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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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Protocols

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 or imbalance. Stroke survivors and families fight to navigate the complex healthcare system with little assistance post-hospital discharge, often leading to early hospital readmission worse stroke outcomes. TM-SAFER feasibility study examines whether stroke survivors and their caregivers find 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

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3 hospital discharge, 6 weekly TR home visits are led by rotation of specialists (pharmacist,
4 physical/occupational therapist, speech therapist, rehabilitation physician, social worker, geriatrician
5 specialized in fracture prevention) followed by satisfaction survey administered by epidemiologist on
6 week 7. Specialists visually assess patients in real time, educate them on secondary stroke and fall
7 prevention, and suggest ways to improve function including direct medical interventions when
8 indicated. Primary outcomes include rate of patient/caregiver participation in all 6 TR home visits
9 and satisfaction score measured via surveys. The study started December 31, 2015 with plan to enroll
10 up to 50 patients over 24 months. Feasibility study results will inform us as to whether a randomized
11 controlled trial is warranted to determine efficacy of TR home visit intervention in improving stroke
12 outcomes.

16 ***Ethics and Dissemination***

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18 Ethics approval obtained by Institutional Review Board and Committee for the Protection of Human
19 Subjects, IRB NUMBER: HSC-MS-14-0994. Study results will be submitted for publication in a peer-
20 reviewed journal.

21
22 Key words: stroke, rehabilitation, telemedicine, neurology, protocols
23
24

25 **Strengths and Limitations of this Study**

- 27
28 • Study incorporates a multidisciplinary team of specialists who have the opportunity to
29 intervene quickly on medical problems for stroke rehabilitation patients discharged to the
30 community.
- 31
32 • The study population includes underserved stroke rehabilitation patients who may be
33 uninsured, living in rural locations, and Spanish speaking with limited access to healthcare
34 resources.
- 35
36 • The study uses an IT security approved videoconferencing application and conducts all TR
37 home visits in a private setting to protect patient confidentiality.
- 38
39 • The videoconferencing application may be difficult for older or cognitively impaired stroke
40 patients to use, and may require caregiver assistance.
- 41
42 • The videoconferencing technology may not work in rural locations with poor reception.
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45 **Background**

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48 Stroke survivors and their caregivers tackle numerous barriers after hospital discharge including
49 cognitive / physical disability, rotation of caregivers, social isolation, lack of socioeconomic
50 resources, and geographical constraints which may limit their access to follow up healthcare and put
51 patients at risk for further disability and hospital readmission.^{1,2} Despite the expansive manpower and
52 resources invested, 14% of ischemic stroke patients discharged from the hospital are readmitted
53 within 30 days.³ According to a randomized controlled trial on a post discharge follow-up service for
54 stroke survivors, hospital readmission is common, and follow-up intervention after discharge is a
55 way to prevent readmission for patients, particularly in those with long inpatient rehabilitation.¹
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3 However, under the present system, we have not developed enough transitional care programs that
4 address the barriers preventing community stroke survivors from achieving their highest potential.

5 One approach to fill this gap during the critical period between patient discharge from inpatient
6 rehabilitation program to community is TR home visits. Various forms of telemedicine exist
7 including automated systems that trigger alerts, mobile apps, and videoconferencing sessions with
8 1:1 contact with a healthcare provider. The purpose of these various forms of telemedicine is to
9 increase access to healthcare resources for patients who are often located at a distance from a hub
10 medical center and cannot travel to visit their healthcare provider in person. Previous telemedicine
11 studies to improve transitional care have been conducted in diabetes⁴, renal transplant⁵, and heart
12 failure populations⁶, and have shown promising results including a 21% reduction in hospital
13 readmission rate for remotely monitored heart failure patients. Telemonitoring has also been used in
14 the stroke population to improve lower extremity strength in veterans up to 2 years post stroke⁷,
15 reduce depression and strain on stroke caregivers⁸, and incorporate telemedicine home based
16 rehabilitation in stroke patients up to 2 years post stroke⁹. However, there are currently no
17 transitional care telemedicine education home programs focused on directly intervening with stroke
18 rehabilitation patients immediately after discharge from inpatient rehabilitation facility.

19 TM-SAFER feasibility study brings the team of rehabilitation specialists to the patient's home
20 immediately after hospital discharge to empower stroke survivors. By weekly communication via
21 videoconferencing application on iPad, patients have the opportunity to receive individualized care
22 with different rehabilitation specialists including pharmacist, physical/occupational therapist, speech
23 therapist, rehabilitation physician, social worker, and geriatrician specialized in fracture prevention.
24 These are specialists who may have been involved in the patient's care while in the hospital and can
25 provide continued follow up of medical issues, and when required, direct medical interventions in
26 order to prevent events that could lead to hospital readmission. The primary purpose of this
27 feasibility pilot study is to determine if stroke survivors are able to participate in TR home visits
28 immediately post-hospital discharge, and whether stroke survivors and their families find these
29 sessions valuable. We are looking at issues of whether this novel videoconferencing technology is
30 easy to use for this often older and cognitively impaired population. We also assessing whether
31 patients and caregivers feel that TR home visits increase access to healthcare resources, intercept
32 medical problems early on, save time and money, protect confidentiality, and offer patients /
33 caregivers the opportunity to ask questions that are specific to their recovery.

34 35 36 37 38 39 40 41 42 43 44 45 46 **Objectives**

47 48 49 *Primary Objectives*

50 This prospective feasibility study is evaluating patient compliance and satisfaction with a TR home
51 visit intervention led by a multidisciplinary team in the first 6 weeks after discharge from inpatient
52 rehabilitation. We hypothesize that at least 70% of patients will participate in all 6 TR home visits.
53 Additionally, we anticipate that 80% of patients will report satisfaction with TR home visits at the
54 level of 70% or more. Our goal is to provide valuable transitional rehabilitation care for stroke
55 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 plan to observe percent medication refill, aspiration risk via swallow evaluation¹⁰, MoCA cognitive score¹¹, and change in PhQ9 Depression Screen Scores¹², Fall Efficacy Scale Scores¹³, Reintegration to Normal Living Index scores¹⁴, and FRAX scores¹⁵ 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 injuries, 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 to cognitive impairment, patient's caregiver. The patients and their caregivers will be loaned an iPad 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 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. 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 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 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.

Intervention: TR Home visit

Participants enrolled in the study will receive weekly TR home visits by a team of rehabilitation specialists who may have been involved in the care of the patient during their hospital stay. The benefit this team may provide is seamless continuity of care and more efficient evaluation of follow up issues. The order of contact by specialists is based on what we consider to be the most critical for preventing recurrent stroke, fall related injuries, and other secondary complications. During the course of the study, a revision was made to have the ability to change the order of calls based on patient'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 set up medication pill box organizer, percent medication refill, and reasons for noncompliance 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 Hmg-CoA reductase inhibitors for secondary stroke prevention. On week 2, physical/occupational therapists (PT/OT) will use videoconferencing to visually assess patients in the home environment, implement strategies to reduce fall risks such as adjusting equipment, and administer a fall related self-efficacy scale (assess fear of falling) and a reintegration to normal living index (assess patient quality of life). On week 3, a speech therapist (ST) will use visual information to 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 physician will visually examine patient via videoconference and identify signs of recurrent stroke, fall related 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 reports and medical record review. On week 5, the social worker will assess whether patients received education on programs for the indigent, went to their doctor/therapy appointments, and obtained all necessary equipment, and assess patient for depression via PHQ9 depression screen. On week 6, a geriatrician with specialty training in osteoporosis and fracture prevention will administer the FRAX questionnaire for assessment and offer recommendations on prevention of bone fractures. On week 7, an epidemiologist will administer a patient satisfaction survey. The epidemiologist will also ask whether we addressed 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 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.

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.

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.

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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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Figure 1: Study Identification, Inclusion & Exclusion Criteria

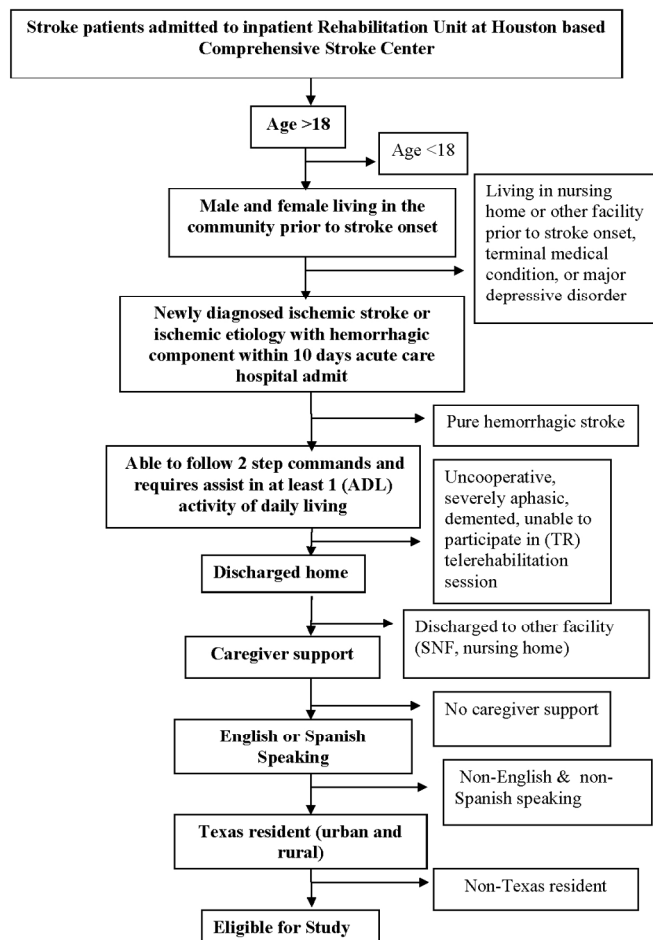


Figure 1: Study Identification, Inclusion & Exclusion Criteria

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

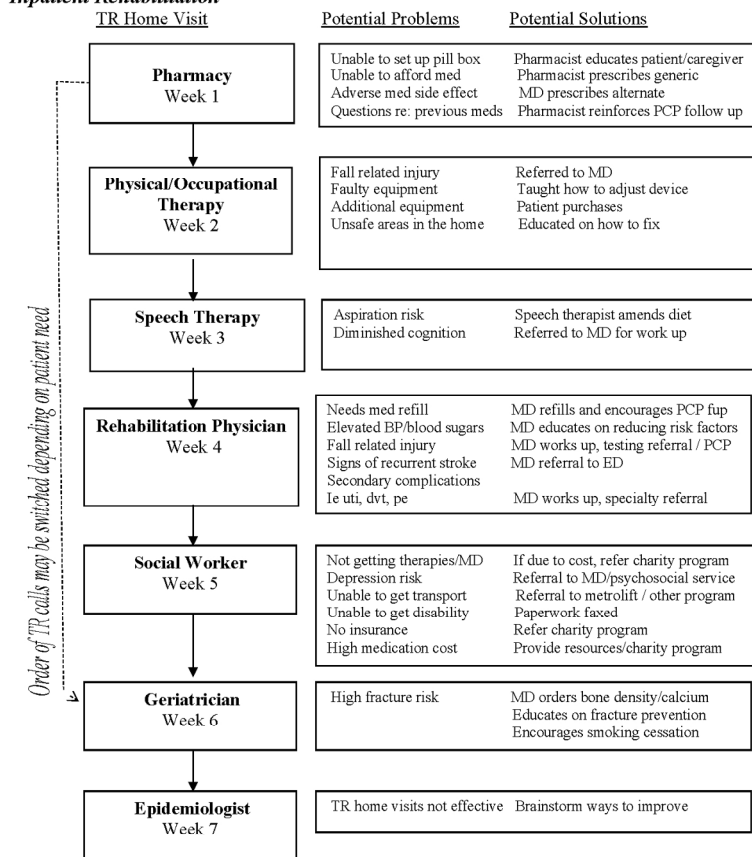


Figure 2: Telerehabilitation (TR) Home Intervention after Discharge from Inpatient Rehabilitation

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Figure 3. Telerehabilitation Data Collection

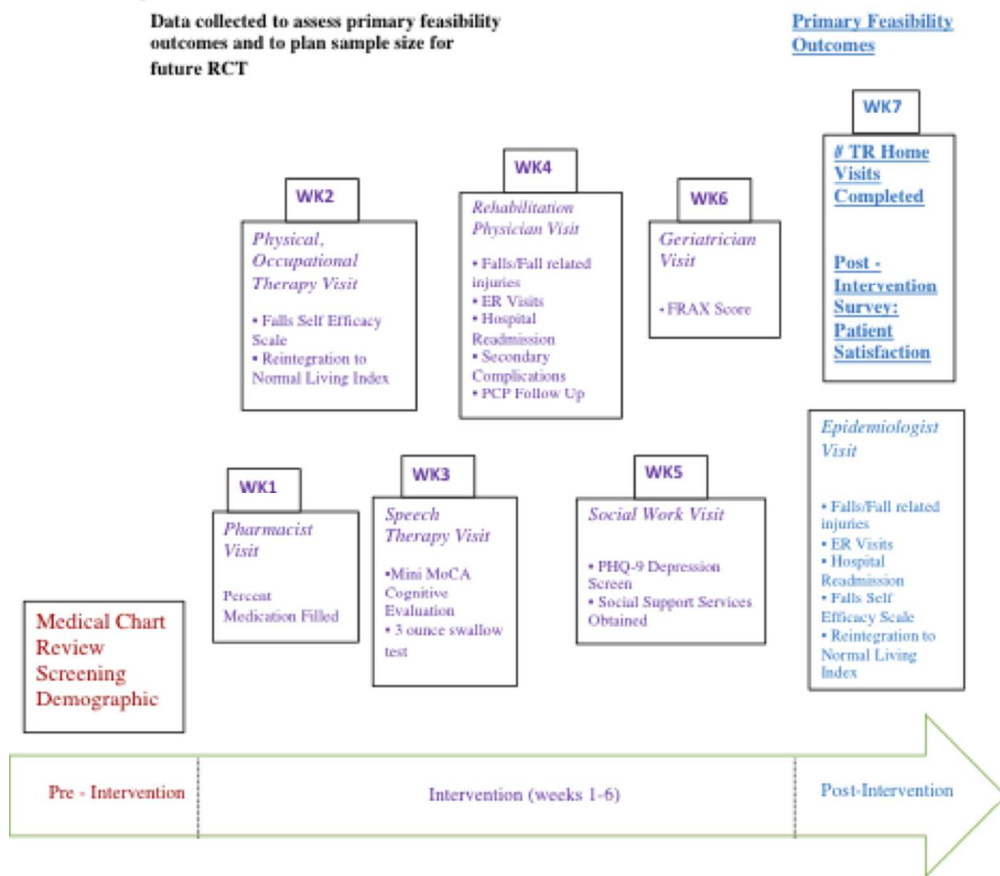


Figure 3. Telerehabilitation Data Collection

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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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Primary Subject Heading:	Rehabilitation medicine

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Protocols

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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Introduction

The aftermath 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 little 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 their caregivers find 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 stroke patients are recruited from a Houston based comprehensive stroke center inpatient rehabilitation unit, loaned an iPad with

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3 data plan, and trained to use IT security approved videoconferencing application. After hospital
4 discharge, 6 weekly TR home visits are led by rotating specialists (pharmacist, physical/occupational
5 therapist, speech therapist, rehabilitation physician, social worker, geriatrician specialized in fracture
6 prevention) followed by satisfaction survey on week 7. Specialists visually assess patients in real
7 time, educate them on secondary stroke and fall prevention, and suggest ways to improve function
8 including direct medical interventions when indicated. Primary outcomes are proportion of eligible
9 patients consenting to the study, participation rate in all 6 TR home visits, and satisfaction score. The
10 study started December 31, 2015 with plan to enroll up to 50 patients over 24 months. Feasibility
11 study results will inform us as to whether a randomized controlled trial is warranted to determine
12 efficacy of TR home visit intervention in improving stroke outcomes.
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15 ***Ethics and Dissemination***

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17 Ethics approval obtained by Institutional Review Board, Committee for the Protection of Human
18 Subjects, IRB NUMBER: HSC-MS-14-0994. Study results will be submitted for publication in a peer-
19 reviewed journal.
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22 Key words: stroke, rehabilitation, telemedicine, neurology, protocols
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25 **Strengths and Limitations of this Study**

26 **Strengths**

- 27 • Study incorporates a multidisciplinary team of specialists who have the opportunity to
28 intervene on medical problems for stroke rehabilitation patients discharged to the community.
- 29 • The study population includes underserved stroke rehabilitation patients who may be
30 uninsured, living in rural locations, and Spanish speaking with limited access to healthcare
31 resources.
- 32 • The study uses an IT security approved videoconferencing application and conducts all TR
33 home visits in a private setting to protect patient confidentiality.

34 **Limitations**

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

38 **Background**

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40 Stroke survivors and their caregivers tackle numerous barriers after hospital discharge including
41 cognitive / physical disability, rotation of caregivers, social isolation, lack of socioeconomic
42 resources, and geographical constraints which may limit their access to follow up healthcare and put
43 patients at risk for further disability and hospital readmission.^{1,2} Despite the expansive manpower and
44 resources invested, 14% of ischemic stroke patients discharged from the hospital are readmitted
45 within 30 days.³ According to a randomized controlled trial on a post discharge follow-up service for
46 stroke survivors, hospital readmission is common, and follow-up intervention after discharge is a
47 way to prevent readmission for patients, particularly in those with long inpatient rehabilitation.¹
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3 However, under the present system, we have not developed enough transitional care programs that
4 address the barriers preventing community stroke survivors from achieving their highest potential.

5 One approach to fill this gap during the critical period between patient discharge from inpatient
6 rehabilitation program to community is TR home visits. Various forms of telemedicine exist
7 including automated systems that trigger alerts, mobile apps, and videoconferencing sessions with
8 1:1 contact with a healthcare provider. The purpose of these various forms of telemedicine is to
9 increase access to healthcare resources for patients who are often located at a distance from a hub
10 medical center and cannot travel to visit their healthcare provider in person. Previous telemedicine
11 studies to improve transitional care have been conducted in diabetes⁴, renal transplant⁵, and heart
12 failure populations⁶, and have shown promising results including a 21% reduction in hospital
13 readmission rate for remotely monitored heart failure patients. Telemonitoring has also been used in
14 the stroke population to improve lower extremity strength in veterans up to 2 years post stroke⁷,
15 reduce depression and strain on stroke caregivers⁸, and incorporate telemedicine home based
16 rehabilitation in stroke patients up to 2 years post stroke⁹. However, there are currently no
17 transitional care telemedicine education home programs focused on directly intervening with stroke
18 rehabilitation patients immediately after discharge from inpatient rehabilitation facility.

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

40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 **Objectives**

56 57 58 *Primary Objectives*

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3 This prospective feasibility study is evaluating several feasibility objectives, including the proportion
4 of eligible patients who consent to the study, patient compliance and satisfaction with a TR home
5 visit intervention led by a multidisciplinary team in the first 6 weeks after discharge from inpatient
6 rehabilitation. We hypothesize that the majority of eligible patients approached for the study will
7 consent, and that at least 70% of participants will complete all 6 TR home visits. Additionally, we
8 anticipate that 80% of participants will report satisfaction with TR home visits at the level of 70% or
9 more. Our goal is to provide valuable transitional rehabilitation care for stroke survivors through
10 weekly contact with specialty rehabilitation providers and identify various reasons patients may or
11 may not find the study intervention beneficial.
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15 16 **Secondary Objectives**

17 This feasibility study will provide important data for sample size estimates and inform on the
18 logistics for a future randomized controlled trial. We plan to observe percent medication refill,
19 aspiration risk via swallow evaluation¹⁰, Montreal Cognitive Assessment (MoCA) score¹¹, and
20 change in Patient Health Questionnaire (PhQ9) Depression Screen Scores¹², Falls Self Efficacy Scale
21 Scores¹³, Reintegration to Normal Living Index scores¹⁴, and Fracture Risk Assessment Tool (FRAX)
22 scores¹⁵ to assess fracture risk in patients participating in the study. We will also observe changes in
23 medical care plan, primary care physician follow up, number of falls, fall related injuries, recurrent
24 strokes, Emergency Department (ED) visits, and hospital readmissions.
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30 **Methods**

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33 This is a prospective, feasibility pilot study conducted at a single site from December 31, 2015 –
34 December 31, 2017. Stroke patients admitted to an inpatient rehabilitation department of a Houston
35 Comprehensive Stroke Center are recruited by the principal investigator (PI) and/or bilingual
36 research coordinator. The PI and/or bilingual research coordinator will obtain informed consent from
37 either patient or, if patient is unable to consent due to cognitive impairment, patient's caregiver.
38 Total number of patients eligible for study who refuse to consent, and reasons for refusal, will be
39 recorded. The enrolled study patients and their caregivers will be loaned an iPad with data plan and
40 instructed in the use of IT approved videoconferencing application. This application includes built-in
41 security to maintain patient confidentiality, and also allows us the ability to speak with and visually
42 assess stroke patients in their home for problems including speech difficulty, arm or leg weakness, or
43 gait disturbance. All videoconference calls are conducted in a private office setting to protect patient
44 information. Participants will be given advance notification of their weekly TR home visit
45 appointment times at discharge as well as complimentary medication pill box organizer. We will
46 monitor compliance with participation in each TR home visit. Following 6 TR home visits, stroke
47 patients and/or caregivers will be surveyed to assess program acceptability and satisfaction with care.
48 At the end of the study, participants are asked to return the iPad via provided pre-addressed stamped
49 envelope. We expect the study to last 24 months.
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58 **Eligibility Criteria**

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3 This study will be enrolling patients from an inpatient rehabilitation unit of a Houston
4 comprehensive, certified stroke center. A large percentage of our patient population includes
5 uninsured, Spanish speaking, and rural patients who are particularly underserved. These patients have
6 a higher rate of stroke and poorer post-stroke outcomes.
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8 Entry criteria are structured to enroll adult male and female patients with newly diagnosed
9 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 independent, living in the community as Texas resident, and English and / or Spanish speaking. Full,
12 detailed study inclusion and exclusion criteria are shown in Figure 1.
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18 **Intervention: TR Home visit**

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21 Participants enrolled in the study will receive weekly TR home visits by a team of rehabilitation
22 specialists who may have been involved in the care of the patient during their hospital stay. The
23 benefit this team may provide is seamless continuity of care and more efficient evaluation of follow
24 up issues. The order of contact by specialists is based on what we consider to be the most critical for
25 preventing recurrent stroke, fall related injuries, and other secondary complications. During the
26 course of the study, a revision was made to have the ability to change the order of calls based on
27 patient's needs. Full detailed study intervention scheme is shown in Figure 2.
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30 On week 1, the pharmacist will use videoconference to visually assess the patient's ability to
31 set up a medication pill box organizer, percent medications refilled, and reasons for noncompliance
32 including medication cost or side effects. The pharmacist will also recommend generic or alternate
33 medications as indicated, and educate patients/caregivers on the importance of antiplatelet
34 medications and Hmg-CoA reductase inhibitors for secondary stroke prevention. On week 2,
35 physical/occupational therapists (PT/OT) will use videoconferencing to visually assess patients in the
36 home environment, implement strategies to reduce fall risks such as adjusting equipment, and
37 administer a falls self efficacy scale (assess fear of falling) and a reintegration to normal living index
38 (assess patient quality of life). On week 3, a speech therapist (ST) will use visual information to
39 identify choking, coughing, delayed swallow to assess risk for aspiration pneumonia as well as
40 administer cognitive screening via the MoCA score. On week 4, the stroke rehabilitation physician
41 will visually examine patient via videoconference and identify signs of recurrent stroke, fall related
42 injury, provide assessment of common factors leading to falls including urinary tract infection,
43 pneumonia, deep venous thrombosis, and seizure. Stroke rehabilitation physician will assess for
44 stability or improvement in blood pressure, blood sugar, and other laboratory values through patient
45 reports and medical record review. On week 5, the social worker will assess whether
46 patients/caregivers received education on programs for the indigent, went to-doctor/therapy
47 appointments, and obtained all necessary equipment. In addition, the social worker will assess the
48 patient for depression via PHQ9 depression screen. On week 6, a geriatrician with specialty training
49 in osteoporosis and fracture prevention will administer the FRAX questionnaire for assessment and
50 offer recommendations on prevention of bone fractures. On week 7, an epidemiologist will
51 administer a patient satisfaction survey. The survey will assess whether we addressed
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3 patient's/caregiver's concerns, if the intervention saved patients time and money, and identify if
4 patients had any falls, new strokes, ED visits, or readmission to the hospital. Epidemiologist will
5 also administer falls self efficacy scale and reintegration to normal living index for the second time
6 on week 7 to observe change in fear of falling and quality of life previously measured on week 2.

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8 In case of medical emergencies during a TR home visit session, all providers will be given
9 training via educational manual on when to direct patient and/or families to call 911 for
10 emergency. Research coordinator will be in contact with study participants for the duration of the
11 study, and will relay any important issues to the rehabilitation physician who will then communicate
12 with the rest of the team for follow up as needed.
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15 16 **Primary outcomes**

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19 The primary feasibility outcomes include response rate, defined as proportion of eligible patients who
20 consent; patient/caregiver participation with all 6 TR home visit interventions; and acceptability of
21 TR home visits by patients and caregivers measured via satisfaction survey. Additional data collected
22 to plan for future randomized controlled trial are shown in Figure 3.
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25 26 **Sample size**

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29 A sample size of 50 is selected for this feasibility study, based on an estimate of the number of
30 available patients who would meet the inclusion/exclusion criteria during the planned study period.
31 Between August 2013 and August of 2014, there were 121 stroke patients admitted to our rehab unit.
32 Of these, 80 had ischemic stroke and 41 had hemorrhagic stroke. Excluding those who were
33 discharged to another facility and enrolled in other studies, we estimate we will have up to 50 eligible
34 patients over a 24 month period.
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37 38 **Statistical analyses**

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41 Descriptive statistics will be performed on the enrolled patient population. Assessment of primary
42 feasibility aims include: 1) Calculating the response rate as number of eligible patients divided by
43 number who consented 2) Calculating proportion of patients who completed all 6 TR Home visits,
44 and various levels of compliance i.e. 6/6, 5/6, and so on. We will also determine if there are
45 particular sessions that cannot be completed. 3) Patient satisfaction surveys will be tallied to obtain a
46 satisfaction score and the proportion of patients with mean satisfaction score >70%.
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49 We will also assess factors that may affect patient/caregiver participation and program
50 compliance such as category/level of education, race/ethnicity, gender, age, type of deficit,
51 geographic location and insurance. These factors will be assessed as predictors in analysis of
52 variance (ANOVA), with number of sessions as the continuous dependent variable. Statistically
53 significant differences ($p < .05$) between levels of these variables will inform us of their impact on
54 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 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.

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

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18 **Contributors:** MMJ is principal investigator of the study and drafted the paper. All of the
19 coauthors contributed to the study design and completion of the manuscript. Specifically, RBG
20 contributed to data analysis considerations. MMJ, RBG, NR, KK, MG, PS, KV carried out
21 interventions and contributed to measureable outcomes included in the study. FV and AT
22 contributed to database management. AT coordinated intervention sessions. MS, JG, SS
23 served as senior mentors overseeing the project throughout its development. All authors were
24 involved in the final approval of the article.
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30 investigator initiated. Funding and sponsorship of the study is provided by TIRR (The Institute
31 for Rehabilitation and Research), grant number 8153101-02, and Lone Star Stroke Consortium.
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34 **Competing interests:** None declared
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3 Figures Legends
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5 ***Figure 1 Study Identification, Inclusion & Exclusion Criteria***
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8 ***Figure 2 Telerehabilitation (TR) Home Intervention after Discharge from Inpatient***
9 ***Rehabilitation***
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12 ***Figure 3 Telerehabilitation Data Collection***
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Figure 1 Study Identification, Inclusion & Exclusion Criteria

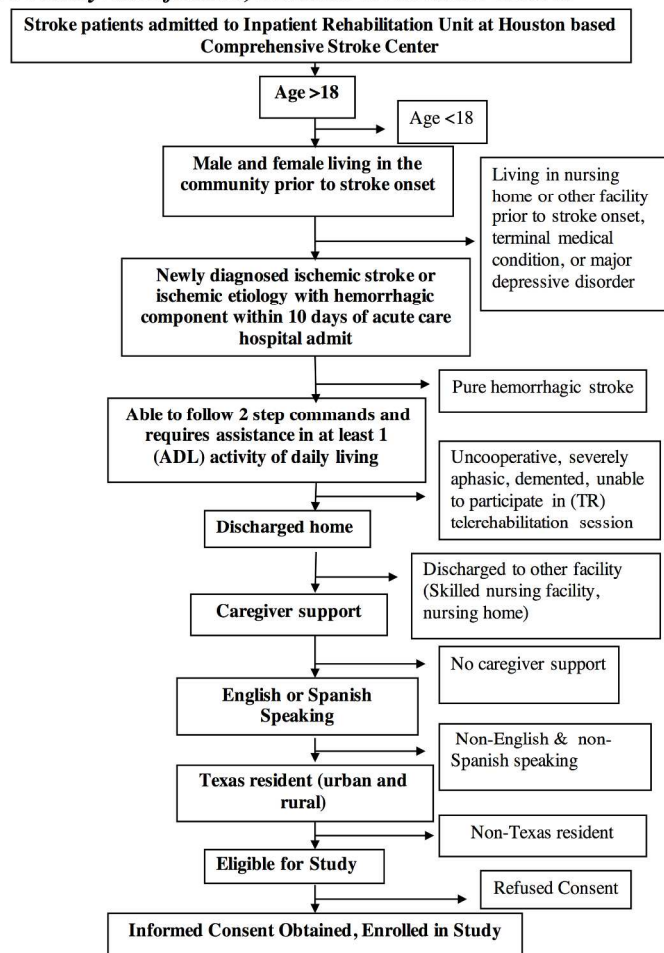
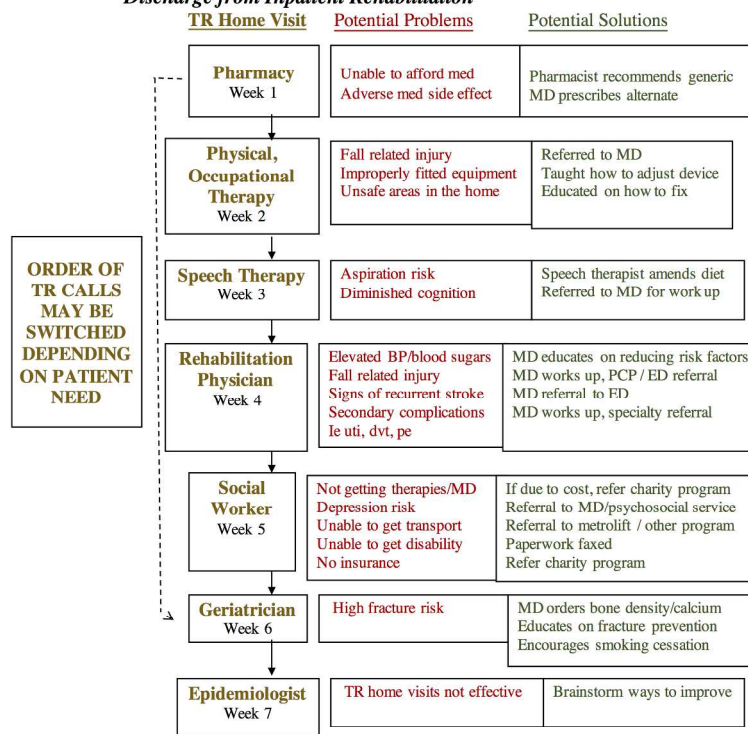


Figure 1 Study Identification, Inclusion & Exclusion Criteria

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



MD, Medical Doctor; PCP, Primary Care Physician; BP, Blood Pressure; ED, Emergency Department; UTI, Urinary Tract Infection; DVT, Deep Venous Thrombosis; PE, Pulmonary Embolism.

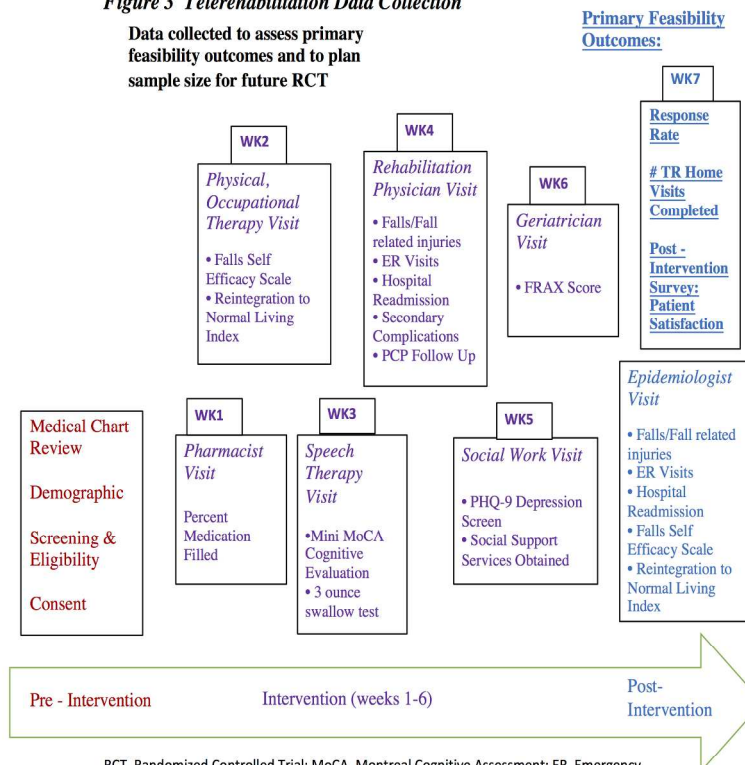
Figure 2 Telerehabilitation (TR) Home Intervention after Discharge from Inpatient Rehabilitation

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Figure 3 Telerehabilitation Data Collection

Data collected to assess primary feasibility outcomes and to plan sample size for future RCT



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, Telerehabilitation

Figure 3 Telerehabilitation Data Collection

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