Telerehab at Home: Mobile Tablet Technology for Patients With Poststroke Communication Deficits— A Pilot Feasibility Randomized Control Trial

NCT02615132

December 22, 2016

A. APPLICANT INFORMATION

Proposed Project Title
TeleRehab for Patients with Post-Stroke Communication Deficits using Mobile Technology

Primary Investigator

Karen Mallet, M.H.Sc., M.Ed. SLP (C)
Speech-Language Pathologist
Champlain Regional Stroke Network and the Ottawa Hospital – Civic Campus
1053 Carling Avenue, Ottawa, ON K1Y 4E9

Co-PI: Dariush Dowlatshahi MD PhD FRCPC
Assistant Professor, University of Ottawa
Scientist, Ottawa Hospital Research Institute
Ottawa Hospital Civic Campus C2182b
1053 Carling Ave, Ottawa, ON K1Y 4E9

Primary Research Site
Ottawa Hospital Research Institute

B. LAY SUMMARY

Post-stroke communication deficits (PSCD) are a common symptom of patients having sustained a stroke. These deficits include difficulty to produce or understand language, motor speech disorders and cognitive-communication disorders. It is estimated that approximately 40% of stroke survivors will have communication disorders post stroke (Berthier, 2005).

Provincially, we know that 39.8% of mildly disabled stroke survivors were discharged home without services and 13.8% were referred to outpatient rehabilitation services in 2012/13 (Hall et al., 2014). In the Champlain Region, the overall percentage of patients being referred to outpatient rehabilitation services was only 4.1% in 2012/13 (provincial benchmark 12.8%). Meanwhile, 27.9% of patients were admitted to inpatient rehabilitation (Hall et al., 2015). A one month audit at the Ottawa Hospital Civic Campus (October 2014) revealed that 3/39 (7.6%) of patients attended outpatient rehabilitation.

The Champlain Region has identified a gap in services with regards to outpatient and/or community rehabilitation services. That is, the only dedicated outpatient stroke services available in the Champlain Region are at Elizabeth Bruyère. There is the possibility of accessing general outpatient speech and language services at the Montfort Hospital, the Queensway Carleton Hospital and Perth Hospital. However, there are no outpatient services for Renfrew County or the Eastern Counties.

Community Care Access Centers (CCAC) are another source of outpatient rehabilitation. However, these services are limited and are not in keeping with Canadian Stroke Best Practice

Recommendations, where it is recommended that clients should have a minimum of 45 minutes per day up to 3 hours per day, 3 to 5 days per week based on patient's needs and goals (Dawson et. al., 2013). Between 2011 and 2013, the mean number of rehabilitation visits provided in the Champlain Region for CCAC was between 3.3 and 5.2 visits [this included the following disciplines Physiotherapy (PT), Occupational therapy (OT), Speech Language Pathology (SLP) & Social Work (SW)] (Hall et al., 2014).

Other than publically funded/supported services, patients could access the services of SLPs through community services such as the Aphasia Center of Ottawa (fee for service), the University of Ottawa Inter-professional Clinic (Francophones only) and private SLPs (fee for service). Unfortunately, these are either cost prohibitive or language prohibitive.

Patients being discharged home who require SLP services are sometimes placed on a waitlist to access these services. While others, are not able to access outpatient services because of a variety of reasons including: patient lives at too great a distance from the rehabilitation facility (>30 minutes); unable to access reliable transportation to and from outpatient services; or the patient does not have the stamina to participate in the demands/schedule of outpatient therapy and travel to and from outpatient service (Champlain Regional Stroke Rehabilitation System – Patient Flow Algorithm, 2014).

In this randomized controlled study, our objective is to test the value of providing a mobile platform-based Speech Language Therapy (SLT) program to patients discharged from an acute care hospital with stroke and PSCD and awaiting outpatient rehab services versus standard of care treatment. We will offer iPad-based SLT/standard of treatment to a convenience sample of 20 patients with post-stroke communication deficits. The primary outcome will be feasibility (recruitment rate, adherence rate, retention rate, and protocol deviations), and the secondary outcome will be improvement in PSCD.

C. OBJECTIVES

Research question:

Is it feasible, practical and effective to deliver SLT using mobile technology (iPad) to patients with PSCD being discharged home/primary residence from the acute care setting?

Rationale

PSCD affects 15-40% (Berthier, 2005) of patients during the recovery phase after stroke. It limits post-stroke rehabilitation, and is associated with increased disability and mortality. While screening can identify those patients at risk of PSCD, targeted treatment is not always available. Although quality of life in patients with PSCD is difficult to measure directly, the disruption in communication with its likely effects on employment status and social networks suggests that its impact can be profound (Nichols-Larsen et al., 2005). Patients with PSCD have greater morbidity than stroke patients without PSCD. While most, if not all, patients with post-stroke PSCD have some functional recovery, residual deficits are common.

Objective 1: To test the feasibility and practicality of using mobile technology (iPad) for delivering SLT to patients with PSCD being discharged HOME/PRIMARY RESIDENCE from the acute care setting

Objective 2: To explore the efficacy of using mobile technology in delivering SLT in patients with PSCD being discharged HOME/PRIMARY RESIDENCE from the acute care setting.

D. APPROACH

Study population: Patients being discharged HOME/PRIMARY RESIDENCE from the acute care setting at TOH and requiring communication therapy. According to a 2013 Ottawa Hospital census, 50 patients per month are admitted to the Neurology inpatient service with a primary diagnosis of stroke. Also, **an ongoing TOH research project using a similar design was able to recruit approximately 3 to 5 patients per month over a 6 month period.** For this study we have selected a convenience sample of 20 patients over an 18 month period.

Patient identification and selection: All patients admitted to the Civic Campus' Neurology inpatient service with a diagnosis of stroke AND communication deficit (as assessed by an SLP) that are being discharged home/primary residence awaiting outpatient SLP services will be screened by research personnel for study eligibility. Patients will first be approached by clinical SLP or clinicians within the circle of care and must give permission to speak to research personnel.

Design and Methods:

This is an 18 month randomized controlled trial, recruiting post-stroke patients presenting with communication deficits.

Inclusion criteria (all criteria must be fulfilled):

1. Patients with diagnosis of stroke being discharged from the Neurology unit and/or the Neurology Acute Care Unit in the Civic Campus of TOH.
2. Patients presenting with overall mild to moderate communication deficits,
   And/or
3. Patients with score ≥ 1 on the best language and/or dysarthria parameters of the National Institute of Health Stroke Score (NIHSS)
4. Stroke Patients being discharged to their HOME/PRIMARY RESIDENCE awaiting outpatient speech and language therapy services.
   And/or
5. Patients being discharged to their HOME/PRIMARY RESIDENCE who would benefit from SLP therapy services but are unable to receive these secondary to various accessibility challenges (i.e. remote geographical location, limited service availability, transportation, unable to pay for SLP services).

Exclusion criteria:

1. Patients with pre-existing speech, language disorders or cognitive disorders (such as dementia).
2. Patients with severe debilitating disease(s) that, in the opinion, of the investigator will not be able to perform the required tasks of the study (ex: end-stage malignancy, ALS).
3. Patients with severe comprehension deficits
4. Patients who will be accessing the services of a private SLP while awaiting outpatient rehab.
5. Patients currently enrolled in another mobile-platform-based study.

Intervention: The intervention will consist of patients being randomly assigned to either standard of care or receiving an iPad upon being discharged home from the acute care setting. The iPad will be programmed with specific apps chosen from the following list:

1. Tactus Therapy suite of Speech-Language therapy mobile applications, which include the following modules: Language, Category, Conversation and Questions.
2. Speech sounds on cue for iPad by Multimedia Speech Pathology
3. Lingraphica TalkPath Therapy
4. Search 4 It
5. This is to That
6. Just Saying
7. Get+Together
8. RhymieStymie
9. Morphos
10. iVolution
11. Blankety-Blank
12. Chain of Thought
13. Scrabble
14. Fit brains
15. Constant Therapy
16. Boggle for iPad
17. Pop words
18. Anagram Twist
19. Word explorer

The apps chosen will be specific to their communication therapy needs. These apps will be monitored remotely by an SLP. A weekly check-in with the patient will be had with an SLP and/or research coordinator using one of the following: Skype, Facetime and/or Telephone.

Patients will then be randomized to one of two groups on a 1:1 ratio:

Group I (Treatment Group): The study SLP will cater the specific regimen to individual patients based on the pattern of communication deficits. In keeping with the Canadian Stroke Best Practice Recommendations (Dawson et al., 2013) and Quality Based Procedures Handbook (Health Quality Ontario; Ministry of Health and Long-Term Care, 2015), the study SLP will instruct the patient to use the apps for at least one-hour per day, until they are admitted to outpatient SLP services or for a maximum of 8 weeks, whichever comes first. Throughout the telemedicine treatment phase, patients' progress will be monitored remotely by a study SLP through Apps/Skype/Facetime/Telephone consultation on a weekly basis.

Patients will also be instructed to record the amount of time they spend using the iPad in an

electronic form on the device itself.

Group 2 (Control Group):
Patients will be sent home with standard of care.

Data collection All patient data will de-identified. We will retain age at enrollment, sex, co-morbid medical history (vascular and neurologic conditions: MI, CAD, HTN, DM), stroke type and severity (NIHSS and MRS stroke scores). We will also retain baseline and follow-up language testing results, and total usage time of the iPad. We will also gather information on the number of patients discharged with stroke diagnosis between March 1, 2016 and June 30, 2017, with the help of Health Records at the Ottawa Hospital. This will help our study to identify the total number of patients who might have been eligible for inclusion in the study.
Outcomes & analysis plan. We will assess the primary outcome of *feasibility* by determining:

1. Recruitment rate = the number of patients enrolled divided by the total number of patients admitted with stroke. We will also estimate the proportion of the discharged PSCD population that can benefit from this intervention.
2. Adherence rate = the number of patients who completed the full course of intervention divided by the total number of patients enrolled. This measure will determine whether discharged PSCD patients can actually tolerate and complete the therapy.

Both groups will have a study SLP assessment prior to being admitted to outpatient SLP services (post-intervention) or after 8 weeks of enrolment, whichever comes first.

We will measure the secondary outcome of the study by measuring any potential improvements in communication by comparing pre and post-intervention SLP assessments. The latter will be performed by a blinded study SLP. Patients randomized to the treatment group arm will also be asked to complete an electronic survey at the end of the study to collect their feedback. The survey is voluntary.

Significance:
Our research will allow to test, for the first time, the feasibility of delivering SLT via telemedicine (iPad) to patients with PSCD being discharged home from the acute care setting.

Specifically:

1. This research project will demonstrate that using mobile technology may allow for timely, continuous and seamless provision of SLT for this stroke population who would otherwise go without while awaiting outpatient rehab.
2. Using mobile technology may widen, and even provide, accessibility to SLT services for patients with PCSD at their home, therefore eliminating historical barriers (i.e. transportation, distance and fatigue) to accessing services.
3. This study will demonstrate the significant cost-effectiveness of using mobile technology as a means of delivering SLT in stroke patients residing in a large geographical region (i.e. Champlain region).
4. This innovative approach may provide a model to local, provincial and national health care facilities that have no outpatient SLT services.

Table 1. Timelines	
Timeline	**Activity**
mid July – September, 2015	**Draft research proposal and final plan project plan**
	Begin informing Speech-Language Pathologists about project
September-October, 2015	**Submit application to Research Ethics Board of the Ottawa Hospital Research Institute**
October, 2015	**Obtain approval from Research Ethics Board of the Ottawa Hospital Research Institute**
October 2015-March, 2017	**Patient recruitment**
March 2017-April 2017	**Complete data analysis** **Prepare manuscript**

Table 2. Proposed budget		
Item	**Details**	**Amount**
Project coordinator	0.4 FTE X $80,000+28% benefits	**$40960**
Research assistant	0.2 FTE X $36,000+ 28% benefits	**$9216**
Conference travel	3-day meeting: flight ($600), accommodation ($200), meals (2 days @ $50/day)	**$900**
iPad app purchases	Constant therapy app annual subscription ($250) X3/year X2 years + various app purchases ($200)	**$1700**
Dissemination of findings	Publication fees and conference participation costs	**$800**
iPad air 2 Wifi only + cases	3 iPad Air 2 + 3 cases X $594 + 13% tax	**2013.66**
Parking costs for patients	20 patients X $10 parking voucher	**$200**
	Total	**$55,790.**

References

Berthier, M. L. (2005). Poststroke aphasia: epidemiology, pathophysiology and treatment. Drugs Aging, 22(2), 163-182.

Dawson AS, Knox J, McClure A, Foley N, and Teasell R, on behalf of the Stroke Rehabilitation Writing Group. Chapter 5: Stroke Rehabilitation. In Lindsay MP, Gubitz G, Bayley M, and Phillips S (Editors) on behalf of the Canadian Stroke Best Practices and Standards Advisory Committee. Canadian Best Practice Recommendations for Stroke Care: 2013; Ottawa, Ontario Canada: Heart and Stroke Foundation and the Canadian Stroke Network.

Hall R, Khan F, O'Callaghan C, Kapral MK, Levi J, Cullen A, Wu J, Fang J, Bayley M. Ontario Stroke Evaluation Report 2014: On Target for Stroke Prevention and Care. Toronto, ON: Institute for Clinical Evaluative Sciences; 201Hall R, Linkewich B, Khan F, Levi J, Zhou L, Fang J, Lumsden J, Martin C, Morrison K, Moore P, Kelloway L, Kapral MK, O'Callaghan C, Bayley M. Ontario and LHIN 2013/14 Stroke Report Cards and Progress Reports: Driving knowledge exchange and implementing stroke best practices. Toronto, ON: Institute for Clinical Evaluative Sciences; 2015.

Health Quality Ontario; Ministry of Health and Long-Term Care. Quality-based procedures: clinical handbook for stroke (acute and postacute). Toronto: Health Quality Ontario; 2015 February. 148 p. Available from: http://www.hqontario.ca/evidence/evidence-process/episodes-of-care#community-stroke.

Nichols-Larsen DS, Clark PC, Zeringue A, Greenspan A, Blanton S. Factors influencing stroke survivors' quality of life during subacute recovery. Stroke. 2005 Jul;36(7):1480-4