Institutional Review Board
Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378
email: IRB@twu.edu
http://www.twu.edu/irb.html

DATE: October 19, 2016

TO: Dr. Hui-Ting Goh
Physical Therapy - Dallas

FROM: Institutional Review Board (IRB) - Dallas

Re: Approval for Efficacy of Non-Invasive Brain Stimulation on Dual-Task Walking After Stroke: A rTMS Study (Protocol #: 19219)

The above referenced study has been reviewed and approved by the Dallas IRB (operating under FWA00000178) on 10/18/2016 using an expedited review procedure. This approval is valid for one year and expires on 10/18/2017. The IRB will send an email notification 45 days prior to the expiration date with instructions to extend or close the study. It is your responsibility to request an extension for the study if it is not yet complete, to close the protocol file when the study is complete, and to make certain that the study is not conducted beyond the expiration date.

If applicable, agency approval letters must be submitted to the IRB upon receipt prior to any data collection at that agency. A copy of the approved consent form with the IRB approval stamp is enclosed. Please use the consent form with the most recent approval date stamp when obtaining consent from your participants. A copy of the signed consent forms must be submitted with the request to close the study file at the completion of the study.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc. Dr. Mary Thompson, Physical Therapy - Dallas

Texas Woman's University Institutional Review Board

Application for Expedited and Full Review

For office use only:

Protocol #: _____

Name of Principal Investigator (PI): Hui-Ting Goh, PhD Phone: 214-689-7723

Status: ☒ faculty ☐ student ☐ staff ☐ other : _____ E-mail: hgoh1@twu.edu

Department: School of Physical Therapy

Colleague ID# (this is the 7-digit # on your ID): 0598520

Title of Study: Efficacy of non-invasive brain stimulation on dual-task walking after stroke: a rTMS study

If the PI is a student, provide the following information for the faculty advisor:

Name of advisor: _____ E-mail: _____

TWU Department: _____

Estimated beginning date of study: 10/1/2016 Estimated duration of study 2 years

Campus (Denton, Dallas, or Houston) Dallas Level of review: ☒ expedited ☐ full

Type of Project : (check all that apply) ☐ thesis ☐ professional paper ☐ dissertation ☐ class project ☒ faculty research ☒ pilot ☐ other _____

Has project has been submitted for funding (internal or external)? ☐ yes ☒ no

If yes, funding source: _____

Signatures:

Principal Investigator (PI): Signature certifies that the investigator has primary responsibility for all aspects of the research project.

_____ _____

Principal Investigator Date

Faculty Research Advisor (for student research only): Signature certifies that the faculty member has read, reviewed, and approved the content of the application and is responsible for the supervision of this research study.

_____ _____

Faculty Research Advisor Date

Academic Administrator: Signature certifies that the administrator has read, reviewed, and approved the content of the application.

_____ _____

Academic Administrator (Department Chair, Program Director, or Associate Dean) Date

METHODOLOGY

Please refer to instructions when completing this form. The application must be typed using a font no smaller than 11-point.

1. Describe the purpose of study, including research questions and/or hypotheses.

Purpose: The purpose of this pilot study is to examine the feasibility and efficacy of a non-invasive brain stimulation technique, repetitive transcranial magnetic stimulation (rTMS) in dual-task walking in individuals post-stroke. Our long-term objective is to use the technique as an adjunct rehabilitative tool to enhance gait recovery after stroke.

Background: Control of human movements requires sophisticated coordination between motor system and cognitive system. In able-bodied, the interaction between the two systems is often faultless and allows automatic execution of well-learned motor skills, such as walking. However, such coordinated interaction is often disrupted after brain insults (e.g. stroke). Numerous studies have shown that patients with stroke have difficulty in dual-task performance, for instance talking while walking[1-4]. Therefore, dual-tasking has been deemed as an important outcome to determine the effectiveness of gait rehabilitation[5]. To date, there is very limited research on how to enhance dual-task gait in stroke[6-9].

Non-invasive brain stimulation, such as rTMS, has been found to be an effective adjunct tool to traditional behavioral training to improve recovery of arm-hand function after stroke[10]. rTMS can be used to up-regulate or down-regulate the excitability of the targeted neural network and subsequently affect the behaviors supported by that neural network. For example, in a previous research we applied 5Hz rTMS on the primary motor cortex (M1) in young healthy adults and found that it significantly increased M1 excitability[11]. Similarly, we demonstrated that application of 1Hz rTMS on the dorsal premotor cortex (dPM) significantly decreased corticospinal excitability and interfered with participant's ability to learn the motor task under dual-task conditions[12]. Although the efficacy of rTMS has been well-demonstrated in recovery of upper extremity motor function after stroke, its usefulness for gait recovery is understudied[13,14].

There have been attempts to use non-invasive brain stimulation to improve dual-task walking in humans[15-17], including neurological involved population[17,18]. To date, there is no study that examines the efficacy of non-invasive brain stimulation in dual-task walking in individuals post-stroke. In addition, previous research has primarily focused on stimulating left dorsal lateral prefrontal cortex (DLPFC). Most studies found that up-regulating excitability of the left DLPFC improved dual-task cost but had little effect on gait performance[18]. One possible explanation is that the DLPFC does not play an important role in governing gait performance during dual-tasking even though it has significant impact on task switching[19]. Therefore, other neural networks, such as the supplementary motor area (SMA) that has been found to be associated with gait recovery[15,20-22] may also play an important role in modulating dual-task gait. The purpose of this pilot project is to examine the efficacy of rTMS applied to different neural loci in improving dual-task gait in individuals post-stroke.
Research question: Would rTMS applied to different neural loci result in different dual-task gait performance in patients with stroke?

2. Participant Information:

a. Description of participants in study:

Ten men and women with a diagnosis of left hemisphere stroke and age >18 years will be recruited to participate in this pilot project.

b. Approximate number of participants: 10

c. Vulnerable populations as participants (check all that apply):

Prisoners ..... ☐
Pregnant women..... ☐
Fetuses / neonates ..... ☐
Minors ..... ☐

NOTE: Researchers must comply with the federal mandate to report child abuse. See instructions for details.

d. Age (or age range) of participants: > 18 years

Provide the rationale for inclusion/exclusion on the basis of age:

1. This study will not include individuals age below 18 years for a few reasons. Stroke is relatively uncommon in persons younger than 18 years. Further, rTMS safety data in children and adolescents are less well-established. We exclude individuals younger than 18 years for both scientific merit and safety concern.

e. Sex of participants ..... ☐Male ☐ Female ☒ Both

Provide the rationale for inclusion/exclusion on the basis of sex:

f. Participants will be excluded based on ethnicity: ..... ☐Yes ☒ No

If yes, provide a description of the exclusion criteria and the rationale for using these criteria:

g. List and provide rationale for any other inclusion/exclusion criteria:

Inclusion criteria:

1. Age above 18 years
   2.Stroke is very unlikely in individuals age below 18 years. Further, there are limited data to support the safety of rTMS in individuals younger than 18 years.

2. Diagnosis of Left hemispheric stroke at least 6 months ago
   2.Left dorsolateral prefrontal cortex has been shown to play an important role in human dual-task performance. We therefore specifically target those with left hemispheric lesion since they demonstrate greater deficits in dual-tasking. We exclude acute and subacute (< 6 months) stroke because spontaneous recovery is very likely to occur

during acute and subacute phases. This will lead to difficulty in result interpretation with the current single group design.

3. First time stroke OR complete gait recovery from prior stroke
   2. Individuals with more than one stroke often have more than one lesion location or involve more than one hemisphere. This would potentially complicate the rTMS application. We therefore exclude those with multiple strokes such that our sample can be more homogenous.

4. Able to walk independently for at least 10 meters with or without walking aids
   2.Participants are required to walk independently for the behavioral testing.

5. Have at least minimal movements (> 5 degree of motion) at the affected ankle
   2.Stroke survivors with big lesions at the motor areas often have difficulty to actively control distal segments (hands or ankle) and show very little responses to TMS stimulation. In our past experience, we found that resting motor threshold cannot be reliably measured in those with very little active movements.

6. Score > 26 on Mini Mental State Exam (MMSE)
   2.Participants are required to score > 26 to rule out any cognitive impairments that would interfere with their comprehension of instructions.

7. Ability to participate in the informed consent process

Exclusion criteria:

1. Diagnosis of other neurological conditions, such as Parkinson Disease, Alzheimer, Spinal Cord Injury, Multiple Sclerosis
   2.This is to ensure that our sample is representative of stroke.

2. Other comorbidities which could interfere with gait (i.e. amputation, severe osteoarthritis)
   2.This is to ensure that any potential gait deviations observed can only be attributed to stroke.

3. Unstable clinical conditions
   2.This is to ensure safety during testing. Individuals with unstable clinical conditions, eg. uncontrolled hypertension, will not be included.

4. Non-ambulatory prior to onset of stroke
   2.This is to ensure that any potential gait deviations observed can only be attributed to stroke.

5. History of significant head trauma
   2.This is a contraindication of high frequency rTMS.

6. Electrical, magnetic, or mechanical implantation: cardiac pacemakers or intracerebral vascular clip
   2.This is a contraindication of TMS.

7. Metal implantation in the oral cavity, head/neck area and lower extremity
   2.This is a contraindication of TMS.

8. Pregnancy
   2.This is a contraindication of TMS.

9. History of seizures or unexplained loss of consciousness
   2.This is a contraindication of TMS.

10. Immediate family member with epilepsy
    2.This is a contraindication of TMS.

11. Use of seizure threshold lowering medicine
    2.This is a contraindication of TMS.

12. Current abuse of alcohol or drugs
    2.This is a contraindication of TMS.

13. Anticipated inability to complete the study
    2.This is to ensure that participants can complete the study (all 3 visits).

14. History of psychiatric illness requiring medication control

    2.This is a contraindication of TMS.

3. Describe the participant recruitment process in detail. Make sure that you attach any recruitment materials or scripts in the attachment section.

Research participants will be recruited through local advertising and word-of-mouth by PI and research assistants (advertising flyer attached). The potential participants will contact the PI or research assistants via email, phone or face-to-face for a short meeting within which the research project will be explained by the PI or the research assistants using the Consent Form as a guide. This meeting will take approximately 10-15 minutes. It should be noted that if the participant indicates he/she does not wish to participate after the meeting, he/she would not be enrolled. The signed consent will be obtained upon the agreement to participate. The original consent will be kept in the research file, one copy will be placed with the PI and the participant will receive a copy.

4. Research Procedures:

a. In the space below, describe in detail the research procedures (do not use an attachment):

1. **Screening and Baseline assessment**: Upon the consent, participants will be screened for their eligibilty in addition to the criteria. We will use Mini Mental State Exam (MMSE; 3.Appendix 1) and TMS safety-screening questionnaire (3.Appendix 2) to ensure that participants do not have any cognitive impairments or contraindications for TMS. In addition, they will be asked to perform a 10 meter walk test to ensure they are able to walk 10m independently.

Once the eligibility is determined, each participant will be assessed with the Fugl-Meyer Motor Assessement (FMA; 3.Appendix 3)[23] scale to quantify their motor impairment and a Trail-Making Test (TMT; 3.Appendix 4)[24] to assess their executive function.

2. **Assessements**: Each participant will be tested with a gait assessment, followed by a counting task performance and a neurophysiological assessement.

   2a. Gait Assessment: The gait assessment consists of walking at self-selected speed on the GaitRite carpet walkway. Gait performance (time taken, gait speed, stride cycle, step length) will be recorded by the GaitRite. The assessment will be repeated 3 times with about a 1 minute break between trials.
   The walking test will then be repeated for another 3 trials under a dual-task condition in which the participants will perform the walking task in conjunction with a counting task. Before the 'Go' command, the tester will verbally provide a random number ranged from 30 to 100. They are then asked to perform the TUG test and count backward by 3 from the given number (e.g. 87, 84, 81, …). During the dual-task TUG test, the participants will be asked to priortize the counting task.
   In addition to the GaitRite measurement, the gait assessment will be video-recorded such that participants' performance on the counting task can be quantified offline (number of correct responses).

   2b.Counting Task assessment: After the participants finish the gait assessment, the counting task will be repeated 3 times while they are seated.

   2c. Corticospinal excitability assessment: After the counting task assessment, participants will go through a series of corticospinal excitability assessement using single pulse transcranial magnetic stimulation (TMS, Magstim^{R} Company, UK) . Surface electromyography (EMG) electrodes will be placed on the right Tibilias Anterior muscle with the participants seated on a reclining chair and wearing a pair of earplugs. EMG data will be sampled at 2000Hz and band-pass-filtered at 15-500Hz (Mega 600, Mega Electronics Ltd, Finland). The EMG data will be recorded and stored using MegaWin software (Mega Electronics Ltd, Finland) and analyzed offline using Matlab program (The Mathowroks, Inc, Natick MA). A Magstim 200 stimulator (Magstim Company, UK) will be used to deliver the TMS pulse via a double cone coil (Figure 1).

Figure 1. Double cone coil.

   Neuronavigation system Brainsight TM (Rogue Research, Canada) will be used to reliably place the TMS coil over the scalp to precisely target the selected area. Stimulation will begin at 40% of maximum stimulator output and will be systematically increased to yield a motor evoked potential (MEP) from the tibialis anterior. A 'hot spot'of the right tibialis anterior will first to be determined. Hot spot is defined as the site at which the largest MEP is obtained at the lowest TMS stimulation intensity. Once the hot spot is determined, the resting motor thershold (RMT) will be defined. Resting motor threshold is the stimulation intenisty that yield a MEP peak-to-peak amplitude > 50 **μ**V in 5 out of 10 consecutive trials. Once RMT is decided, the stimulation intensity

will be set at 120% RMT and 10 stimulations will be delivered to the hot-spot such that suprathreshold MEP can be recorded. These MEPs measures will be stored and analyzed offline to quantify corticospinal excitability.

3. **rTMS protocols:** After the corticospinal excitability assessment, participants will receive a high frequency rTMS applied to different areas at different visits.
During each visit, they will receive 5Hz rTMS delivered to the target area (hot spot of the right tibialis anterior at the M1, left SMA, or left DLPFC). The 5Hz rTMS will be delivered in the form of 24 10-second trains with a 30-second intertrain interval (a total of 1200 pulses) via a air-filled figure of 8 coil (Figure 2). The stimulation intensity will be set at 90% of individual RMT. We have previously shown that this protocol was effective to upregulate corticospinal excitability[11].

Figure 2. Air-filled coil for rTMS

After the rTMS protocol, corticospinal excitability will be reassessed using single pulse TMS again (procedure 2c). Participants will then perform the gait assessment (procedure 2a) and the counting task (procedure 2b).
Each participant will be tested for 3 visits (each visit will be 7±2days apart between two successive visits). Each visit will start with the assessment and be followed by a rTMS protocol. The target area for the rTMS protocols varies across visits (e.g. visit 1: Left SMA, visit 2: Left M1, and visit 3: Left DLPFC). The order will be pseudo-randomized and counterbalanced within each group.

4. Outcomes and data analysis: The primary outcome of this project is participant performance on the TUG test under single and dual-task conditions. The time taken to complete the TUG test under the two conditions will be used to derive dual-task cost ($TUG_{dual} - TUG_{single}/TUG_{single}$). The dual-task cost will be compared across three rTMS protocols using repeated measure ANOVA.
The secondary outcomes of the projects include gait parameters obtained from the GaitRite, MEPs measured under procedure 2c. These measures will be analyzed using repeated measure ANOVA as well.

b. Is video recording a part of the study? ☒Yes ☐ No

With sound ☒ Without sound ☐

c. Is audio recording a part of the study?..... ..... ☒Yes ☐ No

If you answered "yes" to question #4b or 4c, describe the purpose of the recording and who will have access to these recordings.

The video recording will be used to quantify the number of corrected responses participants made on the counting task.

d. Is internet / email a part of the study? ..... ☐ Yes ☒ No

If you answered "yes" to question #4d, describe how the internet and/or email will be used.

5. What is the time commitment for the participants? Include the number of sessions, maximum time commitment per session, and the maximum cumulative time commitment.

Each participant will be tested over 3 sessions (7 ± 2 days between two successive sessions). Thus, the whole experiment will take place over ~ 3 weeks. Each session is estimated to take about 2.5 hour. Thus, the maximum cumulative time commitment for each participant is approximately 7.5 hours.

6. Site / location of the study.

a. Will participants be affiliated with a specific non-TWU agency, institution, or organization? ..... ☐ **Yes** ☒ **No**

If yes:

Name of the site(s)?

*Affiliation of the **principal investigator** to this site(s)?*

*Affiliation of the **participants** to this site(s)?*

Agency approval letters are required by the IRB before data can be collected at a site. If you answered "yes" to 6a, attach the signed agency approval letter on letterhead from each agency. If agency approval cannot be obtained prior to submitting the IRB application, explain here.

b. Describe the setting of the study (i.e. physical location, surroundings, privacy aspects, etc.)

The study will take place at the TWU – Dallas Campus. Participants will undergo TMS procedure on the 1st floor in the Human Neurophysiology Lab. The gait assessment will take place on the 1st floor in the Motor Skill Lab.

POTENTIAL RISKS AND PROTECTION OF PARTICIPANTS

7. Explain the potential risks to the human participants involved in this research. All risks must be identified and listed on the consent form (if applicable).

RISK	STEPS TO MINIMIZE RISK
Loss of confidentiality	The investigators will attempt to maintain confidentiality to the extent that is allowed by law. The study will take place at Texas Woman's University, School of Physical Therapy – Dallas Campus. Codes, rather than names, will be used in the data analysis and in the final report. The data will be stored in a locked file cabinet. The data recorded on papers will be stored for approximately 5 years and then will be shredded. The data recorded on disks will be stored for 5 years and then will be deleted. It is anticipated that data will be published in books and/or journals. However, names or other identifying information will not be included in any publication.
4.Loss of time The study requires 3 sessions and each session lasts 2 to 2.5 hours. The loss of time could potentially impact participants' life.	To minimize the impact of loss of time, all visits will be scheduled based on participant's convenience. For example, on the same day that they come to Dallas Stroke Center for speech therapy appointments or during weekends.
Loss of balance The gait assessment involves walking and turning in which participants may experience loss of balance.	To minimize this potential risk, the tester will walk alongside the participants during testing. All testers are trained to detect and assist loss of balance during gait.
5.Fatigue The study requires 3 sessions and each session lasts 2 to 2.5 hours. The length of the testing is necessary to obtain data needed. However, this might potentially result in fatigue due to the lengthy testing.	To minimize this potential risk, we will schedule sufficient resting time between tests. In addition, participants may withdraw anytime if they are too fatigued to continue.
RISK	STEPS TO MINIMIZE RISK

Headaches It has been shown that with repetitive stimulation on the scalp (in rTMS protocols), a small number of participants (< 28% cases) would develop transient headaches. The developed headaches usually resolved within 3-4 hours and respond well to over-the-counter pain medicine, such as 6.Tylenol.	To minimize this potential risk, we will exclude participants who are prone to develop headaches (e.g. history of migraine). We will use subthreshold intensity for rTMS protocols that will reduce the likelihood of developing headaches. In addition, the tester will stop the testing when they develop headaches during the test. 6.If participants do develop headaches and require pain medication, we will ask them to take the pain medication that has been approved by their primary care physicians.
RISK	STEPS TO MINIMIZE RISK
Changes in auditory threshold There is a risk of alteration in auditory threshold after TMS protocols as TMS produces loud click when it is charged. The changes in auditory threshold are transient (lasts about 1 day) and not different from going to a music concert.	To minimize the risk, we will provide earplugs during TMS testing.
RISK	STEPS TO MINIMIZE RISK
Seizure Risk of seizure is associated with high frequency rTMS and is higher in those who have history of seizure, on medication that are known to reduce seizure threshold. Risk of seizure is also higher when the rTMS parameters are set outside of the safety limits.	We will use a safety-screening questionnaire adapted from the recommendation of the international committee[25,26]. This questionnaire will help us to identify those at high risk of developing seizure and they will be excluded from participation. The rTMS protocols adopted in this project are within recommended safety limits[25,26] and we have previously conducted rTMS experiments using the same protocols without any adverse events[11,12].

(Use continuation pages if necessary)

8. Will participants be told about the intent of the study prior to participating? ..☒ Yes ☐ No
If "no," provide an explanation of why deception is necessary and the debriefing method to be used to fully inform the participants of the study's intent.

9. Explain when and how the participants will be given the opportunity to ask questions.

Participants will have the opportunity to ask questions anytime during the initial meeting with researchers or throughout the duration of the study.

10. Identifiable Data

Outline the steps to ensure the confidentiality of identifiable data. Identifiable data includes documents, audio and video recordings, electronic data, and blood or other human specimens.

a. Explain what identifiable data, if any, will be collected.

Name, date of birth, gender, self and family medical history

b. Where will identifiable data be stored? (Specify precise location, preferably in a locked file cabinet with limited access.)

Identifiable data will be stored in a locked file cabinet in the School of Physical Therapy, Dallas Campus research lab room 8811. Access will be limited to the researchers.

c. Give the date that identifiable data will be destroyed (mm/dd/yy). If identifiable data will be stored for an indefinite period of time, please explain.

The identifiable data will be destroyed by 12/31/2020 by shredding all paper documents. Electronic data will be destroyed by 12/31/2020 by deleting all files containing identifiable data from any and all electronic devices including computers and portable storage devices.

d. Identify specific ways that identifiable data will be destroyed at the end of this period of time.

The identifiable data will be destroyed by 12/31/2020 by shredding all paper documents. Electronic data will be destroyed by 12/31/2020 by deleting all files containing identifiable data from any and all electronic devices including computers and portable storage devices.

e. Because the academic component of TWU is classified as a non-covered HIPAA entity, identifiable health or health-related data cannot be transmitted electronically. You must be able to answer "no" to at least one of the following questions in order for your study to be approved.

Does this research involve health or health-related data? ..... ☒ Yes ☐ No
If yes, are the data identifiable? ..... ☒ Yes ☐ No
If yes, will data be transmitted electronically? ..... ☐ Yes ☒ No

BENEFITS/REMUNERATION

11. What will the participant receive for taking part in the study (*i.e., financial remuneration, free services, access to information, and access to an intervention)***? I***f there are none, state below that there are no direct benefits to the participant.*

Each participant will receive a gift-card worth USD 150 upon the completion of the experiment (3 visits). In addition, they will have access to their own information (gait, neurophysiological data).

12. What are the generalizable benefits of this study? *(e.g., contribution to knowledge in field).*

This study will expand the knowledge in the field of neuroscience. In particular, it will identify important neural circuitry that supports human dual-task motor performance.

13. Explain when and how the participants will be provided with the results of the study.

Upon the completion of the study, the participants will receive a summary of the results (abstract format) upon their request.

INFORMED CONSENT PROCEDURES

14. Written Informed Consent

a. Explain the PROCESS you will use to obtain informed consent.

Prospective participants will have the opportunity to read a written informed consent form describing this study and ask questions regarding this study with research study personnel. Each participant will sign the informed consent form in order to participate in this study after Institutional Review Board approval.

b. Unless there are unusual circumstances, investigators are required to document informed consent by obtaining the participant's signature (or the signature of their parent or guardian) on a written consent form. Explain when and how that signature will be obtained. Explain where the signed consent forms will be stored (specify precise location, preferably in a locked file cabinet with limited access), how long the signed consent forms will be kept, and identify specific ways that the signed consent forms will be destroyed at the end of this period of time. Note that a copy of the signed consent forms will need to be placed on file with the IRB when the study file is closed.

The signature will be obtained after the prospective participant has read the written informed consent and agreed to participate. The signed consent forms will be stored in a locked file cabinet in the School of Physical Therapy, Dallas Campus research lab room 8811 where only the researchers have access to it. The signed consent forms will be kept until 12/31/2020 and then be destroyed using a paper shredder. A copy of the signed consent form will be placed on file with the IRB when the study file is closed (estimated closing date May 2018).

c. If you will not use a written consent form, provide a detailed rationale and explain how informed consent will be obtained

N/A

RESEARCH TEAM MEMBERS

15. Provide a list of all research team members other than the investigator and faculty advisor.

A current **human subjects** training certificate (less than 3 years old) must be on file for the investigator, advisor, and all research team members before an approval letter will be sent. These training certificates may be sent directly to the IRB separately or attached to this application in the attachment section. If a current training certificate is already on file with the IRB, there is no need to attach another copy.

Name	Delaina WalkerBatson
TWU 7-digit Colleague ID # (if applicable)	0066102
Email Address:	DWalkerBatson@mail.twu.edu
TWU Department or Name of Other Institution	Communication Sciences& Disorders, Stroke Center-Dallas
Role on Project	Co-Investigator

Name	Alex Newton
TWU 7-digit Colleague ID # (if applicable)	1071827
Email Address:	mnewton4@twu.edu
TWU Department or Name of Other Institution	School of Physical Therapy
Role on Project	Research Assistant

Name	Isheanesu Nyangani
TWU 7-digit Colleague ID # (if applicable)	0996599
Email Address:	inyangani@twu.edu>
TWU Department or Name of Other Institution	School of Physical Therapy
Role on Project	Research Assistant

Name	Renee Vanasse
TWU 7-digit Colleague ID # (if applicable)	1107511
Email Address:	rvanasse@twu.edu
TWU Department or Name of Other Institution	School of Physical Therapy
Role on Project	Research Assistant

Name	Kevin Palm
TWU 7-digit Colleague ID # (if applicable)	1106859
Email Address:	kpalm@twu.edu
TWU Department or Name of Other Institution	School of Physical Therapy
Role on Project	Research Assistant

(Attach additional sheets if necessary)

ATTACHMENTS

16. List and describe all attachments (Include forms, scripts, flyers, consent forms, agency approval letters, human subjects training certificates, signed confidentiality agreement forms, referral lists, surveys, questionnaires, or any other instrument used in the study.) Attachments should be listed below in the same order in which they are attached.

Advertising flyer
TMS safety questionnaire
3.Mini Mental State Exam, Fugl-Meyer, Trail-Making Test
IRB training certificates for each research personnel (6 copies)

SUBMISSION INSTRUCTIONS

The application should be submitted to the appropriate campus IRB.

Denton and Dallas

Mail the signed original to the address below. If electronic submission is preferred, combine all parts of application into single .pdf document and email to irb@twu.edu. If the application is submitted electronically as a fully signed .pdf, the original copy is not required.

TWU's Office of Research & Sponsored Programs
Institutional Review Board
PO Box 425619
Denton, TX 76204-5619

Applications may also be hand delivered to the Denton campus ACT 7th floor or the Dallas campus Office of Research IHSD 8th floor.

Houston

All parts of the application (including the signed cover page and appendices in order) should be combined into one single .pdf or Word document and emailed to irb-houston@twu.edu. The original copy is not required. If you have any difficulty with preparing a .pdf file, please contact the Houston Office of Research via email for assistance.

RESPONSE TIMES

Upon receipt of the application, the investigator will receive an email notifying them that the application has been received, the level of review that the application has been assigned, and the protocol number that has been assigned. Applicants can expect to receive a response from the IRB regarding the review within three weeks for an expedited application and within two weeks from the date of the meeting for a full review application. Note that these times are estimates and additional time may be required during certain times of the academic calendar such as summer, semester breaks, and Holidays.

References:

1. Bowen A, Wenman R, Mickelborough J, Foster J, Hill E, Tallis R. Dual-task effects of talking while walking on velocity and balance following a stroke. *Age Ageing.* 2001;30(4):319-323.
2. Choi JH, Kim BR, Han EY, Kim SM. The effect of dual-task training on balance and cognition in patients with subacute post-stroke. *Ann Rehabil Med.* 2015;39(1):81-90.
3. Plummer-D'Amato P, Altmann LJ. Relationships between motor function and gait-related dual-task interference after stroke: a pilot study. *Gait Posture.* 2012;35(1):170-172.
4. Yang YR, Chen YC, Lee CS, Cheng SJ, Wang RY. Dual-task-related gait changes in individuals with stroke. *Gait Posture.* 2007;25(2):185-190.
5. Plummer-D'Amato P, Altmann LJ, Saracino D, Fox E, Behrman AL, Marsiske M. Interactions between cognitive tasks and gait after stroke: a dual task study. *Gait Posture.* 2008;27(4):683-688.
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