FULL TITLE: **Volunteer facilitated Discharge Assistance and Supports at Home (DASH) for people with stroke: An Effectiveness Trial**

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| Short Name: | DASH |
| Principal Investigator | Dr. Michelle L. A. Nelson |
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**TABLE OF CONTENTS**

**[1] Abbreviations**

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| CIHR | Canadian Institute for Health Research |
| DASH | Discharge Assistance and Supports at Home |
| MODC | March of Dimes Canada |
| PDCDS | Post Discharge Coping Difficulty Scale |
| PHQ-9 | Patient Health Questionnaire-9 |
| REB | Research Ethics Board |
| RCT | Randomized Controlled Trial |
| SSQOL | Stroke Specific Quality of Life Scale |

## [2] Synopsis

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| **Title:** | Volunteer facilitated Discharge Assistance and Supports at Home (DASH) for people with stroke: An Effectiveness Trial. |
| **Principal Investigator:** | **Dr. Michelle L. A. Nelson**<br>Senior Investigator<br>Bruyère Health Research Institute<br>Email: MiNelson@bruyere.org |
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| | **Dr. Patrice Lindsay**<br>Director, Health Systems Change<br>Heart and Stroke Foundation of Canada<br><br>**Dr. Tim Ramsay**<br>Senior Scientist, Clinical Epidemiology<br>Ottawa Hospital Research Institute<br><br>**Dr. Robert Simpson**<br>Staff Physiatrist, Toronto Rehabilitation Institute<br>Assistant Professor, Department of Medicine<br><br>**Dr. Kednapa Thavorn**<br>Health Economist and Research Scientist<br>Ottawa Hospital Research Institute |
| Study Design: | Pragmatic, randomized effectiveness trial. The trial will precede with a vanguard phase (n=30 participants) that will directly inform the full trial. |
| Population: | Individuals who have experienced a stroke living in or returning to the community. |
| Inclusion: | 1. Confirmed diagnosis of stroke<br>2. Either undergoing or recently completed in-patient rehabilitation within the last 3 weeks<br>3. Lived at home pre-stroke<br>4. Discharged directly home (to own residence or that of a family member)<br>5. Live in one of the program implementation areas (i.e., Toronto, Ottawa) |
| Exclusion: | 1. Discharged to additional hospital inpatient care, nursing home, or other long-term care<br>2. Inability to communicate in English<br>3. Inability to provide informed consent due to cognitive deficits |
| Referral requirements | 1. Participants eligible for inclusion under any referral type<br>a. Self-referral<br>b. Clinician referral<br>c. MODC referral<br>d. Any referral<br>2. Participants may enrol in the study up to three weeks post-discharge, permitting one week for MODC volunteer matching and study set-up.<br>Enrolment window consistent across all entry points. |
| Intervention & Comparator: | **Group A, Usual Care + Education Materials + DASH**<br>**Intervention:** Participants randomized to the volunteer- |

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| | supported home-from-hospital intervention will receive usual discharge care provided at their hospital site within the specified geographical catchment (Toronto and Ottawa).<br><br>**Group A** will receive stroke educational materials dispersed by the research team at two different time points (4-weeks and 8-weeks post-discharge), In addition, participants in Group A will receive weekly one-to-one visits with a trained MODC volunteer for a duration of 8 visits to receive help with i) instrumental activities of daily living assistance (e.g., assistance with meal preparation, light house duties, and transportation), ii) psychosocial support (e.g., befriending visits), and iii) informational supports (signposting to other community services).<br><br>**Group B, Usual Care + Education Materials Only:** Participants randomized to **Group B** group will also receive usual discharge care provided at their hospital site within the geographical catchment (Toronto and Ottawa) and will receive the same stroke educational materials at the same two time points (4-weeks and 8-weeks post-discharge). Participants randomized to Group B <u>will not</u> receive the volunteer-supported intervention. |
| Feasibility Outcomes | Feasibility outcomes will be assessed during the vanguard phase on the first n=30 randomized participants and will include trial recruitment rates, adherence to the trial protocol, and study withdrawal rates. |
| Primary outcomes: | Coping at 3-months post hospital discharge.<br><br>We will assess coping at 3- and 6-months post-discharge using the following measure as our primary outcome:<br>1. Post Discharge Coping Difficulty Scale (PDCDS)<br>The PDCDS evaluates post-discharge satisfaction, including aspects related to stress, recovery, self-care, and managing medical needs; family difficulties; the need for help and emotional support; confidence in self-care and medical management skills; and overall adjustment. Ten PDCDS items are measured by a 11-point Likert scale, providing a range of scores between 0-100, with higher scores indicating a greater difficulty with coping. |
| Secondary outcomes: | We will also assess for sustained coping, quality-of-life-, depression, and social isolation and loneliness at 3- and 6- |

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| | months post-discharge using the following measures as secondary outcomes:<br>1. 6-month coping (T2) Post Discharge Coping Difficulty Scale (PDCDS)<br>2. Quality of life assessed using the Stroke Specific Quality of Life Scale (SSQOL).<br>3. Depression is assessed by a 9-item depression severity scale, the Patient Health Questionnaire (PHQ-9).<br>4. Social Isolation and loneliness will be assessed using the UCLA Loneliness Scale (Version 3). |
| Timeline: | Volunteer assistance provided for 8 visits (approximately 8-weeks). Primary and secondary outcomes will be followed up at 3- and 6-months. Participants randomly assigned to Group A will participate in approximately 29 hours of study related activities, and Group B will participate in up to 3 hours of study related activities.<br><br>Group A: Provide informed consent (1 hour), T0 demographic data capture (30 minutes), needs assessment with MODC (2 hours), DASH intervention visits (3 hours/week x 8 weeks = 24 hours), T1 outcome measures (45 minutes), T2 outcome measures (45 minutes), same with 6-month interventions = 29 hours<br><br>Group B: Provide informed consent (1 hour), T0 demographic data capture (30 minutes), T1 outcome measures (45 minutes), T2 outcome measures (45 minutes) = 3 hours |
| Analysis: | We will conduct all analyses using an intention-to-treat principle. We will assess baseline characteristics of patients by treatment group using frequency distributions, including measures of central tendency and dispersion.<br>For our **primary outcome**, we will assess whether T1 PDCDS scores are significantly different between treatment groups using a chi-square test analysis.<br><br>**Secondary outcomes:** We will compare secondary outcome scores in both groups, at 3- and 6-months, using a linear regression model. We will examine PDCDS change between T1 and T2 scores (3- to 6-month delta) by group using comparable subgroups as this is likely to be better able to detect smaller changes in coping. A sensitivity analysis will examine coping in all randomized participants to assume that they failed to cope (all individuals who died, were hospitalized, were lost, or had a |

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| | repeated stroke). Additionally, we will examine mean differences in PDCDS scores between treatment groups using t-test analyses. The effect of the intervention on depression, quality of life, and loneliness will also be examined using the same analytical techniques and assumptions applied. |
| Consent: | Written informed consent will be obtained from all potential participants (stroke survivors) prior to study enrolment. |
| Funder | Canadian Institute for Health Research, March of Dimes Canada |

**[3] Lay Abstract**

Acute stroke often leads to adult disability in Canada, and about 108,707 Canadians experience a stroke each year. While most people survive stroke (80%) and return home, some survivors are left with ongoing challenges that require them to seek help in the community. These challenges can lead to stress for the individual and their caregiver. Research on volunteer-supported home-to-hospital programs has shown positive outcomes. However, despite the growing evidence that supports volunteer engagement in care transitions, we have yet to determine the impact of a complex psychosocial volunteer-delivered care transition intervention for stroke survivors. This study will assess whether a volunteer-delivered transitional care intervention, designed by Bruyère Health Research Institute in partnership with March of Dimes Canada (MODC), for adults discharged home from a stroke rehabilitation unit following an acute stroke can improve coping compared to usual care. MODC will implement the volunteer-support transition program across two Ontario regions for stroke rehabilitation sites. Those allocated to the intervention group will receive an initial visit from the Volunteer Coordinator and then weekly one-on-one visits by a trained volunteer for eight weeks. The volunteer may assist the study participant with instrumental daily living activities and psychosocial and informational support. Those not receiving the intervention will receive educational material at 4- and 8-week time points in addition to their usual care. All study participants will complete validated patient-reported outcome measures at 3- and 6-months post-hospital discharge.

**[4] Background, Rationale & Significance**

**4.1. Background**

Stroke is a considerable health event impacting approximately one in 90,000 Canadians this year.[1] Due to advancements in stroke care, most people who experience a stroke are discharged home directly from acute care or after inpatient rehabilitation.[2] Once home, stroke survivors report health and social challenges, such as impaired mobility, fatigue, depression and anxiety, incontinence, social inactivity, and isolation.[3,4] These impairments also place significant stress on caregivers, who are tasked with facilitating care transition between hospital and home and providing ongoing support in the home.[5] For many stroke patients, increased levels of dependence following discharge[6] and elevated rates of 30-day

(24.3%)[7] and 1-year (62.2%)[8] hospital readmissions indicate unmet needs and poor community reintegration. Home and community-based service gaps related to psychosocial well-being, information, and personalized and tailored services significantly contribute to these challenges.[6,9–13] However, well-facilitated and supported community reintegration for those with stroke could reduce or avoid adverse health outcomes, re-hospitalization, and added caregiver burden.[14,15] While significant strides have been made in evidence-based stroke care and recovery, there remains a considerable need to understand how to effectively organize transitional services to optimize recovery for stroke survivors once they return home.[16–18] Additionally, it is important to understand how stroke survivors can better self-manage their recovery with minimal input from healthcare professionals.[18] Widespread health human resource shortages, made worse by the global COVID-19 pandemic, have exacerbated barriers to accessing home and community-based services.[19] It is, therefore, crucial for health and social systems to find effective ways to support the growing number of stroke survivors[20] needing intersectoral services,[21] especially as the availability of caregivers and healthcare professionals to assist continues to decrease.[22]

Given the intersection of complex patient demographics and financial pressures, volunteerism in health and social care systems has gained significant appeal among policymakers.[23] From a societal perspective, volunteering has the potential to tailor services to local needs, engage underserved communities, address service gaps, and potentially reduce the need for funded services.[24] While research on volunteer-led stroke transition models is emerging nationally and internationally,[24,25] 'Home from Hospital Service' volunteer patient-support services are notably prevalent in the United Kingdom. For example, the Worcestershire Enhanced Home from Hospital Service in 2015/16 assisted 1462 clients with the help of 57 volunteers, who collectively provided 2127 hours of support. Despite the vital contributions of voluntary sector organizations in delivering transitional care support, research has concentrated mainly on formal health care providers,[26,27] with comparatively less attention to voluntary sector organizations. However, research is available on volunteer and partnership engagement that supports care transitions and independent living,[28,29] including the role of lay volunteer navigators in facilitating effective transitions from hospital to home.[28,30–32]

Recent systematic evidence of volunteer-supported transitions highlighted the need for more research focused on the impact and sustainability of these models.[33,34] Canada is well-positioned to answer this call to research, bolstered by a vibrant culture of volunteerism and civic engagement, with approximately 86,000 registered charities across the country.[35] In 2018, over 24 million Canadians volunteered, representing 79% of people aged 15 and older, contributing roughly 5 billion hours – equivalent to more than 2.5 million full-time, year-round jobs.[36] Systematic review evidence and the World Health Organization recognize the valuable contributions of volunteers to health services and patient care,[34,37–39] as volunteers play a crucial role as members of the healthcare workforce.[40,41] Many voluntary service organizations already offer stroke recovery services, with clinicians actively referring patients to these programs. For example, March of Dimes Canada

(MODC) has developed the *AfterStroke* Program,[42] which creates a network of community-based programs and services to support stroke survivors and their families at crucial moments in their recovery. *AfterStroke* includes group-based education on stroke, opportunities for community participation, and emotional support through a personalized goal-setting approach.

### 4.2. Rationale & Significance

As patient complexity and financial pressures increase, health and social care volunteerism has become increasingly appealing among policymakers.[23] The UK's 'Home from Hospital Service' model presents a promising opportunity for adaptation in Canada. Our partnering organization, MODC, is dedicated to addressing unmet patient needs by developing a volunteer-based, hospital-to-home discharge program for Canadian stroke survivors and their families. Given Canada's strong volunteer sector, our collaboration with MODC is timely and strategic. This effectiveness trial will assess the DASH program's impact on stroke survivors' coping ability at home and explore its broader applicability.

Through our partnership with MODC, we have designed the Discharge Assistance and Supports at Home (DASH) program to offer volunteer-supported transitional care to stroke survivors. While discharge assistance has demonstrated potential, prior efforts have yet to incorporate volunteers or be evaluated through randomized controlled trials (RCTs). Our study incorporates effective research to facilitate a real-world application of the DASH program in the Canadian context. We aim to assess the impact of DASH on post-stroke coping, with the potential for broader application among other vulnerable populations.

The results from this RCT could significantly impact health and social care systems. If the DASH intervention proves effective, the findings may enable organizations like MODC to efficiently scale the program by identifying key factors contributing to the successful implementation of community-oriented, volunteer-led transitional care. Furthermore, the insights gained could be applied to other populations facing challenges from hospital to home, such as older adults and various rehabilitation groups. Should the intervention demonstrate effectiveness, our research might also encourage Canadian policymakers to foster meaningful collaborations with the voluntary sector, recognizing their crucial role in communities across Canada and their potential to enhance patient outcomes.

### 4.3. DASH Study Aim – Effectiveness Trial Research Objectives

This study aims to assess the effectiveness of a volunteer-delivered transitional care intervention in enhancing coping post-hospital discharge amongst stroke survivors and its impact on quality of life, depression and social isolation.

An implementation arm of this study is detailed elsewhere and has received Research Ethics Board (REB) approval from Mount Sinai Hospital (REB #24-0092-E).

## [5] Outcomes

### 5.1. Feasibility Outcomes

Feasibility outcomes to be assessed during the vanguard phase of the trial will include:

i) Rate of study recruitment
ii) Adherence to the trial protocol
iii) Rate of withdrawal from the study

For the vanguard phase, our recruitment target is one participant per treatment group, per site, per week, up to n=30 participants. If recruitment drops below this rate, we'll explore and implement strategies to boost enrollment.

We will determine adherence to the trial protocol among those randomized to the DASH intervention arm as having at least one (1) home visit from a DASH volunteer. If adherence falls below 95%, we plan to increase our sample size in the full trial to offset any higher-than-expected non-adherence rates.

We will monitor study withdrawal closely. If withdrawal exceeds 5% among the first 30 participants (i.e., 2 participants), we will analyze the reasons for withdrawal and adjust our protocol accordingly to minimize dropouts. This 5% threshold is aligned with recent data from pragmatic RCTs in hospital settings.[43]

If we accomplish the above-listed metrics, our n=30-participant vanguard phase within 6 months will demonstrate feasibility. If we succeed, we will continue with the full trial to examine our primary and secondary outcomes. Participants in the vanguard phase will be included in the full trial.

### 5.2. Primary Outcome (Appendix A)

The primary outcome of interest is coping as measured by the Post-discharge Coping Difficulty Scale (PDCDS) at 3 months post-discharge from the hospital (T1).[44] Three months (T1) was selected when recently discharged stroke survivors are at greatest health vulnerability. The PDCDS was chosen as it is a valid and reliable measure of coping and adjustment[44,45] used with stroke patients.[46] The PDCDS evaluates post-discharge satisfaction, including aspects related to stress, recovery, self-care, and managing medical needs; family difficulties; the need for help and emotional support; confidence in self-care and medical management skills; and overall adjustment. Ten PDCDS items are measured by a 11-point Likert scale, providing a range of scores between 0-100, with higher scores indicating a greater difficulty with coping. A quantitative summary of responses will indicate the extent to which study participants cope post-discharge.

### 5.3. Secondary Outcomes (Appendix A)

Secondary outcomes will be administered at 3- (T1) and 6-months (T2) post-hospital discharge to assess the difference in scores for coping, quality-of-life, depression, and social isolation and loneliness, using the following outcome measures:

i) We will use the PDCDS to assess longitudinal coping ability (6-months; T2) and ascertain the degree of change in coping scores for all participants (change score = T2-T1).
ii) The Stroke Specific Quality of Life Scale (SS-QOL, 49-item) assesses quality of life.[47]
iii) A 9-item depression severity scale assesses depression, the Patient Health Questionnaire (PHQ-9).[48]
iv) Social Isolation and loneliness will be assessed using the UCLA Loneliness Scale (Version 3).[40,41,42]

The T1 and T2 time points were selected for the same reasons listed for the primary outcome. Study participants will be dichotomized into binary high or low scores based on the median scores for each secondary outcome measure. Scores less than the empirical median will indicate lower quality of life and increased levels of depression, social isolation, and loneliness. Section 7.1 provides detailed descriptions of outcome measure tools.

### 5.4. Outcome Adjudication

Research staff who are unblinded to the participants' randomization arm will assess the study outcomes.

## [6] Study Design

### 6.1. Study Overview

We will conduct a multicentre (Toronto and Ottawa), two-group, randomized trial to evaluate the effectiveness of a volunteer-assisted hospital-to-home care transition intervention compared to augmented usual care.

### 6.2. Stroke Survivor Participant Inclusion Criteria

i) Confirmed diagnosis of stroke
ii) Currently undergoing or recently completed an in-patient rehabilitation stay or program within the last 3-weeks
iii) Lived at home pre-stroke
iv) Discharged directly home (to own residence or that of a family member)
v) Live in one of the program implementation geographical catchment areas as determined by postal code (i.e., Toronto, Ottawa)

### 6.3. Stroke Survivor Participant Exclusion Criteria

i) Discharged to additional hospital inpatient care, nursing home, or other long-term care facility
ii) Inability to communicate in English
iii) Inability to provide informed consent due to cognitive deficits

### 6.4. Stoke Survivor Participant Recruitment

We have identified two primary recruitment strategies for the DASH intervention that allow participants to enroll up to 3 weeks post-discharge from the hospital. These intervention recruitment strategies include hospital-based and community-based recruitment.

#### *6.4.1. Hospital-based Recruitment*

Primary recruitment from participating clinical sites (i.e., hospitals and rehab clinics) within the targeted geographical catchment (Toronto, Ottawa) will begin before hospital or clinical discharge. We will identify and collaborate with "unit champions" (i.e., clinical leads or care providers) in stroke recovery units/programs at recruitment sites to facilitate the identification of potential participants. For the recruitment process, unit champions will be provided with the following recruitment materials: (1) recruitment flyer (Appendix B), (2) research study brochure (Appendix C), (3) DASH consent form (Appendix E), and (4) recruitment script and workflow document (Appendix D).

Under this recruitment strategy, stroke survivor participants will have two main recruitment pathways. First, potential participants can contact a research team member directly using the contact information in the recruitment materials. Alternatively, potential participants can provide and give permission to a unit champion to share their contact information with our research team confidentially. A team member will then initiate initial and follow-up contact with them directly via email to facilitate an informed consent discussion (Appendix L). A research team member will also conduct hospital site visits as needed.

#### *6.4.2. Community-based Recruitment*

Potential stroke survivor participants may also be recruited through various streams of community referrals, which include, but are not limited to:

i) MODC clients who express interest in participating in DASH and wish to be screened for eligibility
ii) Individuals who become aware of DASH through word of mouth
iii) Individuals who did not enrol in DASH during their hospitalization or rehabilitation period
iv) Individuals who become aware of DASH through online promotion (Appendix K) (e.g., LinkedIn) or trial profiling (e.g., Sinai News)

MODC, our community study partner, will receive the same recruitment materials listed above (Appendix B-D) to facilitate recruitment. As with hospital-based recruitment, individuals in the community can contact us directly using contact information from recruitment materials or through community organizations like MODC. A data analyst will generate monthly audits of regional enrollment numbers from hospital and community recruitment strategies and discuss them during regular advisory team conference calls. As needed, we will adapt recruitment strategies to meet the needs of the stroke population.

#### *6.4.3. Ineligible Stroke Survivor Participants*

If an individual is approached for study recruitment and expresses interest in participating but is subsequently found ineligible for the trial, they will receive an information package with resources supporting transitions from hospital to home post-discharge (Appendix F). We will invite excluded participants to provide consent for us to access their information for future data linkage exercises and to contact them regarding the potential for future research opportunities. Excluded participants may freely refuse this request.

#### *6.4.4. DASH Volunteer Recruitment*

We have partnered with MODC, which will mobilize volunteers to administer the DASH intervention. To mimic the effectiveness of a real-world intervention, MODC will be responsible for facilitating all processes related to volunteer efforts, including onboarding (e.g., criminal record and vulnerable sector checks) and training. Integrated as a process within MODC, this strategy will establish a streamlined pathway for potential volunteers interested in the DASH project.

### 6.5. Informed Consent

#### *6.5.1. Obtaining Stroke Survivor Participant Consent*

After determining eligibility (Appendix G), all eligible individuals will be contacted by a research team member via telephone (up to one hour in length) to collect informed consent (Appendix E). During the call, the research team member will highlight important details outlined in the information letter and address any questions or concerns. Participants can provide consent by either (a) scanning and emailing the signed consent form to us or (b) providing verbal consent during the call (Appendix M). Once consent is provided, the participant will be enrolled.

Potential participants may feel unprepared to enrol in our research study upon initial contact or be unable to make an informed decision until they are discharged home. Consent to participate in the trial will be allowed at any time following the inclusion/exclusion screening and initial contact with the research team, up to three weeks after the initial interaction. We are permitting a three-week consent period because the transition period from hospital to home may be unpredictable and challenging for a vulnerable demographic. A longer period to provide consent to participate will enable potential participants to make an informed decision once they have had a chance to return home.

#### *6.5.2. Obtaining DASH Volunteer Consent*

Once MODC has notified a research team member of a potential volunteer participant interested in the DASH trial, a team member will initiate contact with that person to retrieve informed consent via telephone or email (Appendix N and O). Informed consent will be collected using the same process outlined above with stroke survivor participants. Once informed consent is provided, the individual will be enrolled.

### 6.6. DASH Intervention Trial

#### *6.6.1. Stroke Survivor Participant Randomization*

The participant randomization process for the DASH trial will be facilitated through REDCap, with data housed on the secure Bruyère Health Research Institute network. Following participants' enrollment in the trial, a member of our research team will complete the randomization process and notify the participants of their group allocation. Randomization will occur in a 1:1 ratio with permuted blocks of variable size. REDCap provides a comprehensive and secure randomization service for clinical trials and is accessible via a web browser. Any data associated with randomization will be housed on the secure REDCap platform on the Bruyère Health Research Institute network.

#### *6.6.2. Randomization Study Arms*

Enrolled participants will be randomized to either ***Group A (Usual Care + Education Materials + DASH Intervention)*** or ***Group B (Usual Care + Education Materials)***. As documented in their discharge instructions, participants in either group will receive the usual care from their respective hospital sites. Usual care at hospital sites is fragmented but typically includes education materials, appointments with outpatient medical providers (stroke clinics, neurology follow-up, primary care), and referrals to community-based support for activities of daily living (e.g., Home and Community Care Support Services). To support retention in the study, participants randomly assigned to Groups A and B will receive educational materials distributed by a research team member at two separate time points during the intervention (4 and 8 weeks post-discharge).

***Group A – Usual Care + Education Materials + DASH intervention:*** Participants randomly assigned to Group A will receive the following intervention components:

i) An initial visit (virtual or telephone, per participant preference) from an MODC staff member will occur within 4 days after randomization to conduct a needs assessment and goal prioritization assessment, informing a personalized support plan. This plan will support the matching of the DASH volunteer to the study participant and guide the intervention delivery throughout the intervention.
ii) One-on-one weekly visits in the stroke survivor participants' residence by a DASH volunteer for approximately 8 weeks (about 2 months). The intervention will begin within approximately one week of the intake assessment. Volunteer support could span three types: i) instrumental activities of daily living assistance (e.g., assistance with meal preparation, light house duties, and transportation), ii) psychosocial support (e.g., befriending visits), and iii) informational supports (signposting to other community services).
iii) Educational materials sent electronically at 4 and 8 weeks post-discharge.

***Group B - Usual Care + Education Materials:*** Participants randomly assigned to Group B will receive the following study component:

i) Educational materials will be sent at the 4- and 8-week post-discharge time points, aligning with the 8-week DASH intervention timeline.

Upon completion of the study, both groups will receive the community signposting resource (Appendix F) as well as be directed to additional MODC services and supports to assist their continued stroke recovery.

## [7] Data Collection & Outcome Measures

**T0 (Baseline)**
After the research team obtains informed consent, we will collect demographic information from all stroke survivors at baseline (T0) (Appendix H). The process may take 30 minutes per participant. MODC will collect volunteer demographic information as part of their initial enrollment processes (Appendix I) which will be shared with Bruyère Health Research Institute as permitted through our data sharing agreement.

**T1 (3-months post-discharge)**
A research team member will collect all primary and secondary outcome measures (described in section 7.1 below) from all study participants via telephone at 3 months post-hospital discharge (T1). Near the respective 3-month post-discharge mark, a research team member will contact the study participants via telephone or email to schedule a data collection time and date at the participant's preference. T1 data collection is estimated to take up to 45 minutes per participant.

**T2 (6-months post-discharge)**
A research team member will collect all primary and secondary outcome measures from all study participants via telephone 6 months post-discharge (T2). Near the respective 6-month post-discharge mark, a research team member will contact the study participants via telephone or email to schedule a data collection time and date at the participant's preference. T2 data collection is estimated to take up to 45 minutes per participant.

### 7.1. DASH Stroke Survivor Participant Outcome Measures

#### *7.1.1. Primary & Secondary Outcome – Post Discharge Coping Difficulty Scale (PDCDS)*

The PDCDS is a 10-item scale with Likert response categories ranging from 0-10. The PDCDS was selected because it is a validated and reliable measure of coping and adjustment that has been previously used with stroke patients. This patient-oriented tool captures post-discharge experiences directly aligned with the intervention under study, as opposed to some of the more commonly used transition measures, which assess functional, medical or health system factors in the transition from hospital to home.

#### *7.1.2. Secondary Outcome – Stroke Specific Quality of Life Scale (SS-QOL, 49-item)*

The SS-QOL, a 49-item self-report questionnaire developed for stroke patients, will assess participants' quality of life. As a patient-centred outcome measure, it has been established as a reliable and validated tool.

***7.1.3. Secondary Outcome – Patient Health Questionnaire (PHQ-9)***

The nine-item PHQ-9 will assess participants' indications of depression**.** As a self-rated, brief, and highly valid instrument for detecting depression in the general population, the PHQ-9 has also performed well in post-stroke patients.

***7.1.4. Secondary Outcome – UCLA Loneliness Scale (Version 3)***

Participants' indications of social isolation and loneliness will be assessed using the ***UCLA Loneliness Scale (Version 3)***. Revised to a 20-item questionnaire, the applicability of the UCLA Loneliness Scale (Version 3) is far-reaching (i.e., age, gender, and cultural demographics) and includes the stroke population with high internal consistency.

**7.2. Volunteer Data Tracking Log**

During the intervention phase (T0-T1), MODC will ask DASH volunteers to log visit data (date of visit, length of visit, types of activities completed) using their organizational volunteer data tracking log (Appendix J). This data will be shared with the research team, as part of the data sharing agreement, to provide qualitative information on the nature of the interactions that took place between the volunteer and stroke survivor participant.

**[8] Schedule of events and duration of follow-up**

| | **Baseline Data** (T0) | **DASH Intervention** (8-weeks) | **3 Month Follow-up** (T1) | **6 Month Follow-up** (T2) |
|---|---|---|---|---|
| Demographic Information | X | | | |
| MODC Needs Assessment | X | | | |
| DASH Intervention | | X | | |
| Primary Outcome: Coping – PDCDS | | | X | |

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|---|---|---|---|---|
| Secondary Outcomes: PDCDS, SS-QOL, PHQ9, UCLA Loneliness | | | X | X |
| Volunteer data tracking logs | | X | | |

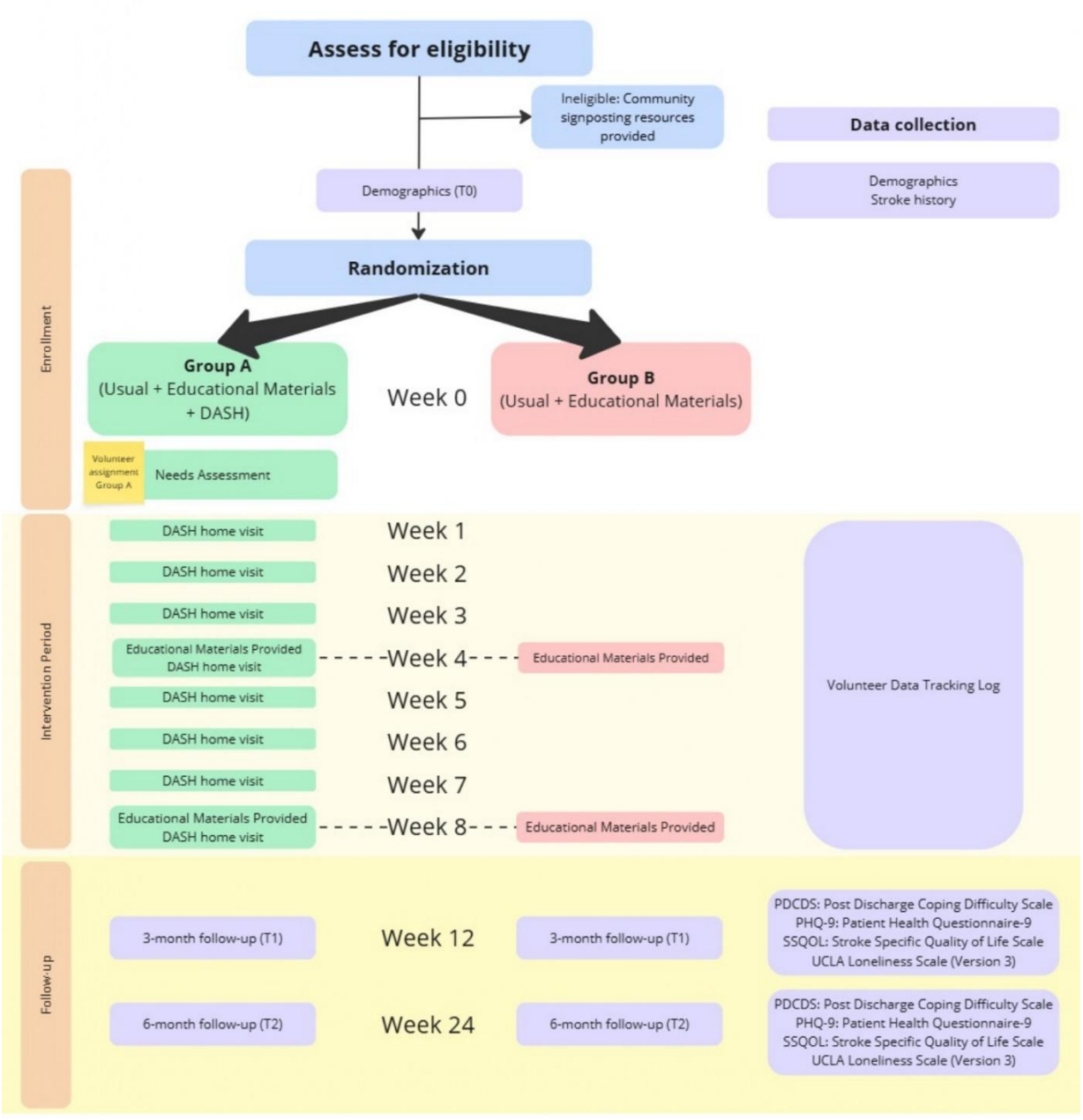


Figure 1. Flowchart for DASH trial.

### 8.1. Follow-up Tracking of Study Participants

Stroke survivor participants will be followed from the point of randomization (T0) to 6 months post-hospital discharge (T2). Additionally, participants will have the opportunity to opt-in for post-intervention interviews to share their experiences with the DASH intervention. The consent form (Appendix E) includes a separate section where participants can indicate whether they want to be contacted at a later date by the research team for a one-time follow-up interview. Interested participants will be followed up with an additional consent form if they choose to participate (as part of the implementation study approved by Mount Sinai Hospital, REB #24-0092-E).

## [9] Statistical Analysis

### 9.1. Sample Size

Our sample size is based on the alternate hypothesis that the DASH volunteer intervention would improve individuals coping following a stroke by at least 10%, representing a minimally important difference relevant to patients. We assume that at baseline, 60% will be coping (our best estimate based on consultations with experts). With a power of 80% and a type 1 error rate of 5%, we will require a total sample of 712 patients (2-sided chi-square test). We further assumed a 15% rate of repeat stroke or loss to follow-up. Doing so will increase the required sample size to 838 patients. Therefore, enrolling 840 will allow us to detect meaningful changes under real-world conditions.

### 9.2. Analysis of Primary Outcome Measure

We will conduct all primary analyses using an intention-to-treat principle. Our primary analysis will assess whether T1 PDCDS scores are significantly different between treatment groups using a chi-square test analysis.

#### *9.2.1. Pre-planned subgroup primary outcome*

Our pre-planned sub-group analysis will examine T1 PDCDS scores by baseline covariate subgroups (e.g., identifying gender, categorizing age, living alone or not, and rural vs. urban location) to determine if coping was significantly different when equity considerations were applied. Specifically, we will conduct a gender-based analysis (plus) in accordance with CIHR policy. Our sub-group analysis will repeat the same statistical analyses as our primary analysis plan.

### 9.3. Analysis of Secondary Outcomes

We will also compare secondary outcome scores in both groups at 3- and 6 months, using a linear regression model. We will examine PDCDS change between T1 and T2 scores (3- to 6-month delta) by group using comparable subgroups as this is likely to be better able to detect smaller changes in coping. A sensitivity analysis will examine coping in all randomized participants to assume that they failed to cope (all individuals who died, were hospitalized, were lost, or had a repeated stroke). Additionally, we will examine mean differences in PDCDS scores between treatment groups using t-test analyses. The effect of the intervention on depression, quality of life, and loneliness will also be examined using the same analytical techniques and assumptions applied.

### 9.4. Data Collection for Study Withdrawal, Losses to Follow-Up, and Death

We will try to capture T1 and T2 outcome data on all study participants, including those who withdraw from the study and those who are lost to follow-up. We will use the contact information provided by the study participants to facilitate primary and secondary outcome data collection at both T1 and T2. For those who die while enrolled as study participants, we will assign an indication of death on outcome data collection at the appropriate time (i.e., T1, T2, or both).

### 9.5. Analysis of DASH Volunteer Data Tracking Log

DASH volunteer tracking logs (Appendix J) will be reviewed to determine the average duration of visits and the types of activities conducted during interactions with stroke survivor participants. We will review this data for purely descriptive measures, including frequency of activities, mean number of hours, and mean number of visits. Volunteer data tracking logs will help determine the fidelity of the intended intervention.

## [10] Withdrawal Procedures

Participants can withdraw from the study at any time. Research or MODC staff may also identify if a stroke survivor or volunteer should be withdrawn from the study (e.g., unsafe environment, abuse or violence), which will be discussed on a case-by-case basis. If a stroke survivor participant or volunteer chooses to withdraw from the study, we will:

A. Ask the participant to voluntarily provide a reason for their withdrawal (e.g., not interested in the services anymore, health declines, or 'other' etc.)
B. Ask participants to voluntarily participate in a post-implementation exit interview as outlined on the consent form

## [11] Protocol Amendments, Deviations, and Violations

### 11.1. Protocol Amendments

All protocol amendments will be submitted to the applicable ethics committee.

### 11.2. Protocol Deviation

A protocol deviation refers to non-compliance with the protocol approved by the REB. Deviations are only allowed with prior written consent from the sponsor or coordinating center, except in cases where a change is required to address an immediate risk to participants.

### 11.3. Protocol Violation

A protocol violation is an inadvertent deviation from the approved protocol that either increases risk or reduces benefit. Such violations may impact participants' rights, safety, or welfare. All protocol violations will be reported to the REB, sponsor, or coordinating center. Examples of protocol violations include enrolling a participant who does not meet the

eligibility criteria or incorrectly assigning a participant to a study intervention group other than the one they were randomized to.

### [12] Reporting Adverse Events

Although we are not anticipating any adverse events, interventions in uncontrolled environments have an inherent level of risk in real-world conditions. Adults have an elevated risk of morbidity and mortality after experiencing a stroke, which is most common in the short-term following hospital discharge. Therefore, some participants in our sample may experience adverse health events while enrolled in our trial. However, we suspect the added supervision and support provided to DASH intervention participants will mitigate any additional risk to our participants' health.

### [13] Trial Management

#### 13.1. Operational management

The trial will follow a structured approach to operational management in partnership with MODC, with Dr. Michelle L.A. Nelson overseeing this process. Dr. Nelson's team will train study personnel (i.e., recruitment champions and research coordinators) to assist in each site's recruitment and consenting processes. Training will include instruction on participant eligibility screening based on inclusion and exclusion criteria, obtaining informed consent, randomization allocation of participants, and data collection methods. Dr. Nelson's team will also develop the trial database and facilitate data quality and reviews. The trial will use REDCap to manage the trial by randomizing participants, storing captured data and entry, and compiling data for analysis. Dr. Nelson's team will also consult MODC on research procedures for all DASH volunteers affiliated with MODC.

#### 13.2. Role of Co-investigators

Co-investigators of the DASH trial are comprised of academic experts in clinical trials (MBayley, MFralick, TRamsay, RSimpson, IGraham), implementation science (IGraham, HSingh, MSaragosa, PLindsay), health economics (KThavorn), and policy (CSperling, RMiller, PLindsay, MBayley). Patient-engaged research should be prioritized to improve healthcare interventions' uptake and ongoing utilization.[52] Therefore, we have partnered with Brina Ludwig-Prout to conceptualize this study. Brina is actively engaged in Hennick Bridgepoint Hospital's (Sinai Health) Patient Family Advisory Committee and is an active co-researcher with MLANelson. Our trial Executive Committee oversees all project management processes (MLANelson, BLProut, HSingh, MSaragosa, IGraham, CSperling) and will meet regularly throughout the project. Our Research Program Advisory Group (all investigators, site leads, and representatives of advisory committees) will inform the overall direction and priorities of the project and will meet bi-monthly. The Implementation Advisory Group will comprise individuals with lived experience (with a specific focus on Equity, Diversity, and Inclusion), representatives of charities and organizations providing services to people with stroke and decision-makers. This group will provide advice on research approaches and help interpret research outputs specific to scale/spread considerations.

### 13.3. Study Monitoring

Prior to initiating recruitment at each participating site within Toronto and Ottawa, an in-person or virtual site visit will occur to ensure all trial procedures (e.g., consent, data collection) are reviewed, and all training materials are confirmed with study personnel and partnering staff. Members of Dr. Nelson's team will have regularly scheduled meetings to update on study progress and procedures and address any questions that have arisen over the period. Dr. Nelson and/or team members will regularly check-in with partnering recruitment sites to ensure trial procedures are sustained and answer any questions that may arise.

## [14] Knowledge Translation, Trial Registration, and Data Sharing

### 14.1. End of Project Knowledge Translation

We will use the Guide to Knowledge Translation Planning at CIHR: Integrated and End-of-Grant Approaches to guide our end-of-project knowledge translation activities.

**Goals**

The goals of our End-of-Grant Knowledge Translation activities are to inform future research initiatives in the community and volunteer sector, to advocate for greater uptake of community and intersectoral partnerships in the third sector, to inform or change policy relevant to community and volunteer organizations to support safe care transitions from hospital to home, and to inform or change practice should our volunteer assisted discharge intervention prove to be effective in helping individuals cope post-stroke.

**Audience**

Our Knowledge Translation Strategy will balance traditional and non-traditional knowledge translation approaches to address a diverse targeted audience, including study participants, family and friends of study participants, MODC clientele, community third-sector organizations, health care professionals and service providers, academic researchers, and policy makers.

**Strategies**

In partnership with MODC, we will use the following vehicles to disseminate our findings:

i) Social media release from key accounts (MODC & Bruyère Health Research Institute), online forums (MODC website, Care In Common website), webinars, and workshops.
ii) Create data briefs, infographics, visual summaries, and other accessible formats to distill complex research findings into user-friendly formats.
iii) Provide summary briefings to stakeholders.

In addition, we will use the following vehicles to diffuse our research findings:

i) Conference presentations: We will submit our findings for conference presentations.

ii) Publications: We will submit to both peer-reviewed and open-access journals, with results made available via preprint servers in advance of peer-review.

Should our trial demonstrate positive implementation and effectiveness results, we may additionally work with knowledge users to:

i) Adapt knowledge for use in other populations, including cultural relevancy to other groups (e.g., Indigenous, Francophone), other chronic health conditions (e.g., Dementia), or geographic regions (e.g., Rural).
ii) Ensure sustainability through an economic evaluation of the DASH intervention.

**Expertise**

Our research team is comprised of multi-disciplinary backgrounds with experts in:

i) Research experience
ii) Publication experience
iii) Presentation experience
iv) Clinicians and knowledge brokers
v) Third-sector organization management

**Resources**

The following will be resourced through study funding to aid in knowledge translation activities and dissemination of study findings:

i) Publication fees, conference registration fees
ii) Production/printing fees

### 14.2. Trial registration

The trial will be registered at clinicaltrials.gov and/or other relevant international trial registries.

### 14.3. Data sharing

Data from this study will be available to all study team members as de-identified data.

## [15] Ethical Considerations and Processes

The investigators will ensure that this study is conducted in accordance with the Tri-Council Policy Statement and boundaries adjudicated by the REB committee at Bruyère Health Research Institute and partnering recruitment sites. The following steps will be taken to ensure the ethical conduct of the DASH study trial:

i) The study protocol will be submitted to the Clinical Trials Ontario Research Ethics Board for approval.
ii) All potential stroke survivor participants will receive consent forms. The forms explain why the research is being conducted and outline the research activities.

They also provide the names of the principal investigators, their contact information, and that of the Clinical Trials Ontario Research Ethics Board so that participants (prospective and consented) can contact research team members with questions related to the study and their participation.

iii) Potential stroke survivor participants will be given sufficient time to read relevant material and ask questions. Stroke survivors will be assured that participation in the DASH study trial will not impact their usual care plans. Volunteers will be assured that involvement in this study will not impact their current or future volunteer opportunities within MODC or other organizations. Similarly, withdrawing from this research study may occur at any time and will not impact their relationship with MODC.

iv) Participants must give written informed consent before participating in any research study. The signed consent forms will be stored securely and electronically in SharePoint/OneDrive on Bruyère Health Research Institute's secure closed servers.

v) Once informed consent is provided and enrollment is complete, stroke survivor participants and volunteers will be assigned a unique coded participant identifiable number (e.g., SSP001 or V001).

vi) All computerized databases housing stroke survivor and volunteer data will identify participants by numeric codes only.

vii) Upon request, and in the presence of the investigator or his/her representative, participant study records will be made available to the study sponsor, monitoring groups representative of the study sponsor, representatives of funding groups, and applicable regulatory agencies for the purpose of verifying clinical trial procedures and/or data, as permitted by local regulations.

viii) Data collected from participants will be stored securely for ten years. After ten years, a professional company will shred all paper data and permanently delete electronic data. Computer media will be disposed of in an environmentally friendly manner. The principal investigator's (MLAN) responsibility is to request authorization for destruction at the completion of the retention period and/or for the sponsor to inform the investigator/institution when these documents may be destroyed.

**15.1. Data Management**

The following security measures will be taken immediately to protect the confidentiality of the study participants and associated data.

i. De-identify participants' identifying information immediately by removing personal information from the data and assigning a coded identifiable number.
ii. Maintain a separate, password-protected Master Log of the participants on a secure, centralized server at Bruyère Health Research Institute in the investigators' (MLANelson) Sharepoint/OneDrive secure closed network, which could be accessed remotely by approved research team members with the appropriate login credentials.

iii. Access to data will be based on approved roles, including restricting folder permissions to only those authorized to access individuals named in the application with access to the data.

**15.2. Research Study Honorarium**

In our successful CIHR grant, we have budgeted for stroke survivor participant honorariums. Stroke survivor participants randomized to both Group A (DASH Intervention) and Group B (Usual Care) will receive a $15.00 CAD gift card for completing the T1 data collection and a $25.00 CAD gift card for completing the T2 data collection. Each stroke survivor participant will receive up to $40.00 CAD in gift cards as a token of appreciation for their time and commitment. They will be informed that they shall receive compensation through the informed consent process. Volunteers will also receive an honorarium for their participation, which is detailed in our DASH implementation study (approved by Mount Sinai Hospital REB #24-0092-E).

**15.3. Use of REDCap Services**

REDCap software will house data on the participant randomization sequence. It is vetted data collection software compatible with the Bruyère Health Research Institute network, permitting primary and secondary outcomes to be collected and stored for access by research team members. Using REDCap for the randomization sequence in permeated blocks of variable size will strengthen the randomization of our groups and mitigate the influence of our unblinded data collection procedures.

**15.4. Potential Participant Benefits**

Stroke survivor participants in the DASH trial may experience a range of downstream benefits for themselves and their caregivers. First, participants will receive increased social support through one-to-one volunteer visits, which may reduce feelings of isolation and loneliness. Second, assistance with daily activities, such as meal preparation and light house duties, may ease the transition from hospital to home, allowing for a smoother adjustment to life after a stroke. Third, participants may gain access to community resources and guidance, helping them connect with additional support systems that may benefit their recovery. Finally, participants will receive tailored support based on their specific needs through their personalized intervention plan developed by a MODC staff member.

**15.5. Potential Participant Risks**

Participation in this study entails certain risks, particularly regarding privacy and confidentiality. If personal information is not sufficiently safeguarded, data breaches could occur. However, we will implement rigorous confidentiality agreements and secure data handling protocols per Bruyère Health Research Institute to mitigate these risks.

Clinical trials inherently involve certain risks. For stroke survivors, potential emotional distress may arise from mismatched expectations during pre-planning, inconsistent

volunteer support, or misalignments with their assigned volunteers. Additionally, unforeseen medical issues could occur, potentially exacerbating health symptoms unrelated to study participation and hindering meaningful involvement. Logistical challenges like scheduling conflicts or miscommunication with volunteers may also lead to confusion and stress. To mitigate these risks, we will ensure that the MODC receives the necessary training and supervision to uphold standard care practices and maintain open communication. In a risk-related incident arising from the delivery of DASH (e.g. volunteer-stroke survivor interactions, safety concerns in the home, etc.), MODC will serve as stroke survivor participants' primary point of contact and adhere to established risk assessment guidelines. Each incident will be evaluated individually, and if needed, a member of our research team will assist in discussions with MODC. For risk-related incidents arising from research activities (such as questionnaire responses), the PI will be the primary contact for risk mitigation and resolution.

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