-morbid health conditions, stroke	Sociodemographic Questionnaire	– Age – Gender – Education – Household income – Marital status – Ethnicity – Accommodation – Living arrangement	T1	Means, medians, SDs, range for continuous measures; percent and frequencies for categories

(continued)

Table 2. (continued)

Outcome	Variable	Assessment tool/data source	Measure/scoring	Timing of data collection	Methods of analysis
	Variable history, falls history, medications use		<ul style="list-style-type: none"> - Employment - Informal support - Technology use and comfort - Number and type of co-morbid conditions - Number of strokes - Time since last stroke - Recent fall (<12 months) - Number of prescription medications 		
HRQoL	<ul style="list-style-type: none"> - Change in mental health - Change in physical health 	SF-12 Health Survey – version 2	<ul style="list-style-type: none"> - Mental health component summary score (MCS-12), range: 0–100, higher scores indicate better mental health - Physical health component summary score (PCS-12), range: 0–100, higher scores indicate better physical health - Quality Metric Scoring Software 3.0™ 	T1, T2	Means, medians, SDs, range for T1 and T2; change in MCS-12 and PCS-12 based on mean difference (T1 – T2), with 95% CI; paired t-test
Depressive symptoms	<ul style="list-style-type: none"> - Change in depressive symptoms - Severity of depressive symptoms 	Centre for Epidemiological Studies Depression Scale – Shortened Version (CES-D-10)	<ul style="list-style-type: none"> - Total scale score, range: 0–30; higher scores indicate higher level of depressive symptoms - Score of ≥ 10 indicates the presence of depressive symptoms 	T1, T2	<ul style="list-style-type: none"> - Means, medians, SDs, range for T1 and T2; change in depressive symptoms based on mean difference (T1 – T2), with 95% CI; paired t-test - Presence of depressive symptoms calculated as a binary score (≥ 10 vs. <10)
Anxiety	<ul style="list-style-type: none"> - Change in anxiety symptoms - Severity of anxiety 	Generalized Anxiety Disorder Screener Scale (GAD-7)	<ul style="list-style-type: none"> - Total scale score, range: 0–21; higher scores indicate a higher level of anxiety symptoms - Anxiety severity: severe (≥ 15), moderate (10–14), mild (5–9), minimal (0–4) 	T1, T2	<ul style="list-style-type: none"> - Means, medians, SDs, range for T1 and T2; change in anxiety symptoms based on mean difference (T1 – T2), with 95% CI; paired t-test - Anxiety severity: severe (≥ 15), moderate (10–14), mild (5–9), minimal (0–4)

(continued)

Table 2. (continued)

Outcome	Variable	Assessment tool/data source	Measure/scoring	Timing of data collection	Methods of analysis
Self-efficacy	– Change in self-efficacy	Self-Efficacy for Managing Chronic Disease six-item Scale (SE-MCD)	– Total scale score for responses to each of the six items, range: 6–60; higher scores indicate higher self-efficacy	T1, T2	Means, medians, SDs, range for T1 and T2; change in self-efficacy based on mean difference (T1 – T2), with 95% CI; paired t-test
Collaboration with patients and their IP team	Perceived shared decision-making	CollaboRATE tool	– Total score for responses to each of the three CollaboRATE questions, range: 0–9; higher score means higher level of perceived shared decision-making by the patient	T1, T2	For each question: means, medians, SDs, range for T1 and T2; change in perceived level of shared decision-making based on mean difference (T1 – T2), with 95% CI; paired t-test
Costs (based on Quadruple Aim)					
Costs of use of health and social services, from a societal perspective	Change in costs of use of health and social services: – Family physicians – Physician specialists – Home care (not CCAC) – Outpatient services – Ambulance and 911 calls – Emergency department visits – Hospital visits – Medication use – Equipment use	HSSUI	Total cost of health services use, reported as a Canadian dollar amount, and total costs for each service	T1, T2	Means, medians, SDs, range for T1 and T2; change in costs for use of health and social services based on mean difference (T1 – T2), with 95% CI; paired t-test

CCAC: Community Care Access Centre; T1: baseline; T2: 6 months after baseline measures; SD: standard deviation; IP: inter-professional; MyST: My Stroke Team; SUS: System Usability Scale; CPAT: Collaborative Practice Assessment Tool; SPMQ: Short Portable Mental Status Questionnaire; HRQoL: health-related quality of life; CI: confidence interval; HSSUI: Health and Social Services Utilization Inventory.

^aExample questions based on Normative Process Theory include the following: ‘What did you understand were your tasks and/or responsibilities in relation to the intervention?’ ‘What did you understand were your tasks and/or responsibilities in relation to using MyST?’; ‘How have you reorganized your routine and/or that of others on the team to contribute to and be involved in using MyST?’; and ‘What kinds of resources have been allocated to support you to deliver the intervention?’ and ‘How have you reorganized your routine and/or that of others on the team to contribute to and be involved in using MyST?’; and ‘What kinds of resources have been allocated to support you to deliver the intervention?’ and ‘How have you reorganized your routine and/or that of others on the team to contribute to and be involved in using MyST?’; and ‘Were these resources sufficient?’

acceptability, as well as the benefits and convenience of implementing the intervention.⁷⁹ Implementation refers to how the intervention is delivered. Feasibility of implementing the intervention will be evaluated based on data from the monthly outreach meetings, focus groups with the providers and semi-structured interviews with the managers at the study site. The 1½ hour focus group session with providers, and interviews with managers will occur at 3–4 months following the initiation of the intervention (Figure 2) and will be conducted at the intervention site in a private room at a mutually agreed upon time. Demographic characteristics of the providers and managers will be assessed using standard questions at the start of each focus group session or interview. Participants will be asked about their discipline, years in practice, years working with stroke patients, and length of time working with the intervention. Focus groups will be audio-taped and transcribed verbatim for analysis. Guiding questions will provide information on the perceived impact and barriers and facilitators to implementing the intervention. The principal investigators and RC, who have experience in qualitative research, will conduct the focus groups with the providers and interviews with the managers. Meeting notes of the monthly outreach meetings will also be maintained for qualitative analysis to explore implementation processes, challenges and enablers. In addition to evaluation of providers and managers, the patient participants in the study will be asked a series of questions to obtain feedback on the acceptability of the intervention, which helps to inform the overall feasibility of the intervention.

Questions asked during the focus group sessions and the interviews will be guided by Normalization Process Theory (NPT). NPT helps us to understand how new interventions and ways of working become integrated into practice as a result of individual and collective agency.^{80,81} This theory has been applied in the study of several implementation processes both within and outside of healthcare. Consistent with normalization theory, we will assess how implementation of the intervention is perceived by the providers and their managers in terms of coherence, cognitive participation, collective action and reflexive monitoring. In addition, open-ended questions will be asked about the intervention regarding its perceived benefits, how it should be changed and what providers liked and did not like. This will include questions to assess the usability of MyST in supporting the intervention.

The usability of MyST will also be measured using the 10-item System Usability Scale (SUS). The SUS is a survey for assessing the efficiency and satisfaction of a wide variety of user interfaces, including mobile technology.⁸² The SUS score ranges from 0 to 100, with scores below 70 indicating usability issues that are a cause for concern. The SUS has been shown to be reliable, with Cronbach's α coefficient ranging from 0.85 to 0.91.⁸² All 10 response items were found to correlate highly with one another (0.35–0.69, $\alpha = 0.1$ or better) and factor analysis confirmed the one-factor model.⁸²

The level of fidelity to treatment or the extent to which the providers adhere to the components of the intervention, will be measured using an intervention fidelity scale (Table 1). The fidelity scale is a checklist that uses a simple, present/absent response format. Previous research suggests this format is easier to use and more reliable than complex frequency scales.⁸³ One researcher will review source documents (e.g. visit and case conference records, training manuals) to assess the feasibility of collecting the data on the checklist.

A subset of 8–10 older adult patient participants will provide post-intervention feedback upon completion of the 6-month intervention. Efforts will be made to obtain a diverse sample by age, gender, number of home visits received, socioeconomic status, access to caregiver support and Internet accessibility. These 30-min interviews will be conducted by the RC and will provide information on participants' experience with the intervention including its perceived benefits, how it should be changed and what they liked and did not like. Interviews will be audio-taped and transcribed verbatim.

Feasibility of the study methods. Feasibility of the study methods will focus on determining the optimal design features for a potential future trial, including the number of participants that we can recruit over 6 months to inform the number of study sites needed for a future trial and the time needed to efficiently recruit the sample. Eligibility will be defined as the number of patients eligible to participate among the number of patients screened. Our target is $\geq 50\%$, based on the assumptions that 92% of older adults with stroke would have two or more other chronic conditions (rate observed in study of Ontario older adults with stroke),⁵ and 60% of these would be deemed eligible and agree to the study. Recruitment will be defined as the number of eligible patients that enrol in the study among those who are eligible. We set a target of $\geq 50\%$ for this outcome based on our previous trial.⁴² Retention will be defined as the number of enrolled patients who complete the 6-month intervention among those who are enrolled at baseline. We set a target of $\geq 80\%$ for the retention rate, based on the common view that bias is a concern if attrition exceeds 20%.⁸⁴ Representativeness will be defined as the absence of significant differences between completers and non-completers on a range of characteristics collected at baseline. The representativeness of our study population to the broader population of older adults with stroke referred to the outpatient rehabilitation centre will also be examined on key demographic characteristics (e.g. age, sex). The feasibility of the methods will also be assessed based on the percentage of completers who received at least one home visit ('engagement rate'). Feasibility of data collection questionnaires will be determined by feedback from RAs. The RAs will provide feedback on questionnaire length, perceived clarity and acceptability of questions, applicability of questions to participants and ease of collecting data. Researchers will review the data collected,

explore reasons for missing or inconsistent responses, and review the results from the provider focus groups, manager and patient interviews, and questionnaires for indications of significant issues relating to data collection or analysis.

Primary outcome for a future RCT. The candidate measures for the primary outcome for a future RCT are health-related quality of life (HRQoL), specifically the mental health component summary (MCS) score and the physical component summary (PCS) score from the SF-12. The criteria that will be used to evaluate potential primary outcome measures for a future RCT will include (i) accuracy or lack of ambiguity; (ii) indication that MCS and/or PCS provides preliminary evidence for the preliminary effects of the intervention in this feasibility study; (iii) the face validity and relevance of outcome measures based on feedback from providers, managers and patients; and (iv) ease of data collection based on feedback from the RAs.

Clinical effectiveness outcomes. The preliminary effects of the intervention will be evaluated based on the 6-month change in participants' health outcomes and use of health and social services. RAs, blinded to the purpose of the study, will assess patients' health at baseline and again at 6 months using a structured in-home interview lasting about 2 h. The RAs will be trained in consent and data collection procedures. They will be experienced health professionals who will undergo intensive training to ensure standardization in data collection for all quantitative data collection time points. Prior to initiation of the study, pilot testing of the questionnaires will be conducted. Disagreements in the way questions will be asked or data collection procedures will be discussed among the research team until consensus is achieved, and procedures and training materials will be revised accordingly to clarify discrepancies.

In addition to the health outcomes described in detail below, the patient questionnaire will include patients' self-report on sociodemographic characteristics and chronic conditions across 14 groups including cardiovascular, respiratory, mental/mood disorders, gastrointestinal, endocrine, liver, kidney and urogenital disorders, hearing and vision, neurological, musculoskeletal, pain, substance abuse, infection, and other, and specific subgroup conditions.

Six-month changes in health outcomes

- **HRQoL – mental and physical health**
HRQoL will be measured using the SF-12.⁸⁵ The PCS score (PCS-12) and mental component summary score (MCS-12) will be used to summarize the data. The SF-12, PCS-12 and MCS-12 are well-validated ($R^2 > 0.90$).⁸⁵ PCS-12 and MCS-12 scores range from 0 to 100 and higher scores indicate higher levels of HRQoL.⁸⁶

- **Depressive symptoms**

Prevalence and severity of depressive symptoms will be measured using the Centre for Epidemiological Studies

Depression Scale (CES-D-10).⁶³ The CES-D-10 has been validated in the older adult population and is often used instead of the original 20-item version of the scale when there are restrictions on survey length.⁸⁷ All questions include four response categories (0–3) and scoring produces a continuous score ranging from 0–30, where higher scores indicate higher level of depressive symptoms. Severity will be measured by the mean scale score for each group. Prevalence will be measured using a cut-off score of ≥ 10 . This cut-off corresponds to 16 for the full 20-item CES-D, which is used to identify clients with clinically relevant depressive symptoms.⁸⁸

- **Anxiety**

Prevalence and severity of anxiety will be measured using the Generalized Anxiety Disorder Screener-7 (GAD-7) scale.⁸⁹ The GAD-7 is used in research as a generic measure of anxiety symptoms and is based on the DSM IV criteria for generalized anxiety disorder.⁹⁰ The GAD-7 has good internal consistency and good convergent validity with other anxiety and disability scales^{89,91–93}; all questions include four response categories (0–3) and scoring results in a value ranging 0–21, where higher scores indicate higher levels of anxiety. Severity will be measured by the mean scale score for each group. Prevalence will be measured using a cut-off score of ≥ 5 . This cut-off has been identified as an important threshold for identifying the presence of anxiety disorder⁹¹ and has been used in studies on older adults.⁹⁰

- **Self-efficacy**

Self-efficacy will be measured using the Self-Efficacy for Managing Chronic Disease six-item Scale (SE-MCD). All items are measured using a 10-point response scale ranging from 1 to 10 and where higher scores indicate higher self-efficacy. The score for the scale is the mean of the six items. The items in the scale are common across many chronic diseases, including symptom control, role function, emotional functioning and communicating with physicians. The six-item scale represents several measures which were tested for adequacy of scale, validity and reliability and suggested for use to assess the effectiveness of interventions using diverse populations.⁹⁴

Six-month changes in patient experience

- **Shared decision-making**

The change in the level of shared decision-making between participants and the providers delivering the intervention will be measured using the CollaboRATE tool. The tool is comprised of three questions that evaluate the clinical encounter including explanation of the health issue, patient preferences and their integration, thus serving as a measure of patient engagement and a patient-reported outcome. Each question is scored on a 10-point scale from 0, no effort was made, to a score of 9, every effort was made, along with each respondent's

age, gender and clinician. CollaboRATE has previously been validated in diverse primary care settings.^{95,96}

Six-month changes in provider outcomes

- Collaborative practice

The change in the level of collaborative practice among the IP team will be measured using the Collaborative Practice Assessment Tool (CPAT)⁹⁷ at 3 and 9 months following initiation of the intervention. The CPAT is a 56-item self-report questionnaire that was designed to enable teams to assess their perceptions of collaborative practice.⁹⁷ The CPAT assesses the degree to which providers collaborate to provide comprehensive, timely and appropriate patient care. The CPAT demonstrates good reliability (internal consistency) with Cronbach α coefficients for all subscales ranging from 0.72 to 0.92.^{97,98} Content validity was established at the time of instrument development and construct validity was confirmed by factor analysis in two pilot studies as described in Schroder et al. (2011).⁹⁷

Six-month changes in the costs of use of health services

The use of all types of health services will be determined using the Health and Social Services Utilization Inventory (HSSUI).⁹⁹ The HSSUI consists of questions about the respondent's use of healthcare services, which for this study include: (i) family physician visits; (ii) physician specialist visits; (iii) home care services; (iv) outpatient services; (v) emergency visits and hospitalizations; (vi) medications and natural health products; and (vii) supplies, aids or devices. Inquiries will be restricted to the reliable duration of recall: 6 months for remembering a hospitalization and a visit to the physician, and 2 days for use of a medication. The HSSUI has been previously tested and assessed for reliability and validity^{100,101} and is acknowledged as one of the few published measures of ambulatory utilization that is empirically validated.¹⁰²

Based on patients' self-report of their use of health and social services over the study period (baseline and 6 months) using the HSSUI,⁹⁹ the change in total costs and change in costs per type of service will be examined. A societal perspective will be used in costing the use of services, which implies collecting all costs, regardless of who bears them. The wider the perspective taken, the more applicable the study is to social policy decisions.¹⁰³ The cost data will be derived from 'quantity' data reported on the HSSUI and 2015–2016 'price' data obtained by our team from the Ontario Ministry of Health and Long-Term Care Health Data Branch Web Portal.¹⁰⁴ The product of the number of units of service (quantity) and unit cost (price) is total cost/cost per service. The costs of use of health services measured by the HSSUI will also account for the costs associated with the delivery of the intervention.

Sample size

The sample size for this study was based on feasibility considerations.⁵⁴ Our target sample size will be a sample of between 20 and 40 participants, the size that Hertzog¹⁰⁵ found sufficient for pilot studies that varied in terms of purpose, desired precision and effect sizes. Further, our sample size is based on (i) recruitment target of $\geq 50\%$ based on our previous trial,⁴⁴ therefore up to 60 patient participants will be approached, and (ii) retention target of $\geq 80\%$,⁸⁴ therefore 16–32 patient participants will be expected to complete the feasibility study. The preliminary information on the estimates of change in outcomes from baseline to 6 months will be used to inform the design of the main study.

Analytical methods

Quantitative

Quantitative data will be examined for out of range values and missing data. All analyses will be performed using SAS version 9.4 for Windows. All statistical tests will be performed using two-sided tests at the 0.05 level of significance. Outcome data will be treated as continuous variables and the change in effect will be expressed as mean effect, with standard errors, corresponding two-sided 95% confidence intervals (CI), and associated p -values. Descriptive analyses of participants' characteristics at baseline will be expressed as a mean (standard deviation [SD]) or median (minimum–maximum) for continuous variables and count (%) for categorical variables. Test of differences over time will be examined using paired t -tests for continuous/normal variables and Wilcoxon Signed-Rank Test for categorical/non-normal variables. A sensitivity analysis will also be conducted. If there are discrepancies between the multiple imputation and complete case results, we will explore using different multiple imputation methods (appropriate for the pattern of missingness and data type) to see how robust the analysis is for the chosen method(s) of handling missing outcome data.¹⁰⁶

Qualitative

The qualitative data will be transcribed and coded using NVivo version 10 including focus groups, interviews and monthly outreach meeting notes. A qualitative descriptive approach will be used for analysis.¹⁰⁷ An inductive and deductive approach¹⁰⁸ will be used to code the transcripts based on the main research questions and NPT constructs. Coding will be completed line by line using an inductive approach but organizing the codes within NPT constructs deductively. The RC will code one transcript which will be reviewed by the principal investigator. Once agreement is reached on the coding approach, all remaining transcripts will be coded by the RC. There will be a second reviewer of all coding by a principal investigator with expertise in

qualitative analysis. Special attention will be paid to adding detailed descriptions for all codes to increase consistency in coding and to increase understanding of codes by the research team. The team will meet to review the final coding framework, to merge/clean nodes and their descriptions where repetition or misconceptions exist, and to develop higher level categories within the coding framework where needed. Principal investigators will review any cases where disagreements or inconsistencies in coding or categories exist.

Ethics

This study will be conducted in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.¹⁰⁹ Ethics approval has already been obtained from the Hamilton Integrated Research Ethics Board (#14-612) and will be renewed yearly as required, including handling of protocol amendments. All participants will provide written informed consent. The study has minimal risks for patients, providers/managers. The RC will assign a participant ID to each patient. A list linking this ID number with the participant's name will be kept secure in a locked filing cabinet separate from the data and destroyed at the end of the study. All electronic records and data sets will be stored on password protected computers on a secure network, and access will be limited to the study team. Pseudonyms will be used in reporting focus group findings.

Discussion

This article describes the design of a pragmatic feasibility study of an integrated transitional care intervention. The overarching goal of this study is to determine the feasibility of conducting a large-scale RCT to evaluate this integrated hospital-to-home transitional care strategy to optimize health outcomes for older adults with stroke and multimorbidity. To address this goal, our primary objective will be to assess the feasibility of implementing the intervention in practice. Secondary objectives will be focused on exploring the 6-month change in Quadruple Aim outcomes (health outcomes, patient experience, provider experience and cost), assessing the feasibility of the study methods and selecting a primary outcome for the RCT.

Implications for research

This research will make several important contributions to the existing knowledge base. First, the study will examine both the implementation and preliminary effects of the intervention. The study will also include a cost analysis from a societal perspective, which provides policymakers with critical information on the resource implications of the intervention to facilitate decision-making. There is limited focus in the literature on studying implementation of transitional care interventions. While effectiveness provides information on

whether the intervention works, implementation provides information on the feasibility of intervention implementation, the factors that influence intervention implementation, and implementation outcomes. This is especially relevant as transitional care interventions are highly dependent on numerous macro-level factors such as healthcare infrastructure and resources. Research focused solely on studying the effectiveness of an intervention does not capture the complexity of the interactions among the many contextual factors that influence implementation of the intervention, including cost. This information is needed to enhance understanding of 'real-world' implementation of the intervention and to identify context-specific implementation strategies to enhance the integration of the intervention into usual care practice.^{110,111}

Second, this study will investigate the preliminary effects of a transitional care intervention in a complex population – older adults with stroke and multimorbidity, who are often excluded from RCTs.⁵⁶ The complexity of this population is defined in part by their greater risk of adverse transition outcomes, such as hospital readmissions, diminished HRQoL, death,¹¹² increased use of other health services,⁵ stroke-related complications, and institutionalization compared to those with stroke alone.¹¹³ The inclusion of older adults with stroke and multimorbidity will enhance the generalizability of our results. The overall goal of the intervention is to enhance the quality of transitions from hospital to home to reduce avoidable transitions (e.g. hospital readmissions), and optimize health outcomes for this vulnerable population.

Third, this is the first known study to investigate the preliminary effects of a transitional care intervention among older adults with stroke and multimorbidity over a longer-term follow-up of 6 months. Studies on the effectiveness of hospital-to-home transitional care interventions have involved short-term support (<3 months) rather than ongoing follow-up care over a 6-month period.³ The limited duration of these interventions is important given that community reintegration can take up to 1 year post-stroke, and up to 36% of older adults continue to be disabled up to 5 years later.^{114,115}

A final contribution of this study is that the intervention is supported by a web-based app for promoting communication and collaboration among the IP team to enhance coordination of care. While many e-health communication tools exist, few have considered the potential value of using an e-health tool to support team-based communication, which is essential for coordinating care for older adults with complex needs requiring ongoing care and support. The study will provide useful information for integrating MyST into routine practice, and the modifications to MyST that will be required in future studies to further examine the implementation and effects of MyST in supporting an integrated transitional care intervention.

Overall, our study is designed to be pragmatic, person-centred and to be rich in information, providing data on the

feasibility of the intervention using qualitative approaches, as well as capturing preliminary effects on a range of outcomes (e.g. quality of life, depressive symptoms, costs, IP collaboration) for multiple stakeholders (e.g. patients, healthcare providers, managers). We will work closely with patients, providers and managers to identify and report the types of adaptations made to the intervention. This information will be used to determine future refinements and prepare for a future study to test the intervention on a larger scale.

Implications for practice and policy

There is a need to identify and test a new model of transitional care to address service gaps. The collaborative efforts of identifying and working through the challenges associated with delivering the intervention will help to enhance the credibility of the intervention, foster shared values and understanding regarding the aims or benefits of the intervention, and will help to create a sense of ownership of the project by all involved thereby facilitating implementation and long-term sustainability.

For this feasibility study, implementation of the intervention will involve collaboration between the research team and the outpatient rehabilitation centre, at both the individual and organizational level that include:

- forming an IP team and providing the team with initial and ongoing training and support;
- the addition of a RN and a SW to the usual outpatient rehabilitation centre team as these disciplines are not currently a part of the IP team;
- expanding the responsibilities of the IP team members to include activities that are not a part of usual practice, such as providing home visits, using the MyST app and participating in IP case conference;
- providing initial and ongoing training and support to the IP team members;
- changing roles, responsibilities and scope of work among providers and managers to support the delivery of the intervention, for example, scheduling, staffing, workload, time; and
- strong executive-level support (both financial and human) at the outpatient rehabilitation centre setting.

In summary, the results of this study will provide evidence for the feasibility and preliminary effects of a new and innovative transitional care model that has the potential to significantly improve Quadruple Aim outcomes (health outcomes, patient experience, provider experience, costs) for older adults with stroke and multimorbidity. By triangulating the core elements of successful integrated transitional care interventions: new models of care delivery, technology and practice to policy, this study is positioned to transform the care delivery of outpatient stroke rehabilitation. Innovative impacts of the study include optimization of usual care

practice, providing person-centred care; IP team-based care; a formalized process for communication among providers and patients and across care settings; care coordination and system navigation; comprehensive and ongoing health assessment using validated screening tools; referral management; facilitation of outpatient clinic–community connections; and ongoing self-management education and support.^{3,21}

Conclusions

The increase in the number of community-dwelling older adults with stroke and co-morbidities transitioning from hospital to home underscores the need for strategies to ensure that older adults' transitions between care settings are safe and efficient. This study will provide the first evidence of the feasibility of implementing in practice an innovative hospital-to-home transitional care intervention for older adults with stroke and co-morbidities. The results will help to inform a future trial to determine the effectiveness of the intervention in other contexts and settings. The results will also provide information on any needed adaptations to the intervention and study methods that will be carried forward to the RCT.

Ultimately, the study results will inform policy concerning community-based transitional care interventions to reduce avoidable transitions and optimize transition outcomes. The study includes outcomes for a range of stakeholders (patients, healthcare providers, managers) and includes a cost analysis. It will inform healthcare providers and policymakers by improving our understanding of the potential preliminary effects of the intervention components (care coordination, self-management support through home visits and telephone contacts, and IP case conferences) and improving the quality of transitional care in a complex and underserved population (older adults with stroke and multimorbidity). By studying feasibility of the intervention including implementation and preliminary effects in this study, we hope to enhance the relevance of the study findings to clinicians and policymakers to ultimately improve spread and scale of the intervention.

Authors' note

Trial Registration: NCT02230280

Author contributions

All authors contributed to the design of the study. MMR, RV and AB contributed to the design and implementation of the intervention. MMR wrote the first draft of this manuscript, and all authors contributed to the discussion and editing. All authors read and approved the final manuscript.


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