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Protocol Title: Community health worker Assisted Task specific and Cognitive therapy at Home with Exposure after Stroke (CATCHES)

Purpose: Stroke is a leading cause of disability, with more than 7 million survivors currently in the country and rising due to an aging population. Improvements in organized emergency systems of acute stroke treatments are contributing to declines in stroke mortality observed over the past decade. However, with increasing survival after stroke, the prevalence of stroke is projected to increase to 10 million by 2030.

Ethno-racial inequities are persistent. Almost two thirds of stroke patients are discharged home without effective rehabilitation or community-based support. Fear of falling leads to avoidance behaviors that limit physical activity and community reintegration. Furthermore, acute stroke patients deemed “close to functional baseline” are discharged home directly from the hospital soon after the event. These minor stroke patients, in particular, must integrate back into their home environment, without considered rehabilitation for community reintegration. Physical inactivity in the immediate post-acute stroke period can exacerbate disability and impede community reintegration. Following stroke, many patients have limited access to outpatient care related to impaired mobility, access to transport, and lack of social support. These factors contribute to challenges in developing system-level interventions for post-stroke care, amplified in underserved minorities. Physical inactivity after stroke is high in both inpatient and community settings and is associated with higher cardiovascular risk. Stroke patients have been reported as willing to improve physical activity with support from providers and caregivers. The ‘teachable moment’ concept indicates that people are particularly open to making behavioral changes following major life transitions or health events, such as after having a stroke; and timely clinician-patient interactions are central for success. Fear of falling (FOF) is a psychological condition associated with excessive worrying about losing one’s balance. Individuals with fear of falling are occupied by negative emotions of fearful anticipation of falls, and physical harm that could occur. This leads to avoidance of engaging in day-to-day activities and adoption of overly cautious behaviors. Stroke patients are more likely to experience fear of falling compared to those without a stroke, with fear of falling reported among more than 50% stroke patients returning home after hospitalization.

Rationale: Fear avoidance behaviors lead to physical inactivity. Fear alters perception, planning, and execution of motor skills. Impaired perceptual motor performance is likely mediated by decreased attentional capacity whereby attention is focused on the threat stimulus and/or attentional focus is directed internally which is known to degrade performance. Task Specific Training (TST) is the repeated, active practice of a motor skill or activity that is meaningful to an individual with the goal of skill acquisition and retention. Behavioral avoidance tends to increase fear of a situation and lessens the amount of critical task practice. Task specific training can target this cycle with safe, graded exposure and repetitive practice in threatening situations. It incorporates principles of motor learning

to promote cortical reorganization and behavioral change and related to experience dependent neural plasticity. For stroke rehabilitation, it has been shown to improve physical function. Cognitive Behavioral Therapy (CBT) is a psychotherapeutic intervention that focuses on modifying individuals' thoughts and behavior. People with fear of falling may have difficulty believing that they can accomplish daily tasks such as walking or going up and down stairs without falling. CBT with exposure therapy could help altering those beliefs and associated behaviors by directing safe physical activity while promoting self-efficacy. It includes adaptive thought processes and behaviors, including effective coping skills, goal-setting and behavioral activation strategies for engaging in valued activities. It has been shown to be effective in reducing fear of falling and improving balance among older people. Among individuals with neurological conditions, telehealth delivered CBT been found effective and less time consuming. A previous study among chronic stroke patients, noted CBT with standard physiotherapy to show greater reduction in fear of falling and fear avoidance behaviors. Successful community-based interventions include support from community health workers (CHWs) in home-based stroke care. These can include trained health navigators or peer mentors from underserved communities. CHW based programs can facilitate delivery of health-related services at home and self-efficacy to improve community reintegration. However, less is known about their roles with training by professionals such as psychologists and physical therapists for rehabilitation. Among minor stroke patients, studies must address fear of falling to attain physical independence in underserved community setting– a central aim of this proposal.

Study Design: Here we propose a novel intervention in a feasibility study for preliminary testing, integrating Task Specific Therapy at home guided by Community Health Workers (CHW) under supervision of a licensed Physical Therapist (PT) in conjunction with telehealth based Cognitive Behavioral Therapy (CBT) with reduce task specific fears through repetitive exposure and adaptive behavioral activation strategies to facilitate engagement in physical activity. Participants will be recruited from a single site, Columbia University Medical Center Comprehensive Stroke Center. At the baseline visit (T0), informed consent will be obtained, and baseline questionnaires and measurements completed. A physical activity monitor will be provided. After discharge, Task Specific Training guided by Cognitive Behavioral Therapy with Exposure delivered over 7 one-hour sessions including two intake sessions by specialists and five follow up sessions delivered by CHWs individually at home over 3 months. After the final session at 12 weeks (about 3 months), participants will complete a study end visit (T1) which will include follow up questionnaires and measurements.

Statistical Procedures: Since this will be a pilot feasibility study, we did not conduct a formal power analysis. We aim to recruit at least 30 participants based on pragmatics,

needs of the trial and previous pilot studies suggesting that this sample size is sufficient to provide an accurate indication of feasibility of study procedures. Specifically, a sample size calculation was based on feasibility measure of adherence rates to visits. It is felt that $N = 30$ will be a large enough sample to inform about the practicalities of intervention delivery among patients returning home after an acute stroke. Specifically, with $n = 25$, there is about 85% power at 5% significance (one-sided) to demonstrate an adherence rate of 75% in an arm against a null rate of 50%. We note that in COMPASS-TC study only 35% attended a visit within three months after stroke. Therefore, setting the null rate at 50% is reasonable. All data will be combined, coded, and kept secure in a secure database such as REDCap. As this is a preliminary trial with a small sample, estimates derived will be used to (e.g., standard deviations, attrition rates) to help determine appropriate sample sizes for a future study that is powered to detect meaningful reductions in measures of fear of falling and avoidance. We will calculate the means and standard deviations (or medians and interquartile ranges if variables are non-normal) as well as frequencies and proportions to assess feasibility outcomes. T-tests or chi-square tests will be used to compare demographic and clinical characteristics of participants enrolled in the study, and those who did not complete the study.

Study Procedures:

To be included in the study, patients must be above 18 years of age, plan for discharge home in the local community after minor acute stroke as measured by modified Rankin Scale 2 with no more than slight disability, low balance confidence (Abilities specific Balance Confidence scale <80), and ability to provide consent. Exclusion criteria will include modified Rankin scale 2 at the time of enrollment (moderate or severely disabled), severe stroke (NIH Stroke Scale Score >14 and/or significant aphasia, dysarthria, or cognitive impairment precluding ability to complete study questionnaires as determined by interviewer), legal blindness, terminal non-cardiovascular illness (life expectancy <1 year), co-morbid mental illness, unavailable for follow-up, and/or non-English and non-Spanish speaking.

Patients will be recruited prior to discharge home from Columbia University Irving Medical Center (CUIMC) Comprehensive Stroke Center in the underserved area of Northern Manhattan with a predominant Hispanic population. Dr. Naqvi is a Vascular Neurologist, attending stroke service in the hospital, and in outpatient stroke clinics affiliated that provide outpatient services after discharge to these patients. The stroke clinics provide care to patients in the catchment area of CUIMC which is notable for substantial racial, ethnic, and economic diversity. All baseline study procedures, including informed consent, and data collection, will be performed at bedside by trained research staff and will be

available in English and Spanish. Baseline surveys will be conducted including IPAQ (International Physical Activity Questionnaire) and PROMIS-PF (Patient Reported Outcome Measures Information System) about self-reported physical activity and physical function respectively. Timed Up and Go (TUG) test will be performed, along with FitBit wear instructions and education on device navigation. Patients who qualify based on the inclusion criteria will be enrolled. Within the first two weeks they will receive intake visits with a neuropsychologist who will conduct an intake session through video to assess their cognitive barriers and fear of falling with consider techniques of cognitive restructuring, imaginative exposure, and relaxation techniques to target specific self- defeating beliefs associated with negative emotions. They will receive an in-home assessment with a physical therapist and community health worker to conduct an intake visit for task specific training. Further follow up study visits for a total of 7 study visits will be conducted by the community health worker where Treatment sessions will be tailored to a patient's specific goals and individualized to allow for challenging practice while promoting successful performance to increase self-efficacy. Sessions will be followed by an interdisciplinary discussion for a patient-centered training plan. After study completion, participants and study personnel will be approached to asked to participate in focus groups for qualitative feedback on the intervention. These are expected to last up to 60 minutes and will be audio recorded. The audio of the call will be recorded using HIPAA enabled CUIMC Zoom on an encrypted CUIT-secured device and transcribed using Microsoft Stream or through human transcription. Upon receipt and validation of the transcript, the digital audio files will be retained for analysis. Notes will be taken to identify the key thematic content that emerged from the interviews. These notes will entered into an Excel spreadsheet as a code book, coded for meaning, then grouped according to shared properties and conceptual relationships, and themes will be identified and a codebook constructed from these groupings. The study team will review the initial codes for content validity. An iterative process will be used to allow dominant themes to emerge till saturation. Quotes that represent prevailing opinions and concerns will be identified.

Describe how participants will be recruited: In CATCHES pilot trial, we will identify stroke patients hospitalized for ischemic and hemorrhagic stroke at Columbia University Irving Medical Center. Any person over the age of 18 who is hospitalized for an ischemic or a hemorrhagic stroke with minor symptoms with plan for safe discharge home will be considered for this study. People who are unable to consent will not be considered. A member of the provider team will ask the potential participant if they would be interested in participating in a research study. If yes, a study team member will approach the stroke patient and describe the study. A study team member will obtain one on one written consent to participate in the study. The informed consent process will begin with a concise

and focused presentation of the key information about the research study. Potential subjects will have ample time and opportunity to discuss the information provided.

Describe how participants' written consent will be obtained: A study team member will obtain one on one written consent to participate in the study once they have been approved to be approached in the hospital by the clinical care team prior to discharge. The informed consent process will begin with a concise and focused presentation of the key information in sufficient detail about the research study. Potential subjects will be given ample time with opportunity to discuss the information provided and agree or decline to participate.

Only those participants who have completed the study, and study personnel who were engaged in the study will be invited to take part in providing their feedback regarding the intervention. It will be emphasized that they are not obligated to participate in providing their feedback about the intervention, and their further care will not be affected if they decide not to participate. It will be emphasized to study personnel that they are not obligated to participate to give their feedback regarding intervention processes to improve further iterations of the intervention. . Informed consent process will begin with a concise and focused presentation of the key information about the research study. Potential participants to the focus groups to give feedback will have the opportunity to discuss the information provided and provided contact details to do so. The informed consent process as a whole presents information in sufficient detail regarding the research study and the information sheet will be provided.

Research Question(s)/Hypothesis(es): 1. To integrate and establish feasibility of CATCHES intervention. Hypothesis: A multidisciplinary team providing home based TST with exposure therapy tailored to an underserved urban setting will inform a patient-centered behavioral intervention to reduce FOF among post-acute stroke patients returning home. Feasibility outcomes will include recruitment, retention, and fidelity of implementation. 2. Test effects of the intervention on hypothesized treatment mechanism of fear of falling. Hypothesis: Therapy will reduce task specific fear of falling Primary outcome will be change in Activities-specific Balance Confidence Scale.3. Explore physical activity measures subjectively and objectively. Exploratory outcomes include pre and post Timed Up and Go test, patient reported outcome surveys and activity as measured by wearable devices.

Scientific Abstract: Stroke is a leading cause of disability, with more than 7 million survivors currently in the country and rising due to an aging population. Improvements in organized emergency systems of acute stroke treatments are contributing to declines in stroke mortality observed over the past decade. However, with increasing survival after stroke, the prevalence of stroke is projected to increase to 10 million by 2030. Moreover, ethno-racial

inequities are persistent with the largest rises in stroke prevalence expected to be among those of Hispanic ethnicity and Black race. By 2030, almost a third of the population is projected to be Hispanic (21.1%) or Black (13.8%). Post stroke outcomes are the most optimal when care is focused on the crucial 3 months after stroke hospitalization. Early after a stroke is the “sensitive period” when both recovery potential and risk of further disability from recurrent stroke are greatest. Studies in humans and animal models show that most recovery from impairment occurs in the first 3 months after stroke from spontaneous recovery as well as increased responsiveness to enriched environments and training. Almost 70% of all stroke patients are discharged to a home setting, where they may not be prepared or equipped to return to their routines. Furthermore, acute stroke patients deemed “close to functional baseline” are discharged home directly from the hospital soon after the event. These minor stroke patients, in particular, must integrate back into their home environment, without considered rehabilitation for community reintegration. Physical inactivity in the immediate post-acute stroke period can exacerbate disability and impede community reintegration. Following stroke, many patients have limited access to outpatient care related to impaired mobility, access to transport, and lack of social support. These factors contribute to challenges in developing system-level interventions for post-stroke care, amplified in underserved minorities. Physical inactivity after stroke is high in both inpatient and community settings and is associated with higher cardiovascular risk. Stroke patients have been reported as willing to improve physical activity with support from providers and caregivers. The ‘teachable moment’ concept indicates that people are particularly open to making behavioral changes following major life transitions or health events, such as after having a stroke; and timely clinician-patient interactions are central for success. Fear of falling (FOF) is a psychological condition associated with excessive worrying about losing one’s balance. Individuals with fear of falling are occupied by negative emotions of fearful anticipation of falls, and physical harm that could occur. This leads to avoidance of engaging in day-to-day activities and adoption of overly cautious behaviors. Stroke patients are more likely to experience fear of falling compared to those without a stroke, with fear of falling reported among more than 50% stroke patients returning home after hospitalization.

Lay Abstract: Stroke is a leading cause of disability in the country, and ethno-racial inequities are persistent. Almost two thirds of stroke patients are discharged home without effective rehabilitation or community-based support. Falls can occur at home, and associated fear of falling leads to avoidance behaviors that limit physical activity and community reintegration. Here we propose a novel intervention in a feasibility study for preliminary testing, integrating Task Specific Therapy at home guided by Community Health Workers (CHW) under supervision of a licensed Physical Therapist (PT) in conjunction with

telehealth based Cognitive Behavioral Therapy (CBT) with reduce task specific fears through repetitive exposure and adaptive behavioral activation strategies to facilitate engagement in physical activity. The main objective is to assess the feasibility of this intervention. The secondary objective is to explore the underlying behavioral mechanism for behavior change and explore physical activity.

All research personnel involved in the pilot study will have completed training in the intervention protocol. PI will be available for phone calls from research coordinators and other study personnel should any concerns for patient safety arise while interacting with patients over the course of this study. To minimize risks, all procedures will be performed in clinically stable patients who meet eligibility criteria for the pilot study and whose treating providers and/or clinic directors have given permission to be approached to participate in the evidence-based adherence intervention without requiring patient informed consent. Further risks specific to this study that will be addressed. Subjects will be assessed at each visit with a brief neurological history, blood pressure measurement, and NIH Stroke Scale (NIHSS). If a patient does report concerning symptoms with elevated blood pressure above 180/110 or low blood pressures less than 80/50, their primary care and providers will be notified and the patient will be directed to the emergency department for clinical evaluation and advanced imaging, if clinically warranted. Breach of confidentiality is another potential risk, and secure data management strategies will be employed to prevent this. Participants will be excluded if they are at fall risk and have not been deemed to be safe to return home and ambulatory based on physical and occupational therapy evaluations in the hospital.

They will also be assessed with Timed Up and Go test for balance, after they have been assessed for fall risk and deemed safe for discharge home. Potential risks will be mitigated as testers will be therapists skilled in these assessments to prevent falls.

Improved physical activity: Patients may benefit from receiving the sessions to reduce fear of falling and may improve physical activity. This may help patients become more active and help with community reintegration. Patients may also benefit from the attention they receive from study personnel. Contributions to scientific/medical knowledge: While patients in this study may not directly benefit from their participation, we anticipate the results from this study will benefit future research seeking to identify strategies to optimize engagement of minor stroke patients into evidence-based behavioral interventions. The knowledge gained from this study will help us to better understand the strategies that are most effective at promoting engagement in behavioral interventions by minor stroke patients who are traditionally left to rehabilitate back into the community. In particular, we may learn that some theory-informed behavioral mechanisms of avoidance and related

exposure therapy with task specific training as a potential intervention. message-framing strategies are more effective than others. We will also evaluate the feasibility of implementing this intervention for a future scaled intervention.

Participants have the option of not participating or withdrawal from this research study at any time.

Dr. Naqvi (study PI) will be responsible for ensuring subjects' safety on a daily basis. Study PI will be immediately informed of unanticipated problems that may be related to the study protocol as soon as they occur, and will notify the CUIMC IRB, in compliance with their policies. The data safety and monitoring plan will include expedient reporting of unexpected and/or adverse events (i.e., within 48 hours of the research team's knowledge) and a detailed plan to deal with adverse events that might arise during the conduct of the study with a step-by-step algorithm to deal with such events. The Data Safety Monitoring Plan for this study is approved by the National Institute on Aging (NIA). The study will also be monitored by an NIA approved Safety Officer at Columbia.