Study Protocol

Unique Protocol ID: STUDY20190922

NCT05469438

Brief Title: IMAS Optimization and Applicability in Acute and Subacute Stroke.

Official Title: IMAS Optimization and Applicability in Acute and Subacute Stroke.

Document Date: January 2, 2019

[USE THIS BIOMEDICAL PROTOCOL TEMPLATE IF YOUR PROJECT INVOLVES ANY PHYSICAL CONTACT OR MEDICAL INTERVENTIONS WITH PARTICIPANTS]

INSTRUCTIONS:

- Depending on the nature of your research, some sections may not be applicable to your research. Mark these sections with, "N/A" or leave blank as indicated.
- When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.

PROTOCOL TITLE:

IMAS Optimization and Applicability in Acute and Subacute Stroke.

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UH FACULTY ADVISOR:

If the principal investigator's primary role at UH is resident, fellow or student, identify a faculty advisor.

N/A

OTHER DEPARTMENTS INVOLVED IN THIS STUDY (IF APPLICABLE):

Department of Neurology (Cleveland VA and UHCMC)

VERSION NUMBER:

Include the version number of this protocol if assigned by an outside entity.

DATE:

Click here to enter a date.

Objectives

Directions: Describe the purpose, specific aims or objectives. Be sure to also include the hypothesis being tested

The AHA Stroke Rehabilitation guideline states that in the current fiscal climate, "the provision of comprehensive rehabilitation programs with adequate resources, dose, and duration is an essential aspect of stroke care and should be a priority" and recommends the development of "computer-adapted assessments for personalized and tailored interventions" and "better predictor models to identify responders and non-responders" [1]. Patient baseline motor status and potential for motor recovery [2-12] should guide long-term rehabilitation goals. However, acute motor assessment and prognostication remain a clinically difficult task [13, 14]. Conventional clinical assessments (e.g. NIH Stroke Scale, Fugl-Meyer (FM) Scale) [15, 16] that power prognosis are highly dependent on the initial severity and care provider/point of care. In addition, those are often reduced further to even coarser prognostic scales (e.g. Orpington Prognostic Scale (OPS)) [17], which are limited due to ceiling effects, omission of fractionated and complex distal movements, and/or unequal weighting of the two extremities in assessments [18]. Furthermore, many survivors do not even receive comprehensive assessments prior to discharge. Besides, telestroke approaches implemented to address such issues are limited in their scope of care and still not fully developed for functional assessments [19-23]. This is critical because "all patients benefit from a formal assessment of the patient's rehabilitation needs prior to discharge" [24]. A simple portable technology that can holistically aid clinicians in: 1. detailed assessments of motor symptoms; 2. patient classification for rehabilitation; and 3. prediction of recovery, is lacking [12-14, 25-35].

We will investigate our Integrated sensor-based Motion Analysis Suite (IMAS) of motion capture cameras, force sensors, and inertial sensors, to objectively and quantitatively measure acute stroke patient motor status. [redacted]

To this end, we will investigate one Specific Aim:

Aim 1: Assess the feasibility of using our IMAS for assessing acute stroke and predict outcome.

Sub Aim 1.1: IMAS optimization and applicability in an acute stroke setting:

We hypothesize that it is possible to use an integrated set of sensors that can interface with acute or subacute stroke patients undergoing motor exams to extract features of their motor behavior. Thus, we will evaluate the feasibility of our IMAS prototype (with motion capture cameras, accelerometers, gyroscopes, and force sensors). For this purpose, we will assess the IMAS in acute or subacute ischemic or hemorrhagic stroke subjects [redacted] subjects will undergo a series of IMAS upper limb focused tools such as FM, Barthel Index, and OPS assessments. We will also collect demographics, and stroke clinical information and imaging data from Magnetic Resonance (MRI) [redacted]

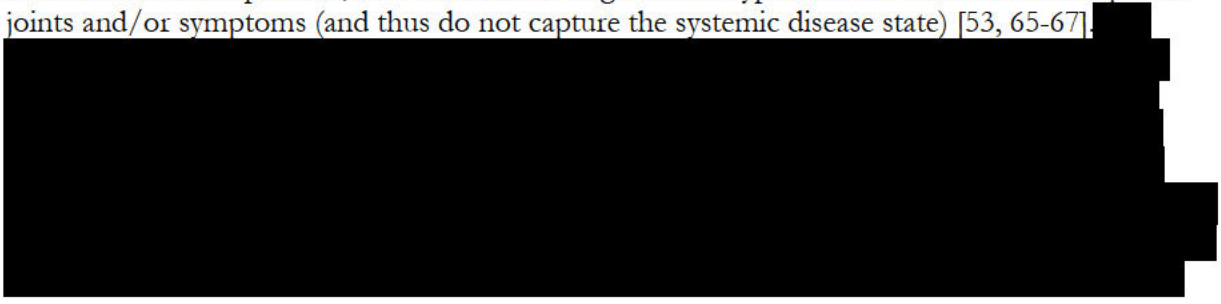
Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how it will add to existing knowledge. Include any relevant preliminary data.

The NIH National Institute of Neurological Disorders and Stroke (NINDS) sponsors this study It aims to investigate the feasibility of clinical use of an Integrated Motion Analysis Suite (IMAS) for stroke assessments. This technology is powered by software to objectively quantify stroke severity and predict stroke motor recovery.

Stroke is a leading cause of disability in the US, with ~6.5M survivors [37, 38]. Most survivors endure motor deficits (~70%) and require rehabilitation [1, 39-43]. Patient motor status and potential for recovery [2-12] should guide long-term rehabilitation goals. However, state-of-the-art tools to predict the extent to which a patient can recover their motor abilities or even to measure current abilities are limited. In fact, many survivors do not even receive comprehensive assessments prior to discharge. Telestroke addresses such issues, yet is limited in its scope of care and still not fully developed for functional assessments [19-23]. This is critical because "all patients benefit from a formal assessment of the patient's rehabilitation needs prior to discharge" [24]. With an aging population, a projected 19% shortfall in US neurologists in the next 10 yrs. [44-47], and a lack of neurologists outside of metropolitan areas [48, 49] the problem is growing. Furthermore, conventional clinical assessments (e.g., NIH Stroke Scale, Fugl-Meyer (FM)) [15, 16] that power prognosis are highly dependent on the care provider/point of care and are often reduced to even coarser prognostic scales (e.g. Orpington Prognostic Scale (OPS)) [17]. These assessments help predict recovery potential and/or tailor rehabilitation. However, these tools are limited given ceiling effects, omission of fractionated and complex distal movements, and/or weighing the upper and lower limbs unequally [18, 50-52]. To address these limitations the AHA Stroke Rehabilitation guidelines specifically call for the development of "computer-adapted assessments for personalized and tailored interventions", "newer technologies such as… body-worn sensors", and "better predictor models to identify responders and non-responders" [1]. However, a simple technology that can holistically aid clinicians in: motor symptom assessments, patient classification, and prediction of recovery is lacking [12-14, 25-35].

Sensor-based measurements of movement kinematics/ kinetics quantify patient motor abilities (e.g., [53-64]). For example, wearable sensors and motion capture cameras offer highly portable options [53, 65-67] to assess motor performance and predict clinical scales [63, 68-70]. However, those are difficult to implement in clinical settings due to size, cost, and complexity [61, 71]). Another limitation pertains, their reliance on single sensor types/modalities or focus on specific joints and/or symptoms (and thus do not capture the systemic disease state) [53, 65-67].



In summary, there is a great clinical need for a simple tool to assess stroke patient's motor abilities and predict likelihood of motor recovery. We will investigate a sensor-based system coupled with statistical algorithms to allow computational analysis of stroke injury, through data dimensionality reduction and prediction methods. This approach will provide the clinician with a tool to aid and augment the classic evaluation process.

Inclusion and Exclusion Criteria

Describe how individuals will be screened for eligibility. Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

Recruited will take place at the following places:

1. University Hospitals Cleveland Medical Center (UHCMC)
2. University of Illinois Hospital and Health System (UI Health)

Both of them have comprehensive neurology treatment and motor rehabilitation services available, including outstanding neurologists who can provide referrals of stroke patients to this study.We will invite those subjects deemed eligible to the lab for the consent process and an opportunity to ask additional questions. The research team will offer eligible patients enrollment in this study once confirmed safe and appropriate.

Information about patients who are not eligible will be shredded and not retained.

	Inclusion Criteria
1.	Providing informed consent to participate in the study.

2.	Age 18 to 85 years old.
3.	Clinical presentation and neuroimaging (CTA-CTP/ MRI-MRA) consistent with the diagnosis of Acute Ischemic or Hemorrhagic Stroke [7, 93-97].
4.	Preserved mental status (Glasgow coma score >12: E(4), V(5), M (4-6)) [98]
5.	Presence of upper limb weakness per the NIHSS (1-2 points in the arm) and ability to perform testing (i.e., NIHSS motor score 1-2 at elbow, wrist, and finger flexion-extension) [16, 99] within 30 days from stroke. (Note that individuals with a prior ischemic or hemorrhagic stroke with available information pertaining superior extremity baseline strength after their previous stroke would qualify).
6.	Presence of upper limb weakness per the NIHSS (2 points in the arm) and ability to perform testing (i.e., NIHSS motor score 2 at elbow, wrist, and finger flexion-extension) [16, 99] in subacute stroke. (Note that individuals with a prior ischemic or hemorrhagic stroke with available information pertaining superior extremity baseline strength after their previous stroke would qualify).
7.	Baseline Modified Rankin score <4 [100, 101].

	Exclusion Criteria
1.	History of dementia per relative/ medical records.
2.	Presence of receptive aphasia at baseline or after the current acute stroke.
3.	Need for rapid clinical response due to conditions such as psychosis, or suicidality.
4.	Unstable medical conditions (e.g., uncontrolled diabetes, uncompensated cardiac issues, heart failure, pulmonary issues, or chronic obstructive pulmonary disease);"
5.	Amputated limbs [16, 99].
6.	Absence of weakness as per the NIHSS (0 points = no drift for motor arm and leg items) or severe motor impairment NIHSS 4 points for motor arm)[16, 99].
7.	Stroke mimics (e.g., infections, medication effects from sedatives, electrolyte imbalances, etc.).
8.	Stroke worsening between assessments.

Number of Research Participants

Directions: Indicate the target number of research participants to be accrued locally, and, if this is a multi-site study, indicate the total number of research participants to be accrued across all sites.

Up to 60 patients with a diagnosis of stroke, and meeting the above criteria will be recruited on both following sites.

1. University Hospitals Cleveland Medical Center
2. University of Illinois Hospital and Health System
3. Sinai Chicago Medical Center (affiliated to Schwabb Rehabilitation Medical Center)

Recruitment Methods

Describe how subjects will be identified (the source of potential research participants), and also how, when, and where they will be recruited. Describe all methods of contact / communication.

We will recruit up to 60 subjects for this study, with the intention of enrolling exactly 30 subjects with stroke to account for screen failures and withdrawals of subjects (e.g., some of the patients who are recruited and pre-screened into the study might worsen or fluctuate and then would be excluded following previous visits).

Potential subjects will be identified by the following sources:
1. Attending physicians or therapists may refer their patients to the study.
2. Via the UHCMC and UI Health inpatient facilities.
3. Possible subjects might also be identified through their medical records and their physicians might be asked to inform the subject about the study.

We anticipate that subjects will be primarily recruited through the University Hospitals Cleveland Medical Center and University of Illinois Hospital and Health System. All patients receiving inpatient care for stroke at University Hospitals Cleveland Medical Center and University of Illinois Hospital and Health System will be eligible for this study. We will also approach colleagues at the other collaborating teaching hospitals and institutions in the greater Cleveland area and Chicago area. Overall, we anticipate a large population with stroke that will be eligible for this study allowing for the effective recruitment of 30 patients.

Eligible patients will be offered enrollment in this study once deemed safe and appropriate by the research team.

Informed consent will be obtained by the study PI and/or a co-investigator in person. The test procedures will be described and the testing equipment will be shown to the subject. Study co-investigators will clearly explain all the procedures and risks of the testing outlined in the consent form. The subject will be given the time needed to consider their decision and will be encouraged to ask questions, both during the initial interview and throughout the study. The PI or a co-investigator will answer any questions regarding the study at the time consent is given. Once enrolled, the subject may pause or terminate his/her participation at any time during the study.
Retention of subjects is feasible, particularly because of the facilities available at the University Hospitals Cleveland Medical Center, which is a top hospital with Comprehensive Stroke Center Certification (Honor Roll Elite Plus Gold Plus status) and University of Illinois Hospital and Health System designed to promote accessibility for a diverse population of patients with mobility issues. Patient retention will be encouraged/ followed by study staff via communication with the patients throughout the research study, such as to check in on patients and help arrange transportation to the medical center.
Patients will also be compensated for their time and effort as detailed in the section below.

Setting
All research related activities in this protocol will be performed at the main University Hospitals Cleveland Medical Center and University of Illinois Hospital and Health System facility. Recruitment

of potential participants would be carried out from the inpatient facilities (preferentially Lerner Tower 4th floor) at University Hospitals Cleveland Medical Center at 11100 Euclid Avenue. For University Hospitals Cleveland Medical Center facility, research procedures will occur inside the laboratory of the DCRU. For University of Illinois Hospital and Health System, research procedures will occur at the following locations:

1. 1740 W Taylor Street, Suite C-100 M/C889, Chicago IL 60612
2. 1801 W Taylor Street, room 1307, 1320 or 1314A, Chicago IL 60612

Consent Process

This study will be obtaining consent but request a partial waiver of HIPAA authorization for screening purposes. Specifically, we would like to collect limited information from the medical record directly pertaining eligibility information about potential subjects from the medical record (i.e,. diagnosis of stroke and other information pertaining to inclusion/exclusion criteria). Individuals with a prior ischemic or hemorrhagic stroke with available information pertaining superior extremity baseline strength after their previous stroke. The research team may contact the patients' caregivers to gather this information to ascertain their eligibility to enter the study.

Sharing of Results with Research Participants

- ☒ Results will <u>not</u> be shared with research participants
- ☐ Results will <u>not</u> be shared with research participants' doctors

Study Design

This study will have 1 screening visit and 5 evaluation visits and use a battery of sensors for acquiring patent movement kinematic and kinetic data.

We will recruit up to 60 subjects for this study, with the intention of enrolling exactly 30 subjects with stroke to account for screen failures and withdrawals of subjects (e.g., some of the patients who are recruited and pre-screened into the study might worsen or fluctuate and then would be excluded following previous visits).

Study Procedures

<u>Pre-screening Procedures:</u>

During the pre-screening process, the investigators will approach the clinical stroke care team to learn about potential candidates admitted with acute or subacute stroke in the privacy of the Stroke team's work room ("Fishbowl") at Lerner Tower 4th Floor at UHCMC or other approved facilities. For University of Illinois Hospital and Health System, research procedures will occur at the following locations:

1. 1740 W Taylor Street, Suite C-100 M/C889, Chicago IL 60612
2. 1801 W Taylor Street, room 1307, 1320 or 1314A, Chicago IL 60612

Once this information is collected, the coordinator will consult with the principal investigator, who will then give approval for the subject to be screened. The pre-screening process will last duration of approximately 15'.

Screening
(Approximate Time: 20 mins)

Screening Procedures:
At Screening the PI and the co-investigators will conduct a review of inclusion/exclusion criteria to determine the subject's eligibility for enrollment. Study procedures will be reviewed with the subject, and documentation of informed consent will be obtained.

At Screening the following procedures will be completed:

- Discuss study-specific procedures with the subject.
- Review inclusion and exclusion criteria.
- PI will review the initial assessment of the subjects to determine which subjects have a diagnosis of stroke.
- Obtain a signed and dated consent form.
- Patient demographics and medical information obtained from Medical records such as collection of stroke lesion information from MRI, collection of time from stroke onset information, etc.

Evaluation 1
Initial Evaluation - (Approximate Time: 90')
This visit might be completed on the same day as the screening visit if time allows and it is convenient for the subject.

- Fugl-Meyer evaluation
- OPS evaluation
- Barthel Index evaluation
- [redacted]
- Adverse events NIH-CDE questionnaire

Note, all patients will undergo stroke standardized multidisciplinary rehabilitation (independent of these experiments).

Evaluations 2-4
Evaluation - (Approximate Time: 90')
These visits will be scheduled in acute or subacute strokes in the wards and other approved testing areas.

During each visit, the subject will complete a series of assessments:

- [redacted]
- Adverse events NIH-CDE questionnaire.

Evaluation 5

This visit will be scheduled after rehabilitation completion (during a standard clinic follow-up). All patients will receive standard physical and/or occupational therapy as indicated by our PT specialists and followed by standardized exercises for home therapy as needed.

Final Evaluation (5) - (Approximate Time: 90 mins)

- Fugl-Meyer evaluation
- OPS evaluation
- Barthel Index evaluation
- [redacted]
- Adverse events NIH-CDE questionnaire.

We will perform up to 4 assessments in the initial phase and then 1 follow up. Subjects will be asked before each 90-minute research session whether they feel up to completing the physical study activities, and also that the study team will verify before the session with nursing that the research session does not conflict with any clinical care, e.g., MRI or therapy session.

DESCRIPTION OF ASSESSMENTS:
A research team member will conduct the following assessments:

Fugl-Meyer (FM): We will conduct a FM assessment (upper limb) [15]. The FM score is a stroke-specific, performance-based impairment index. It is designed to assess motor functioning, sensation and joint functioning in patients with post-stroke hemiplegia. It is applied clinically and in research to determine disease severity, describe motor recovery, and to plan and assess treatment. There are no associated risks with these measures and do not add any more stress than standard physical movements. If subject's become fatigued they will be informed they can take a break at any point during the assessment.

Orpington Prognostic Scale (OPS): We will conduct an OPS assessment [102]. The OPS is an assessment of stroke severity (e.g., motor deficits, proprioception, balance and cognition). It is applied clinically and in research. There are no associated risks with these measures and do not add any more stress than standard physical movements. If subject's become fatigued they will be informed they can take a break at any point during the assessment.

Barthel Index: We will conduct a Barthel Index assessment[100]. The Barthel Index questionnaire measures the extent to which somebody can function independently and has mobility in their activities of daily living (ADL) i.e., feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation and stair climbing. The index also indicates the need for assistance in care. The BI is a widely used measure of functional disability. There are no associated risks with these measures.

[redacted]

[redacted]

These assessments do not add any more stress than standard physical movements. If subjects become fatigued, they will be informed they can take a break at any point during the assessment. During motion tasks patients will not be asked to perform movements that they feel they are incapable of performing or cause excessive stress. Assessments will be made during the neurological examination of the patient (partly to gather data to determine the FM information), and no added risks will be made beyond what is seen in a typical neuro/motor exam. During motion tasks patients will not be asked to perform movements that they feel they are incapable of performing or cause excessive stress. Assessments include:

[redacted]

Data to be Collected for your study
(AFTER consent and HIPAA Authorization have been obtained)
List all data to be collected for the research study or attach a data collection sheet (e.g. laboratory values, physician notes, length of stay, etc.)

Also, the following data will be collected:

- Telephone number
- Email address
- Address
- Medical record number

- Dates related to an individual (e.g., date of admission, birth, surgery, etc)
- Name
- PMH
- Imaging Data
- OPS
- Barthel Index

[redacted]

Data Analysis Plan

We determined the sample size (recruitment up to 60 subjects for n=30 subjects completing the protocol) based on: 1. A sample size of N=15 patients provides at least 80% power (alpha=0.05) to detect a mean difference of 3% in arm movement mean speed, 2.7% in arm movement mean peak speed, and 2.5% in arm movement jerk between an affected and non-affected limb. [redacted]

[redacted] e will then assess if our computational algorithms can predict a patient's FM score and a patient's motor recovery state after rehabilitation.

Data forms and questionnaires: we will code those in a standardized manner, and enter them into our database. We will track and regularly back up digital measures/recordings in our database. Analyses will involve the use of standard statistical software such as R and MATLAB.

Confidentiality

To ensure confidentiality we will:

- Use a unique study identifier (not derived from the participants personal identifiers) to code individuals' data and I will store this ID log separate from study data.
- Store the electronic data in a UH Secure Network Drive for UHCMC and UIC Secure Network Drive for UI Health.
- Store paper research data and documents in locked secure environment safe-locked cabinet. For UHCMC, room#108, 2027 Cornell Road, Cleveland, OH 44106. For UI Health 1801 W. Taylor St., room 1309, Chicago IL 60612.
- De-identified patient data will be shared with the other collaborators on this NIH study. This data involves results from our testing.

As for HIPAA Authorization:

- We are requesting a full or partial waiver of HIPAA for prescreening
- Note, this study requires access to protected health information about patients prior to their consent to assess eligibility for potential participation. Their PHI might come from electronic or paper file medical record access or by way of the healthcare providers' personal knowledge of the patients' health information. Specifically, to collect eligibility information about potential subjects from the medical record such as whether a person or persons have stroke, and other inclusion and exclusion criteria.
- We will keep any potential identifiers for 3 years beyond the conclusion of present study's procedures, data collection and analysis.
- PHI collected for purposes of this research study will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

Risks to Research Participants

List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.

Questionnaires and motor assessments:
There are potential risks of personal discomfort to answer the questionnaires.
There are some potential risks of fall, syncope and fatigue posed to subjects during recording of data with the biomechanical sensor suite. We will make sure that our study team will stand near the subjects

so that we can provide support at any time. If participants become fatigued during testing or are uncomfortable answering any personal questions, they will be informed that they are allowed to take a break at any point during the experiment and that they may end their participation at any time.

Risk of breach of confidentiality
There is a risk of breach of confidentiality because someone who is not a part of the research team involved with this study might view your data either by accident or from malicious actions they take to hack the data. We are protecting against this possibility by only storing information that can be directly linked to you on UH computers, in password-protected files, which are behind firewalls.

Provisions to Protect the Privacy Interests of Research Participants
Directions: Describe the steps that will be taken to protect research participants' privacy interests. (Consider issues such as physical space, proximity to other, and participant preferences)

For University Hospitals Cleveland Medical Center facility, screening, consenting and any research interventions will occur in private patient care rooms at the UHCMC inpatient facilities (Lerner Tower 4th floor). For UI Health, screening, consenting and any research interventions will occur in private patient care rooms at the following locations:
1. 1740 W Taylor Street, Suite C-100 M/C889, Chicago IL 60612
2. 1801 W Taylor Street, room 1307, 1320 or 1314A, Chicago IL 60612

Potential Benefit to Research Participants
Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. If there is no direct benefit, state the potential benefit to society.

There is no direct benefit to subjects for participating in this research study.
However, stroke is a serious issue, particularly in an older adult population. Thus, a benefit for society overall is related to addressing the pressing need for stroke prognosis.

Withdrawal of Research Participants
Directions: Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent. Also include the procedures that will be followed when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

The study doctor will inform the participants about new information or changes in the study that may affect their health or willingness to continue in the study. The study staff may take the participant out of the study without its permission if any of the following occurred:

- If there are subject health changes and the study is no longer in subject best interest

- If new information becomes available that warrants stopping participation
- If the participant does not follow the study requirements
- If the study is stopped by the sponsor, Institutional Review Board (IRB).

If any of these events occurred, the study doctor will explain why the subject needs to stop taking part in the study. We will also talk to the participant about follow-up care if needed. If the subject withdraws from the study prior to its completion for any reason, we will request a final clinical visit to ensure subject safety. In the event that further care is needed, the research team will direct the subject to the appropriate resources. If a subject decided to stop participating, it may decide whether or not to let the study doctor continue to provide its medical information to the organization running the study.

Alternatives to Participation

Directions: List other available clinical treatments, what would be included if a subject continued on standard of care therapy. If this is not a clinical trial, you may select the box indicating that the alternative is not to participate. If there is a viable alternative you must list it in the consent.

This is not a clinical trial. Subjects alternative is not to participate.

Costs to Research Participants

Describe what costs research participants will be responsible for as a result of their participation in the research, including but not limited to: clinical services required by the protocol deemed billable to insurance, transportation to study visits, parking, costs of drugs, cost of therapy, lost broken or stolen devices, etc. Explain who will be responsible for payment of provided services in the event of insurance denials. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source.

There are no costs to research participants or their insurance companies.

Research Participant Compensation

Describe the schedule, payment method, and payment total of any incentives or compensation that research participants will receive for participation in the research (e.g., gift cards or cash with amount, t-shirts, devices, bags, swag, etc.)

Describe the schedule, payment method, and payment total of any reimbursement that research participants will receive for participation in the research (e.g., gift cards or cash with amount, etc.)

Subjects will receive $25/visit or evaluation, which means subjects will be compensated $50 for the day that has 2 evaluations. Study funds will also cover the cost of parking (in the Rainbow parking garage) for evaluation 5. Additional transportation costs will be reviewed by the study PI and may be redeemed on a case-by-case basis.

Funding agency is not providing any payment for injury.

Provisions to Monitor the Data to Ensure the Safety of Research Participants

Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol.

Indicate if there will be a Data and Safety Monitoring Board or Committee. Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc.

We will review adverse events following each patient visit. All adverse events, regardless of attribution to evaluation with the motor analysis suite, will be collected and recorded, using standard adverse event forms. A diagnosis, rather than signs, symptoms, and/or other clinical information, will be recorded when possible. Subjects will be asked in an open-ended manner about the presence of any adverse events. We will assess adverse events per the NIH CDE instrument. All applicable local regulatory requirements related to serious adverse events will be followed during this study. Serious adverse events will be promptly reported to the IRB, the General Clinical Research Center, the NIH. The issue of placing the study on hold will be raised by the investigators with our local IRB if any serious adverse events occur.

The PI or study staff will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance. Data collected will be reviewed by a member of study staff not responsible for the collection of that data set.

Drugs or Devices

No drugs or devices will be used interventionally for this research project.

Additional Information

Directions: If you have any additional information regarding your study not covered in the template, please include it here.

Upon receiving funding, a research fellow and research nurse support through the Dahm's unit will be added to the protocol per the NIH budget that was submitted.

Community-Based Participatory Research

Describe the involvement of the community in the design and conduct of the research.

Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) protects, the community participates fully in all aspects of the research process.

This is not a community-based participatory research project.

International information

If you will be conducting international research, address the following issues:

- Sites/locations
- Data sharing

This is not an international study.

References

Please reference the Investigator Manual for local institutional requirements.

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