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# **BMJ Open**

## TM-SAFER: Telemedicine (TM) Guided Education on Secondary Stroke and Fall Prevention Following Inpatient Rehabilitation: A Feasibility Pilot Study

Journal:	BMJ Open
Manuscript ID	bmjopen-2017-017340
Article Type:	Protocol
Date Submitted by the Author:	17-Apr-2017
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<b>Primary Subject Heading</b> :	Rehabilitation medicine
Secondary Subject Heading:	Neurology

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3 4 5 6	Keywords:	Stroke < NEUROLOGY, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, REHABILITATION MEDICINE, NEUROLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT
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# Protocols

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TM-SAFER: Telemedicine (TM) Guided Education on Secondary Stroke and Fall Prevention Following Inpatient Rehabilitation: A Feasibility Pilot Study

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   *Introduction* The aftermath of stroke leaves many consequences including cognitive deficits, falls due to weakness 38 39
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## 43

# 44 Introduction

45 The aftermath of stroke leaves many consequences including cognitive deficits, falls due to weakness of or imbalance. Stroke survivors and families fight to navigate the complex healthcare system with bittle assistance post-hospital discharge, often leading to early hospital readmission worse stroke outcomes. TM-SAFER feasibility study examines whether stroke survivors and their caregivers field value in Telerehabilitation (TR) home visits that provide individualized care and education by a multidisciplinary team after discharge from inpatient rehabilitation. *Methods and Analysis* A prospective, single arm, pilot study is designed to evaluate the feasibility of weekly TR home visits initiated post-discharge from inpatient rehabilitation. Newly diagnosed ischemic stroke patients are recruited from a Houston based comprehensive stroke center inpatient rehabilitation unit, loaned an iPad with data plan, and trained to use IT security approved videoconferencing application. After For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml 46 47 or imbalance. Stroke survivors and families fight to navigate the complex healthcare system with 48 49 50 51 value in Telerehabilitation (TR) home visits that provide individualized care and education by a 52 53

# 54 Methods and Analysis

55 56 57 58 recruited from a Houston based comprehensive stroke center inpatient rehabilitation unit, loaned an 59 60

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hospital discharge, 6 weekly TR home visits are led by rotation of specialists (pharmacist,	n: fi
physical/occupational therapist, speech therapist, rehabilitation physician, social worker, geriatricia	រោ ฐ
specialized in fracture prevention) followed by satisfaction survey administered by epidemiologist	ong
week 7. Specialists visually assess patients in real time, educate them on secondary stroke and fall	lish
prevention, and suggest ways to improve function including direct medical interventions when	ed a
<sup>2</sup> <sub>10</sub> indicated. Primary outcomes include rate of patient/caregiver participation in all 6 TR home visits	IS 10
1 and satisfaction score measured via surveys. The study started December 31, 2015 with plan to enr	ğ11 🗄
$\frac{12}{3}$ up to 50 patients over 24 months. Feasibility study results will inform us as to whether a randomize	∰d §
4 controlled trial is warranted to determine efficacy of TR home visit intervention in improving strok	å j
<sup>15</sup> outcomes.	v cc
<sup>16</sup> Ethics and Dissemination	1-20
8 Ethics approval obtained by Institutional Review Board and Committee for the Protection of Huma	
<sup>9</sup> Subjects, IRB NUMBER: HSC-MS-14-0994. Study results will be submitted for publication in a pee	
reviewed journal.	40 o
<sup>22</sup> Key words: stroke, rehabilitation, telemedicine, neurology, protocols	in a
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<sup>25</sup> Strong the and Limitations of this Study	ISES ISES
26 Strengths and Limitations of this Study	seig relg

### Ethics and Dissemination

#### Strengths and Limitations of this Study

- Study incorporates a multidisciplinary team of specialists who have the opportunity community.
- The study population includes underserved stroke rehabilitation patients who may uninsured, living in rural locations, and Spanish speaking with limited access to healthcare resources.
- The study uses an IT security approved videoconferencing application and conducts all **G**R home visits in a private setting to protect patient confidentiality.
- The videoconferencing application may be difficult for older or cognitively impaired street

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 The videoconferencing application may be difficult for older or cognitively impaired strategy patients to use, and may require caregiver assistance.
 The videoconferencing technology may not work in rural locations with poor reception.

Background
Stroke survivors and their caregivers tackle numerous barriers after hospital discharge including cognitive / physical disability, rotation of caregivers, social isolation, lack of socioeconomic resources, and geographical constraints which may limit their access to follow up healthcare and pett patients at risk for further disability and hospital readmission.<sup>1,2</sup> Despite the expansive manpower and resources invested, 14% of ischemic stroke patients discharged from the hospital are readmitted within 30 days.<sup>3</sup> According to a randomized controlled trial on a post discharge follow-up service for stroke survivors, hospital readmission is common, and follow-up intervention after discharge is a way to prevent readmission for patients, particularly in those with long inpatient rehabilitation.<sup>1</sup> 

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However, under the present system, we have not developed enough transitional care programs that address the barriers preventing community stroke survivors from achieving their highest potential.

BMJ Open Page 4 of 13 ever, under the present system, we have not developed enough transitional care programs that sets the barriers preventing community stroke survivors from achieving their highest potential. One approach to fill this gap during the critical period between patient discharge from inpatient diltation program to community is TR home visits. Various forms of telemedicine exist ding automated systems that trigger alerts, mobile apps, and videoconferencing sessions with ontact with a healthcare provider. The purpose of these various forms of telemedicine is to ase access to healthcare resources for patients who are often located at a distance from a hub cal center and cannot travel to visit their healthcare provider in person. Previous telemedicine is to improve transitional care have been conducted in diabetes<sup>4</sup>, renal transplant<sup>5</sup>, and heart e populations<sup>6</sup>, and have shown promising results including a 21% reduction in hospital nission rate for remotely monitored heart failure patients. Telemonitoring has also been used proke population to improve lower extremity strength in veterans up to 2 years post stroke<sup>7</sup>, e depression and strain on stroke caregivers<sup>8</sup>, and incorporate telemedicine home based ilitation patients immediately after discharge from inpatient rehabilitation facility. TM-SAFER feasibility study brings the team of rehabilitation specialists to the patient's hors diately after hospital discharge to empower stroke survivors. By weekly communication via conferencing application on iPad, patients have the opportunity to receive individualized card different rehabilitation activity to receive individualized card different rehabilitation activity to receive individualized card different rehabilitation specialists to the patient's hors different rehabilitation on iPad, patients have the opportunity to receive individualized card rehabilitation program to community is TR home visits. Various forms of telemedicine exist including automated systems that trigger alerts, mobile apps, and videoconferencing sessions with 1:1 contact with a healthcare provider. The purpose of these various forms of telemedicine is to increase access to healthcare resources for patients who are often located at a distance from a hub medical center and cannot travel to visit their healthcare provider in person. Previous telemedicine studies to improve transitional care have been conducted in diabetes<sup>4</sup>, renal transplant<sup>5</sup>, and heart studies to improve transitional care have been conducted in diabetes<sup>4</sup>, renal transplant<sup>5</sup>, and heart failure populations<sup>6</sup>, and have shown promising results including a 21% reduction in hospital failure populations<sup>6</sup>, and have shown promising results including a 21% reduction in hospital readmission rate for remotely monitored heart failure patients. Telemonitoring has also been used in the stroke population to improve lower extremity strength in veterans up to 2 years post stroke<sup>7</sup>, reduce depression and strain on stroke caregivers<sup>8</sup>, and incorporate telemedicine home based rehabilitation in stroke patients up to 2 years post stroke<sup>9</sup>. However, there are currently no transitional care telemedicine education home programs focused on directly intervening with stroke rehabilitation patients immediately after discharge from inpatient rehabilitation facility. 

immediately after hospital discharge to empower stroke survivors. By weekly communication via videoconferencing application on iPad, patients have the opportunity to receive individualized care with different rehabilitation specialists including pharmacist, physical/occupational therapist, spece therapist, rehabilitation physician, social worker, and geriatrician specialized in fracture prevention These are specialists who may have been involved in the patient's care while in the hospital and ca provide continued follow up of medical issues, and when required, direct medical interventions in ta mining, order to prevent events that could lead to hospital readmission. The primary purpose of this feasibility pilot study is to determine if stroke survivors are able to participate in TR home visits immediately post-hospital discharge, and whether stroke survivors and their families find these sessions valuable. We are looking at issues of whether this novel videoconferencing technology is easy to use for this often older and cognitively impaired population. We also assessing whether patients and caregivers feel that TR home visits increase access to healthcare resources, intercept medical problems early on, save time and money, protect confidentiality, and offer patients / caregivers the opportunity to ask questions that are specific to their recovery. **Objectives Primary Objectives** This prospective feasibility study is evaluating patient compliance and satisfaction with a TR home visit intervention led by a multidisciplinary team in the first 6 weeks after discharge from inpatient immediately post-hospital discharge, and whether stroke survivors and their families find these 

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2017. Downloaded from http://bmjopen.bmj.com/ on June 7, 2025 neme<u>n</u>t Superieur (ABES). visit intervention led by a multidisciplinary team in the first 6 weeks after discharge from inpatient <sup>54</sup> rehabilitation. We hypothesize that at least 70% of patients will participate in all 6 TR home visits. Additionally, we anticipate that 80% of patients will report satisfaction with TR home visits at the level of 70% or more. Our goal is to provide valuable transitional rehabilitation care for stroke survivors through weekly contact with specialty rehabilitation providers to improve stroke outcomes 

Secondary Objectives This feasibility study will provide important data for sample size estimates and inform on the logistics for a future randomized controlled trial. We relevant to the logistics for a future randomized controlled trial. We plan to observe percent medication refill aspiration risk via swallow evaluation<sup>10</sup>, MoCA cognitive score<sup>11</sup>, and change in PhQ9 Depression Screen Scores<sup>12</sup>, Fall Efficacy Scale Scores<sup>13</sup>, Reintegration to Normal Living Index scores<sup>14</sup>, 

### **18 Methods**

Screen Scores<sup>12</sup>, Fall Efficacy Scale Scores<sup>13</sup>, Reintegration to Normal Living Index scores<sup>17</sup>, and FRAX scores<sup>15</sup> to assess fracture risk in patients participating in the study. We will also observe changes in medical care plan, primary care physician follow up, number of falls, fall related injurtes, recurrent strokes, ED visits, and hospital readmissions. **Methods** This is a prospective, feasibility pilot study conducted at a single site. Stroke patients admitted to an inpatient rehabilitation department of a Houston Comprehensive Stroke Center will be recruited by the principal investigator (PI) and/or bilingual research coordinator. The PI and/or bilingual research coordinator will obtain informed consent from either patient or, if patient is unable to consent due cognitive impairment, patient's caregiver. The patients and their caregivers will be loaned an iPad age with data plan and instructed in the use of IT approved videoconferencing application. This <sup>22</sup> inpatient rehabilitation department of a Houston Comprehensive Stroke Center will be recruited by with data plan and instructed in the use of IT approved videoconferencing application. This application includes build in security to help keep patient confidential, and also allows us the ability to speak with and visually assess stroke patients in their home for problems including speech difficulty, arm or leg weakness, or gait disturbance. All videoconference calls are conducted in a private office setting to protect patient information. Subjects will be given advance notification of their weekly TR home visit appointment times at discharge as well as complimentary medication p box organizer. We will monitor compliance with participation in each TR home visit. Following 6 TR home visits, stroke patients and/or caregivers will be surveyed to assess program acceptability 

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and satisfaction with care. We expect the study to last 24 months. Eligibility Criteria This study will be enrolling patients from an inpatient rehabilitation unit of a Houston comprehensive, certified stroke center. A large percentage of our patient population includes uninsured, Spanish speaking, and rural patients who are particularly underserved. These patients have nologies a higher rate of stroke and poorer post-stroke outcomes. 

Entry criteria are structured to enroll adult male and female patients with newly diagnosed ischemic stroke or mixed ischemic stroke, requiring assistance in at least one Activity of Daily Living (ADL) at the time of enrollment, with caregiver support and who were previously 54 independent, living in the community as Texas resident, and English and / or Spanish speaking. Full detailed study inclusion and exclusion criteria are shown in Figure 1. 

BMJ Open: first published as 10.1136/bmjopen-2017-017340 on 3 September

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## **Intervention: TR Home visit**

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Participants enrolled in the study will receive weekly TR home visits by a team of rehabilitation alists who may have been involved in the care of the patient during their hospital stay. The alists who may have been involved in the care of the patient during their hospital stay. The it this team may provide is seamless continuity of care and more efficient evaluation of follow ues. The order of contact by specialists is based on what we consider to be the most critical for nting recurrent stroke, fall related injuries, and other secondary complications. During the e of the study, a revision was made to have the ability to change the order of calls based on ht's needs. Full detailed study intervention scheme is shown in Figure 2. On week 1, the pharmacist will use videoconference to visually assess the patient's ability to madiantian mill have arganizer paraent mediantian reful and reasons for paraent linear 10 specialists who may have been involved in the care of the patient during their hospital stay. The 11 12 benefit this team may provide is seamless continuity of care and more efficient evaluation of follow 13 <sup>14</sup> up issues. The order of contact by specialists is based on what we consider to be the most critical preventing recurrent stroke, fall related injuries, and other secondary complications. During the 15 16 course of the study, a revision was made to have the ability to change the order of calls based on 17 patient's needs. Full detailed study intervention scheme is shown in Figure 2. 18

19 20 <sup>22</sup> including medication cost or side effects. The pharmacist will also recommend generic or alternate medications as indicated, and educate patients on the importance of antiplatelet medications and 24 Hmg-CoA reductase inhibitors for secondary stroke prevention. On week 2, physical/occupational 25 26 therapists (PT/OT) will use videoconferencing to visually assess patients in the home environment. 27 implement strategies to reduce fall risks such as adjusting equipment, and administer a fall related 28 self-efficacy scale (assess fear of falling) and a reintegration to normal living index (assess patient a 29 30 quality of life). On week 3, a speech therapist (ST) will use visual information to identify choking 31 coughing, delayed swallow to assess risk for aspiration pneumonia as well as administer cognitive 32 screening via the MoCA score. On week 4, the stroke rehabilitation physician will visually exami 33 34 patient via videoconference and identify signs of recurrent stroke, fall related injury, provide 35 assessment of common factors leading to falls including urinary tract infection, pneumonia, deep 36 37 venous thrombosis, and seizure. Stroke rehabilitation physician will assess for stability or 38 improvement in blood pressure, blood sugar, and other laboratory values through patient reports and 39 medical record review. On week, 5, the social worker will assess whether patients received 40 41 education on programs for the indigent, went to their doctor/therapy appointments, and obtained al 42 necessary equipment, and assess patient for depression via PHQ9 depression screen. On week 6, ad 43 geriatrician with specialty training in osteoporosis and fracture prevention will administer the FRAS 44 45 questionnaire for assessment and offer recommendations on prevention of bone fractures. On week 46 an epidemiologist will administer a patient satisfaction survey. The epidemiologist will also ask 47 48 whether we addressed patient's/caregiver's concerns, if the intervention saved patients time and 49 money, and identify if patients had any falls, new strokes, ED visits, or readmission to the hospital 50 Epidemiologist will also administer fall related self-efficacy scale and reintegration to normal living 51 Epidemiologist will also administer fall related self-efficacy scale and reintegration to normal living index for the second time on week 7 to observe change in fear of falling and quality of life previously measured on week 2. In case of medical emergencies during a TR home visit session, all providers will be given training via educational manual on when to direct patient and/or families to call 911 for emergency.
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# **Primary outcomes**

The primary feasibility outcomes include patient/caregiver participation with all 6 TR home visit interventions and acceptability of TR home visits by patients and caregivers measured via satisfaction survey. Additional data collected to plan for future randomized controlled trial are shown in Figure 3.

# Sample size

A sample size of 50 is selected for this feasibility study, based on an estimate of the number of available patients who would meet the inclusion/exclusion criteria during the planned study period. Between August 2013 and August of 2014, there were 121 stroke patients admitted to our rehab unit. Of these, 80 had ischemic stroke and 41 had hemorrhagic stroke. Excluding those who were discharged to another facility or enrolled in other studies, we estimate we will have 50 eligible patients over a 24 month period.

# Statistical analyses

Descriptive statistics will be performed on the enrolled patient population. Primary feasibility aims include calculating proportion of patients who completed all 6 TR Home visits, and various levels of compliance i.e. 6/6, 5/6, and so on. We will also determine if there are particular sessions that cannot be completed. Patient satisfaction surveys will be tallied to obtain a satisfaction score and the proportion of patients with mean satisfaction score>70%.

We will also assess factors that affect patient/caregiver participation and program compliance such as category/level of education, race/ethnicity, gender, age, type of deficit, geographic location and insurance. These factors will be assessed as predictors in analysis of variance (ANOVA), with number of sessions as the continuous dependent variable. Statistically significant differences (p<.05) between levels of these variables will inform us of their impact on participation rates.

# Data monitoring

Data quality control includes data checks on written case report form and transcription into electronic database by PI, research coordinator, and data analyst. The electronic database also contains status of completed or missing reports.

As this study involves TR Home visit videoconference sessions, primary risk includes maintaining confidentiality which we protect by conducting all sessions in private settings, and using University IT approved security application.

# Discussion

Transitional care of stroke rehabilitation patients is an important issue. Cognitive and physical deficits, rural location, lack of socioeconomic resources are all factors that contribute to poor physician and therapy follow up post-discharge, leading to poorer stroke outcomes and permanent disability. The main goal of TM-SAFER feasibility study is to provide patient/caregiver access to healthcare resources, specifically rehabilitation specialists, during the critical post-discharge period. While most telerehabilitation studies focus on improving physical function in chronic stroke patients who may have already developed secondary complications, our study focuses on educating stroke survivors and their caregivers to adopt strategies that will empower them to maintain or improve their function and quality of life before complications develop. Furthermore, most telerehabilitation studies do not incorporate a multidisciplinary team of rehabilitation specialists who may be able to address specific concerns that are unique to stroke survivors. While many clinicians may be concerned about the accuracy of evaluation via videoconferencing technology as opposed to in person visits, and possible liabilities, it is important to note that this intervention is not intended as a substitute for in person care. Rather, it is an important supplement, that enhances communication, and provides valuable information to patients and families struggling in the community to obtain the services they desperately need.

If the TR home visit study intervention is found to be feasible and acceptable to stroke patients, it may provide a means of making future care of stroke rehabilitation patients in the community more efficient and patient friendly. It also may provide a means for rehabilitation providers to intercept medical problems quickly, thereby preventing worse outcomes related to recurrent strokes, falls, fall related injuries, and hospital readmission. Future research is needed to determine whether TR home visits are effective in improving stroke outcomes and whether policy changes on reimbursements for TR services for healthcare professionals and possibly expansion of TR services beyond state lines is warranted.

# Footnotes

**Contributors:** MMJ is principal investigator of the study and drafted the paper. All of the coauthors contributed to the study design and completion of the manuscript. Specifically, RBG contributed to data analysis considerations. MMJ, RBG, NR, KK, MG, PS, KV carried out interventions and contributed to measureable outcomes included in the study. FV and AT contributed to database management. AT coordinated intervention sessions. MS, JG, SS served as senior mentors overseeing the project throughout its development. All authors were involved in the final approval of the article.

**Funding:** Telemedicine Guided Education on Fall and Secondary Stroke Prevention is investigator initiated. Funding and sponsorship of the study is provided by TIRR (The Institute for Rehabilitation and Research), grant number 8153101-02, and Lone Star Stroke Consortium.

# Competing interests: None declared

**Ethics approval:** Institutional Review Board and Committee on Protection of Human Subjects, Houston, Texas, IRB NUMBER: HSC-MS-14-0994.

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BMJ Open: first published as 10.1136/bmjopen-2017-017340 on 3 September 2017. Downloaded from http://bmjopen.bmj.com/ on June 7, 2025 at Agence Bibliographique de I Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.



### Figure 1: Study Identification, Inclusion & Exclusion Criteria

Figure 1: Study Identification, Inclusion & Exclusion Criteria

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Pharmacy

Week 1

Epidemiologist Week 7

#### Figure 2: Telerehabilitation (TR) Home Intervention after Discharge from Inpatient Rehabilitation TR Home Visit Potential Problems Potential Solutions

Unable to set up pill box Unable to afford med

Adverse med side effect

Pharmacist educates patient/caregiver Pharmacist prescribes generic

MD prescribes alternate

TR home visits not effective Brainstorm ways to improve

Figure 2: Telerehabilitation (TR) Home Intervention after Discharge from Inpatient Rehabilitation

215x279mm (200 x 200 DPI)





Figure 3. Telerehabilitation Data Collection

165x153mm (150 x 150 DPI)

# **BMJ Open**

## Telemedicine Guided Education on Secondary Stroke and Fall Prevention Following Inpatient Rehabilitation for Texas Stroke Patients and their Caregivers: A Feasibility Pilot Study

Journal:	BMJ Open
Manuscript ID	bmjopen-2017-017340.R1
Article Type:	Protocol
Date Submitted by the Author:	13-Jun-2017
Complete List of Authors:	Jhaveri, Mansi; University of Texas Health Science Center at Houston, PM&R Benjamin-Garner, Ruby; University of Texas Health Sciences Center Houston, McGovern Medical School, Center for Clinical and Translational Sciences, Department of Internal Medicine Rianon, Nahid; University of Texas Health Sciences Center Houston, McGovern Medical School, Geriatric Medicine Division, Department of Internal Medicine Sherer, Mark; TIRR Memorial Hermann Hospital, Memorial Herman Rehabilitation Network Francisco, Gerard ; University of Texas Health Science Center Houston, McGovern Medical School, Department of Physical Medicine and Rehabilitation, TIRR Memorial Hermann/Memorial Hermann Rehabilitation Network Vahidy, Farhaan; University of Texas Health Sciences Center Houston, McGovern Medical School, Department of Neurology and Institute for Stroke and Cerebrovascular Disease Kobayashi, Kayta; University of Texas Health Science Center Houston, McGovern Medical School, Pharmacy Division, TIRR Memorial Hermann Gaber, Mary; Memorial Hermann Texas Medical Center, Occupational Therapy Division, Inpatient Rehabilitation Shoemake, Paige; University of Texas Health Science Center Houston, McGovern Medical School, Speech Language Pathology Division, Memorial Hermann Vu, Kim; University of Texas Health Science Center Houston, McGovern Medical School, Department of Neurology Grotta, James; University of Texas Health Science Center Houston, McGovern Medical School, Department of Neurology Grotta, James; University of Texas Health Science Center Houston, McGovern Medical School, Department of Neurology Grotta, James; University of Texas Health Science Center Houston, McGovern Medical School, Department of Neurology Grotta, James; University of Texas Health Science Center Houston, McGovern Medical School, Department of Neurology Grotta, James; University of Texas Health Science Center Houston, McGovern Medical School, Department of Neurology Grotta, James; University of Texas Health Science Center Houston, McGovern Medical School, Departme
<b>Primary Subject Heading</b> :	Rehabilitation medicine

Secondary Subject Heading:	Neurology
Keywords:	Stroke < NEUROLOGY, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, REHABILITATION MEDICINE, NEUROLOGY, Protocol guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT
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# Protocols

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Telemedicine Guided Education on Secondary Stroke and Fall Prevention Following Inpatient Rehabilitation for Texas Stroke Patients and their Caregivers: A Feasibility Pilot Study

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 <sup>11</sup> Department of stroke leaves many consequences including cognitive deficits and falls due to imbalance. Stroke survivors and families struggle to navigate the complex healthcare system with flittle assistance post-hospital discharge, often leading to early hospital readmission and worse stroke outcomes. Telemedicine Guided Education on Secondary Stroke and Fall Prevention Following Inpatient Rehabilitation (TM-SAFER) feasibility study examines whether stroke survivors and therefore and education by a multidisciplinary team after discharge from inpatient rehabilitation.
 *Methods and Analysis* A prospective, single arm, pilot study is designed to evaluate the feasibility of weekly TR home visits initiated post-discharge from inpatient rehabilitation. Newly diagnosed stroke patients are recruited 44 Introduction
 45 The aftermath of stroke leaves many consequences including cognitive deficits and falls due to
 46 imbalance. Stroke survivors and families struggle to navigate the complex healthcare system with
 48 little assistance post-hospital discharge, often leading to early hospital readmission and worse struct
 49 outcomes. Telemedicine Guided Education on Secondary Stroke and Fall Prove
 51 Inpatient Rehabilitation (TM-SAFER) feasibility study event
 52 caregivers find value in Telerehability

<sup>54</sup> education by a multidisciplinary team after discharge from inpatient rehabilitation.

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56 57 58 initiated post-discharge from inpatient rehabilitation. Newly diagnosed stroke patients are recruited 59 from a Houston based comprehensive stroke center inpatient rehabilitation unit, loaned an iPad with 60

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- BMJ Open: first published as 10.1136/bmjopen-2017-017340 on 3 September 2017. Enseignen data plan, and trained to use IT security approved videoconferencing application. After hospital discharge, 6 weekly TR home visits are led by rotating specialists (pharmacist, physical/occupational therapist, speech therapist, rehabilitation physician, social worker, geriatrician specialized in fracture prevention) followed by satisfaction survey on week 7. Specialists visually assess patients in real time, educate them on secondary stroke and fall prevention, and suggest ways to improve function including direct medical interventions when indicated. Primary outcomes are proportion of eligible patients consenting to the study, participation rate in all 6 TR home visits, and satisfaction score. The study started December 31, 2015 with plan to enroll up to 50 patients over 24 months. Feasibility ected by 14 study results will inform us as to whether a randomized controlled trial is warranted to determine efficacy of TR home visit intervention in improving stroke outcomes. *Ethics and Dissemination* Ethics approval obtained by Institutional Review Board, Committee for the Protection of Human Subjects, IRB NUMBER: HSC-MS-14-0994. Study results will be submitted for publication in a pegefficacy of TR home visit intervention in improving stroke outcomes. 18 Ethics approval obtained by Institutional Review Board, Committee for the Protection of Human luding for uses reviewed journal. <sup>22</sup> Key words: stroke, rehabilitation, telemedicine, neurology, protocols Strengths and Limitations of this Study <u>gths</u> <u>gths</u> Study incorporates a multidisciplinary team of specialists who have the opportunity intervene on medical problems for stroke rehabilitation patients discharged to the communit
  - The study population includes underserved stroke rehabilitation patients who may discussion uninsured, living in rural locations, and Spanish speaking with limited access to healthcare The study population includes underserved stroke rehabilitation patients who may resources.
  - The study uses an IT security approved videoconferencing application and conducts all

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**Strengths** 

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 The study uses an IT security approved videoconferencing application and conducts all home visits in a private setting to protect patient confidentiality.
 *Limitations* 
 The videoconferencing application may be difficult for older or cognitively impaired streaking patients to use, and may require caregiver assistance.
 The videoconferencing technology may not work in rural locations with poor reception.

 Background

 Stroke survivors and their caregivers tackle numerous barriers after hospital discharge including cognitive / physical disability, rotation of caregivers, social isolation, lack of socioeconomic resources, and geographical constraints which may limit their access to follow up healthcare and patients at risk for further disability and hospital readmission.<sup>1,2</sup> Despite the expansive manpower and resources invested, 14% of ischemic stroke patients discharged from the hospital are readmitted within 30 days.<sup>3</sup> According to a randomized controlled trial on a post discharge follow-up service for stroke survivors, hospital readmission is common, and follow-up intervention after discharge is a way to prevent readmission for patients, particularly in those with long inpatient rehabilitation.<sup>1</sup> 

However, under the present system, we have not developed enough transitional care programs that address the barriers preventing community stroke survivors from achieving their highest potential.

BMJ Open Page 4 of 13 ever, under the present system, we have not developed enough transitional care programs that ess the barriers preventing community stroke survivors from achieving their highest potential. One approach to fill this gap during the critical period between patient discharge from inpatient dilitation program to community is TR home visits. Various forms of telemedicine exist ding automated systems that trigger alerts, mobile apps, and videoconferencing sessions with ontact with a healthcare provider. The purpose of these various forms of telemedicine is to ase access to healthcare resources for patients who are often located at a distance from a hub cal center and cannot travel to visit their healthcare provider in person. Previous telemedicine is to improve transitional care have been conducted in diabetes<sup>4</sup>, renal transplant<sup>5</sup>, and heart roke population to improve lower extremity strength in veterans up to 2 years post stroke<sup>7</sup>, e depression and strain on stroke caregivers<sup>8</sup>, and incorporate telemedicine home based ilitation patients immediately after discharge from inpatient rehabilitation facility. TM-SAFER feasibility study brings the team of rehabilitation specialists to the patient's hor diately after hospital discharge to empower stroke survivors. By weekly communication via conferencing application on iPad, patients have the opportunity to receive individualized card different rahabilitation gapilication dividualized card to a strain on stroke and the programs focused on directly intervening with stroke different rahabilitation agenciliets including a patients have the opportunity to receive individualized card different rahabilitation agenciliets including a patient should be approach and the programs focused on directly intervening with stroke different rahabilitation agenciliets including a patient should be approach and the programs focused on directly intervening with stroke different rahability or cerving the programs focus and the programs focus and the programs focus and th rehabilitation program to community is TR home visits. Various forms of telemedicine exist including automated systems that trigger alerts, mobile apps, and videoconferencing sessions with 1:1 contact with a healthcare provider. The purpose of these various forms of telemedicine is to increase access to healthcare resources for patients who are often located at a distance from a hub medical center and cannot travel to visit their healthcare provider in person. Previous telemedicine studies to improve transitional care have been conducted in diabetes<sup>4</sup>, renal transplant<sup>5</sup>, and heart studies to improve transitional care have been conducted in diabetes<sup>4</sup>, renal transplant<sup>5</sup>, and heart failure populations<sup>6</sup>, and have shown promising results including a 21% reduction in hospital failure populations<sup>6</sup>, and have shown promising results including a 21% reduction in hospital readmission rate for remotely monitored heart failure patients. Telemonitoring has also been used in rehabilitation in stroke patients up to 2 years post stroke<sup>9</sup>. However, there are currently no transitional care telemedicine education home programs focused on directly intervening with stroke rehabilitation patients immediately after discharge from inpatient rehabilitation facility. 

immediately after hospital discharge to empower stroke survivors. By weekly communication via videoconferencing application on iPad, patients have the opportunity to receive individualized care with different rehabilitation specialists including pharmacist, physical/occupational therapist, speed therapist, rehabilitation physician, social worker, and geriatrician specialized in fracture prevention These are specialists who may have been involved in the patient's care while in the hospital and ca provide continued follow up of medical issues, and when required, direct medical interventions in order to prevent events that could lead to hospital readmission. The primary purpose of this mining feasibility pilot study is to determine if stroke survivors are able to participate in TR home visits immediately post-hospital discharge, and whether stroke survivors and their families find these sessions valuable. We are seeking to determine what portion of persons with stroke would consent to this type of study. We are also evaluating what portion of patients have wireless reception of sufficient quality to support the TR Home visits. We are examining whether this povel sufficient quality to support the TR Home visits. We are examining whether this novel videoconferencing technology is accessible for the typical stroke population. This older population may have more limited experience with iPad or similar technologies than the general population. They are likely to have cognitive, motor, and/or sensory deficits which may complicate their abilit to use this technology. They may view TR home visits as intrusive. We seek to determine what portion of participants (persons with stroke and caregivers) believe that TR home visits increase access to healthcare resources, intercept medical problems early on, save time and money, protect confidentiality, and offer patients / caregivers the opportunity to ask questions that are specific to their recovery. 

### **Objectives**

- 58 Primary Objectives

This prospective feasibility study is evaluating several feasibility objectives, including the proportion of eligible patients who consent to the study, patient compliance and satisfaction with a TR home visit intervention led by a multidisciplinary team in the first 6 weeks after discharge from inpatient rehabilitation. We hypothesize that the majority of eligible patients approached for the study will consent, and that at least 70% of participants will complete all 6 TR home visits. Additionally, we anticipate that 80% of participants will report satisfaction with TR home visits at the level of 70% or Protected by copyright more. Our goal is to provide valuable transitional rehabilitation care for stroke survivors through weekly contact with specialty rehabilitation providers and identify various reasons patients may or may not find the study intervention beneficial. 

### Secondary Objectives

This feasibility study will provide important data for sample size estimates and inform on logistics for a future randomized controlled trial. We plan to observe percent medication refill aspiration risk via swallow evaluation<sup>10</sup>, Montreal Cognitive Assessment (MoCA) score<sup>11</sup>, change in Patient Health Questionnaire (PhQ9) Depression Screen Scores<sup>12</sup>, Falls Self Efficacy Scale Scores<sup>13</sup>, Reintegration to Normal Living Index scores<sup>14</sup>, and Fracture Risk Assessment Tool (FRAX scores<sup>15</sup> to assess fracture risk in patients participating in the study. We will also observe change嘉勇 medical care plan, primary care physician follow up, number of falls, fall related injuries, recurre 

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medical care plan, primary care physician follow up, number of falls, fall related injuries, recurrence of strokes, Emergency Department (ED) visits, and hospital readmissions.
Methods
This is a prospective, feasibility pilot study conducted at a single site from December 31, 2015 – and the second of the principal investigator (PI) and/or bilingual research coordinator The PI and/or bilingual research coordinator will obtain informed consent from the patient is unable to consent due to cognitive impairment, patient's caregiver.
Total number of patients eligible for study who refuse to consent, and reasons for refusal, will be instructed in the use of IT approved videoconferencing application. This application includes builtain includes buil security to maintain patient confidentiality, and also allows us the ability to speak with and visually assess stroke patients in their home for problems including speech difficulty, arm or leg weakness, br gait disturbance. All videoconference calls are conducted in a private office setting to protect patient information. Participants will be given advance notification of their weekly TR home visit appointment times at discharge as well as complimentary medication pill box organizer. We will monitor compliance with participation in each TR home visit. Following 6 TR home visits, stroke patients and/or caregivers will be surveyed to assess program acceptability and satisfaction with care. At the end of the study, participants are asked to return the iPad via provided pre-addressed stamped envelope. We expect the study to last 24 months. 

### **Eligibility Criteria**

This study will be enrolling patients from an inpatient rehabilitation unit of a Houston comprehensive, certified stroke center. A large percentage of our patient population includes uninsured, Spanish speaking, and rural patients who are particularly underserved. These patients hav a higher rate of stroke and poorer post-stroke outcomes.

Entry criteria are structured to enroll adult male and female patients with newly diagnosed ischemic stroke or mixed ischemic stroke, requiring assistance in at least one Activity of Daily 10 Living (ADL) at the time of enrollment, with caregiver support and who were previously 11 12 independent, living in the community as Texas resident, and English and / or Spanish speaking. 13 detailed study inclusion and exclusion criteria are shown in Figure 1. 14 15

### 17 **Intervention: TR Home visit** 18 19

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Protected by copyright, including 20 Participants enrolled in the study will receive weekly TR home visits by a team of rehabilitation 21 specialists who may have been involved in the care of the patient during their hospital stay. The 22 benefit this team may provide is seamless continuity of care and more efficient evaluation of follow 23 24 <sup>24</sup><sub>25</sub> up issues. The order of contact by specialists is based on what we consider to be the most critical f 26 preventing recurrent stroke, fall related injuries, and other secondary complications. During the related 27 course of the study, a revision was made to have the ability to change the order of calls based on 28 patient's needs. Full detailed study intervention scheme is shown in Figure 2. 6 29

On week 1, the pharmacist will use videoconference to visually assess the patient's ability to 30 31 set up a medication pill box organizer, percent medications refilled, and reasons for noncompliance 32 <sup>33</sup> including medication cost or side effects. The pharmacist will also recommend generic or alternat 34 medications as indicated, and educate patients/caregivers on the importance of antiplatelet 35 medications and Hmg-CoA reductase inhibitors for secondary stroke prevention. On week 2, 36 37 physical/occupational therapists (PT/OT) will use videoconferencing to visually assess patients in the 38 home environment, implement strategies to reduce fall risks such as adjusting equipment, and administer a falls self efficacy scale (assess fear of falling) and a reintegration to normal living index 39 40 41 (assess patient quality of life). On week 3, a speech therapist (ST) will use visual information to 42 and  $\frac{1}{43}$  identify choking, coughing, delayed swallow to assess risk for aspiration pneumonia as well as administer cognitive screening via the MoCA score. On week 4, the stroke rehabilitation physicia 44 45 will visually examine patient via videoconference and identify signs of recurrent stroke, fall related 46 injury, provide assessment of common factors leading to falls including urinary tract infection, pneumonia, deep venous thrombosis, and seizure. Stroke rehabilitation physician will assess for stability or improvement in blood pressure, blood sugar, and other laboratory values through patient 47 48 49 50 reports and medical record review. On week, 5, the social worker will assess whether 51 52 patients/caregivers received education on programs for the indigent, went to-doctor/therapy 53 <sup>54</sup> appointments, and obtained all necessary equipment. In addition, the social worker will assess the 55 patient for depression via PHQ9 depression screen. On week 6, a geriatrician with specialty training 56 in osteoporosis and fracture prevention will administer the FRAX questionnaire for assessment and 57 58 offer recommendations on prevention of bone fractures. On week 7, an epidemiologist will 59 administer a patient satisfaction survey. The survey will assess whether we addressed 60

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patient's/caregiver's concerns, if the intervention saved patients time and money, and identify if patients had any falls, new strokes, ED visits, or readmission to the hospital. Epidemiologist will also administer falls self efficacy scale and reintegration to normal living index for the second time on week 7 to observe change in fear of falling and quality of life previously measured on week 2. In case of medical emergencies during a TR home visit session, all providers will be given training via educational manual on when to direct patient and/or families to call 911 for emergency. Research coordinator will be in contact with study participants for the duration of the study, and will relay any important issues to the rehabilitation physician who will then communicate with the rest of the team for follow up as needed.
Primary outcomes
The primary feasibility outcomes include response rate, defined as proportion of eligible patients who will the new visit interventions; and acceptability of TR home visits by patients and caregivers measured via satisfaction survey. Additional data collection of pain for future randomized controlled trial are shown in Figure 3.

to plan for future randomized controlled trial are shown in Figure 3. 

#### Sample size

A sample size of 50 is selected for this feasibility study, based on an estimate of the number of available patients who would meet the inclusion/exclusion criteria during the planned study period Between August 2013 and August of 2014, there were 121 stroke patients admitted to our rehab ung Of these, 80 had ischemic stroke and 41 had hemorrhagic stroke. Excluding those who were discharged to another facility and enrolled in other studies, we estimate we will have up to 50 eligi ining, patients over a 24 month period. 

### Statistical analyses

l training, Descriptive statistics will be performed on the enrolled patient population. Assessment of primary and feasibility aims include: 1) Calculating the response rate as number of eligible patients divided by number who consented 2) Calculating proportion of patients who completed all 6 TR Home visits. and various levels of compliance i.e. 6/6, 5/6, and so on. We will also determine if there are particular sessions that cannot be completed. 3) Patient satisfaction surveys will be tallied to obtain nologies satisfaction score and the proportion of patients with mean satisfaction score>70%. 

We will also assess factors that may affect patient/caregiver participation and program compliance such as category/level of education, race/ethnicity, gender, age, type of deficit, geographic location and insurance. These factors will be assessed as predictors in analysis of variance (ANOVA), with number of sessions as the continuous dependent variable. Statistically significant differences (p<.05) between levels of these variables will inform us of their impact on participation rates. 

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# **Ethics and Dissemination**

Ethics approval was obtained by the Institutional Review Board, the Committee on Protection of Human Subjects, Houston, Texas. They judged the study design, ethics, risks and benefits, protection of patient confidentiality, data quality control, and analyses. After approval, the study was started at a Houston based comprehensive stroke center inpatient rehabilitation unit. The study IRB NUMBER: HSC-MS-14-0994.

A manuscript with the results of the study will be published in a peer-reviewed journal.

# Data monitoring

Data quality control includes data checks on written case report form and transcription into electronic database by PI, research coordinator, and data analyst. The electronic database also contains status of completed or missing reports.

# **Risks and Benefits**

As this study involves TR Home visit videoconference sessions, primary risk includes maintaining confidentiality which we protect by conducting all sessions in private settings, and using University IT approved security application. Patients and caregivers accrue benefits of having the team of health professionals who worked with them on the rehabilitation unit follow up with them during the period of transition to their home and community environment.

# Discussion

Transitional care of stroke rehabilitation patients is an important issue. Cognitive and physical deficits, rural location, lack of socioeconomic resources are all factors that contribute to poor physician and therapy follow up post-discharge, leading to poorer stroke outcomes and permanent disability. The main goal of TM-SAFER feasibility study is to provide patient/caregiver access to healthcare resources, specifically rehabilitation specialists, during the critical post-discharge period. While most telerehabilitation studies focus on improving physical ilar technologies function in chronic stroke patients who may have already developed secondary complications, our study focuses on educating stroke survivors and their caregivers to adopt strategies that will empower them to maintain or improve their function and quality of life before complications develop. Furthermore, most telerehabilitation studies do not incorporate a multidisciplinary team of rehabilitation specialists who may be able to address specific concerns that are unique to stroke survivors. While many clinicians may be concerned about the accuracy of evaluation via videoconferencing technology as opposed to in person visits, and possible liabilities, it is important to note that this intervention is not intended as a substitute for in person care. Rather, it is an important supplement, that enhances communication, and provides valuable information to patients and families struggling in the community to obtain the services they desperately need.

If the TR home visit study intervention is found to be feasible and acceptable to stroke patients, it may provide a means of making future care of stroke rehabilitation patients in the community more efficient and patient friendly. It also may provide a means for rehabilitation providers to intercept medical problems, thereby preventing worse outcomes related to recurrent strokes, falls, fall related injuries, and hospital readmission. Future research is needed to determine whether TR home visits are effective in improving stroke outcomes and whether policy changes on reimbursements for TR services for healthcare professionals and possibly expansion of TR services beyond state lines is warranted.

## **Footnotes**

**Contributors:** MMJ is principal investigator of the study and drafted the paper. All of the coauthors contributed to the study design and completion of the manuscript. Specifically, RBG contributed to data analysis considerations. MMJ, RBG, NR, KK, MG, PS, KV carried out interventions and contributed to measureable outcomes included in the study. FV and AT contributed to database management. AT coordinated intervention sessions. MS, JG, SS served as senior mentors overseeing the project throughout its development. All authors were involved in the final approval of the article.

**Funding:** Telemedicine Guided Education on Fall and Secondary Stroke Prevention is investigator initiated. Funding and sponsorship of the study is provided by TIRR (The Institute for Rehabilitation and Research), grant number 8153101-02, and Lone Star Stroke Consortium.

**Competing interests:** None declared

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**Figures** Legends

Figure 1 Study Identification, Inclusion & Exclusion Criteria

Figure 2 Telerehabilitation (TR) Home Intervention after Discharge from Inpatient itation Data . **Rehabilitation** 

Figure 3 Telerehabilitation Data Collection





Figure 1 Study Identification, Inclusion & Exclusion Criteria

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Figure 2 Telerehabilitation (TR) Home Intervention after

Potential Problems

Unable to afford med

Adverse med side effect

Potential Solutions

MD prescribes alternate

Encourages smoking cessation

Brainstorm ways to improve

Pharmacist recommends generic

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- Therapy Week 2
- Fall related injury Physical, Referred to MD Occupational Improperly fitted equipment Taught how to adjust device Unsafe areas in the home Educated on how to fix

**Discharge from Inpatient Rehabilitation** TR Home Visit

Pharmacy

Week 1

Epidemiologist

Week 7

- ORDER OF Aspiration risk Speech Therapy Speech therapist amends diet TR CALLS Referred to MD for work up Week 3 Diminished cognition MAY BE SWITCHED DEPENDING Rehabilitation Elevated BP/blood sugar MD educates on reducing risk factors **ON PATIENT** Fall related injury Signs of recurrent stroke MD works up, PCP / ED referral Physician MD referral to ED NEED Week 4 Secondary complications MD works up, specialty referral Ie uti, dvt, pe Social If due to cost, refer charity program Not getting therapies/MD Referral to MD/psychosocial service Worker Depression risk Unable to get transport Referral to metrolift / other program Week 5 Unable to get disability Paperwork faxed No insurance Refer charity program High fracture risk MD orders bone density/calcium Geriatrician Educates on fracture prevention Week 6
  - MD, Medical Doctor; PCP, Primary Care Physician; BP, Blood Pressure; ED, Emergency Department; UTI, Urinary Tract Infection; DVT, Deep Venous Thrombosis; PE, Pulmonary Embolism.

TR home visits not effective

Figure 2 Telerehabilitation (TR) Home Intervention after Discharge from Inpatient Rehabilitation

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RCT, Randomized Controlled Trial; MoCA, Montreal Cognitive Assessment; ER, Emergency Room; PCP, Primary Care Physician; PHQ-9 Patient Health Questionnaire; FRAX, Fracture Risk Assessment Tool; Response Rate, number of eligible patients divided by number consented; TR, Telerenhabilitation

Figure 3 Telerehabilitation Data Collection

215x279mm (300 x 300 DPI)