Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-44913
Status: Approved
Initial Submit Date: 2/19/2019
Approval Period: 3/22/2021 - 3/21/2026

Section Aa: Title & PI

A1. Main Title

TELEEXERGAME: REMOTELY-SUPERVISED EXERCISE PLATFORM FOR IMPROVING COGNITION AND MOTOR FUNCTION USING TELEMEDICINE

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

Yes

Section Ab: General Information

A4. Co-Investigators

None

A5. Funding Source:

Organization: NATIONAL INSTITUTES OF HEALTH (NIH)

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

No

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?

No, this clinical is not a clinical trial, or does not meet the definition of an Applicable Clinical Trial, or does not need to be registered under the terms and conditions of an award, or is not a clinical trial with results intended to be reported in an journal belonging to the ICMJE. Registration is not required.

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Rapid population aging is increasing the number of older adults who suffer from motor-cognitive declines and associated increases in fall risk and fear of falling. Effectiveness of exercise, as an effective intervention to preserve cognitive function, has been well established and supported by recent studies including systematic reviews and our own prior work. But at the same time individuals with poor motor and cognitive performance generally cannot have regular visits to a rehabilitation center for face-to-face exercise, have highest drop out because of functional limitations, and have poorest adherence to unsupervised exercise programs. Therefore, designing a remote exercise intervention, tailor for those with cognitive impairment, is desperately needed and could make a significant impact in the field, including preserving cognitive function in people with MCI, promoting independent living, and reducing costs associated with consequence of cognitive-motor decline including falls and frailty. We propose to develop an in-home exercise system for adults with mild cognitive impairment or mild dementia that is specifically designed to improve balance and cognition during distractive conditioning while the exercise is remotely supervised by a telemedicine interface.

Section D: Purpose and Objectives

This research study aims to help design and validate a novel technology to remotely provide exercise intervention for people at risk or with some level of dementia. In addition, the platform enables remote assessment of cognitive-motor performance via wearable sensors through playing a simple interactive game named iTMT. A remote exercise intervention tailored to those with cognitive impairments could make significant impact in preserving cognitive function in people with MCI, promoting independent living, and reducing costs associated with consequence of cognitive-motor decline including falls and frailty. This application could in addition further the knowledge in use and development of remote technology to screen cognitive and motor performance and promote independent living in older adults in particular for those who are suffering from cognitive impairment and dementia. Given the large and growing number of older people at risk of developing cognitive impairment and dementia, this knowledge would be important to health providers, clinicians, older people, and their caregivers.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:

Both

Age:
Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:
c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.
For this research design there are two phases.

Phase I: 15 subjects with mild dementia and cognitive impairments will participate in a single arm 6 weeks remote exercise intervention.

Phase II: 100 subjects with mild dementia and cognitive impairments will participate in a randomized controlled trail (RCT) exercise intervention using two arms for 12 weeks. The control group will perform the exercise intervention in a supervised condition and the intervention group will perform the exercise intervention remotely.

Inclusion Criteria:
Male and female patients with MCI and mild dementia (formal diagnosis or MoCA score between 20-26), who are ambulatory (able to walk a distance of 20m with or without walking assistance), living independently in a residential home with a caregiver/informant, and who are willing and able to provide informed consent, will be recruited.

Exclusion Criteria:
Subjects will be excluded if they have a immobility or major mobility disorder or inability to engage safely in the proposed weight-bearing exercise program (e.g., double amputees, patients with active plantar ulcers, patients with major back or lower extremity pain). If they are diagnosed with severe cognitive impairment (MoCA score < 20), other neurological conditions associated with cognitive impairment such as stroke, Parkinson disease, and head injury, and/or any clinically significant psychiatric condition, current drug or alcohol abuse, or laboratory abnormality that would interfere with the ability to participate in the study. Subjects with major hearing/visual impairment will also be excluded.

F2. Procedure

Prior to any study related procedures, all subjects will be consented.

These are the study procedures,

Phase I: The study will consist of a 6 week exercise program with one baseline, 12 at home intervention sessions, 3 weeks follow up, and 6 weeks follow up.

History and Physical Examination: A standard physical examination will be performed at screening. We will record age, gender, presence of diabetes and its type and duration, diabetic treatment, prior foot ulcers (with location and duration), prior amputations or foot surgeries, co-existing medical conditions, and location and duration of the ulcer. We will use Kaplan Co-morbidity Index to score disease severity.

Medical History: We will record socio-demographics (e.g. age, gender, BMI, education, marital status, etc) and medical history (health status including comorbidities, history of falls, history of hospitalization, priory surgery, duration of diagnosed as MCI, co-existing medical conditions, hearing and visual performance, frailty status, etc), medication use, etc. We will examine frailty status using Fried Frailty criteria (Weight loss >10 pounds in preceding year; Grip strength; Low levels of physical activity; 15 foot walk time; Exhaustion). Standard foot questionnaire will be used to assess any potential limitation, which may influence the ability of participants to perform iTMT using ankle-foot trail making. Foot sensation and peripheral neuropathy will be examined using Vibration Perception Threshold (VPT) testing. We will administer the valid and reliable eMINI to exclude individuals with substance use, bipolar, and psychotic disorders. We will document all prescriptions and over-the-counter medications. We will measure height and weight to determine body mass index.

Social Factors: We will evaluate the following factors: marital status, years of education, type of work, tobacco history (pack years, current smoker, current use of chewing tobacco, previous smoker, no tobacco history).

Questionnaires: We will ask the subject to answer a series of health related questionnaires such as quality of life (Promise Global), demographics, anxiety (Beck Anxiety Scale), Pain-Mobility, fear of falling (FES-I), frailty (Fried Frailty), MOCA for cognitive status, and depression (CES-D), Trail-making task A and B, LifeSpace, ePro Lawton and Katz Scale for daily activities. We will also ask them to fill out an acceptability questionnaire at the follow up visit.

Peripheral Neuropathy: We will use Vibration Perception Threshold (VPT) testing, evaluated at the distal great toe, heel and 5th metatarsal.

Gait assessment: Gait performance will be assessed using a validated body worn sensors (LegSys¿, Biosensics LLC, USA). The device uses five sensor modules respectively attached to right and left anterior shins, right and left anterior thighs, and posteriorly to the lower back. Based on the subject¿s height and using a two-link inverse pendulum model the following spatio-temporal gait parameters will be estimated: velocity, stride length, stride time, double support, single support, stride-to-stride variability, and gait initiation. In addition, the center of mass (COM) range of motion during walking will be calculated by using the data from the sensor attached to lower-back. Gait will be assessed over a distance of 20 meters under 2 conditions: (1) walking at habitual speed (2) walking at maximum speed (fast walking).

Balance assessment: Balance will be quantified using validated body worn sensors (BalanSens¿, Biosensics LLC, USA). The system measures ankle and hip motion in three dimensions (3D), 2D COM sway as well as RCI in ML and AP directions. Balance will be assessed according to Romberg protocol during eyes-open and eyes-closed condition during double, semi-tandem, and full tandem stances.

Physical Activity Monitoring: The subject will be given a wearable device (PAMSys) that will be measuring several parameters including number of steps taken, duration of sitting, standing, walking and lying, time taken and number of transitions from sit to stand, and walking speed for 48 hours. At the end of the specific visit, the subject will be given a the device attached to pendant to wear around the neck. Investigators will provide a pre-paid envelope where the subject may place the device and send back it to the investigating team.

Intervention: All recruited subjects will undergo to six weeks exercise program using the Exergaming platform described in the proposal, twice per week for approximately 30 minutes. The first two sessions (week #1), subjects are asked to perform six blocks (each approximately takes 5 min to be completed) of consecutive ankle reaching tasks in upward-downward (i.e. ankle flexion-extension) direction and side-ward reaching task (foot inversion-eversion). They could have reset between each block of exercise before starting the next block. In the sessions 3 and 4 (week #2), reaching tasks on diagonal directions are added, which is required the combined foot inversion-eversion and ankle flexion-extension. To keep the duration of exercise constant, a block from simple reaching task is replaced by a new complex reaching task. From the sessions 5 (week #3), motor-cognitive tasks as described in the following will be added. The tasks make the program more challenging and fun, in addition to potentially having a secondary benefit for older patients who may struggle to execute motor-cognitive tasks.

Motor-Cognitive Exercise program - a motor-cognitive exercise including working memory inspired from paper-pencil Trail-Making test (TMT), which is one of the most popular neuropsychological test, will be added as a part of exercise platform, which may enhance motor-cognitive benefit of the proposed exercise and makes it more challenging and entertaining, after subject master the simple exercise tasks. Specifically, the exercise program includes three level of motor-cognitive complexities including: Fixed-order TMT, Random-order TMT, and Number-Letter-order TMT. For the fixed order TMT, six circles are appeared on the screen. One start circle in white and five target circles in yellow. The target circles are located as a fanwise position in front of the start circle. Each target circle has a number located in the center. From left to right, five target circles have fixed numbers 1, 2, 3, 4, and 5 in sequence. At the beginning of each task, position of the cursor is automatically calibrated to the center of the start circle. By rotating the ankle, subject navigates the cursor to the center of

the first target circle (with number ¿1¿ inside). Then subject navigates the cursor back to the center of the start circle, and goes to the second target circle (with number ¿2¿), and goes on. If subject navigates the cursor to a wrong target circle, an audio feedback indicating mistake would be played. Then subject needs to go back to the start circle and continues the TMT from where the previous mistake was made. If the subject did three consecutive mistakes, a visual cue is appeared to guide the subject to correct the sequence. If the subject achieved to reach to the target in a timely manner, the target is exploded with a reward sound. The random order TMT is similar as the fixed order, but the numbers are shuffled at each trial and does not necessary appeared on the same location than previous trial. In the number-letter order TMT, not only the order of numbers in target circles is randomized, but also numbers are mixed with letters together. Instead of 1, 2, 3, 4, and 5, this task has 1, A, 2, B, and 3 located at the center of each target circle. Subject navigates the cursor to targets with numbers and targets with alphabets alternately. Therefore, after completing target ¿1¿, instead of going to target ¿2¿, subject should move the cursor to target ¿A¿. Each complexity task is provided on progression manner, means, when the subject masters one level (e.g. execution of all TMT within 5 minutes with less than two errors), it could achieve to the next complexity level.

Timed-up-and-go (TUG): Subject may be asked to stand up from a chair, walk 3 meters, walk back to the chair, and sit down as fast and safely as possible.

Upper Extremity Test: Investigators will measure arm motion from each participant by implementing a validated technology based on wearable sensor system named LegSys. This system will assess respectively spatio-temporal parameters of arm motion in a clinical setting. The LegSys system will be used with one sensor (placed on the wrist) to capture arm motion. While being at a comfortable position, the subject will be asked to flex and extend their arm for 20 seconds at a fast speed. Subject will also be asked to repeat this task but counting backwards as they flex and extend their arm (dual task).

Phone calls: We will contact subjects at three and six months after their follow up visit to ask if they have had any accidental falls and other questions regarding their health. Research Coordinators may also call subject for study related questions.

Photos and media: We will be asking permission of the subject to take photos, film videos and/or record audio during the visits in order to monitor their progress throughout the study. Additionally, these photographs might be used for scientific publications/ oral presentations. If the subject's face is in the photo, as per journal policy, we will cover their face.

Phase II: The study will consist of a 12 week exercise program with one baseline, 24 exercise sessions, 6 weeks follow up, 12 weeks follow up, 6 months follow up, and 12 month follow up.

The same questionnaires and physical assessments will be completed at each in person visit as Phase I. In Phase II, 100 subjects will be randomized into either intervention or control group. All recruited subjects will undergo to 12 weeks exercise program using the Exergaming platform described in the proposal, twice per week for approximately 30 minutes. The intervention group will be given the Exergaming system and will perform the 24 exercise sessions remotely. The control group will perform the exercise sessions in person under supervision with the Exergaming system. The first four sessions (week #2), subjects are asked to perform six blocks (each approximately takes 5 min to be completed) of consecutive ankle reaching tasks in upward-downward (i.e. ankle flexion-extension) direction and side-ward reaching task (foot inversion-eversion). They could have reset between each block of exercise before starting the next block. Starting the 5th session (week #4), reaching tasks on diagonal directions are added, which is required the combined foot inversion-eversion and ankle flexion-extension. To keep the duration of exercise constant, a block from simple reaching task is replaced by a new complex reaching task. From the 11th session (week #6), motor-cognitive tasks as described in the following will be added. The tasks make the program more challenging and fun, in addition to potentially having a secondary benefit for older patients who may struggle to execute motor-cognitive tasks.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 115 Worldwide: 115

Please indicate why you chose the sample size proposed:

For Phase I: Considering the timeline and budget limitation, the sample size is limited to 15 subjects. Size was estimated based on preliminary study, described in detail in the research strategy document, in which we have demonstrated that 4-weeks exergame program significantly reduce center of mass (COM) sway in aMCI patients with an effect size of 0.83 compared to baseline. Assuming a pairwise comparison using t-test, 80% power, alpha of 5%, 14 subjects should be sufficient to observed significant difference in balance compared to baseline. For phase II: The sample size was calculated based on our preliminary study described above for training-related improvement in balance (quantified by CoM sway area in medial-lateral direction during eyes-open stance), fear of falling (quantified by FES-I), and cognitive function (quantified by TMT) post exercise in people with confirmed amnestic MCI. Our preliminary results suggested that prior Exergame, COM sway in was 1.60±0.76 cm2 and was improved to 1.05±0.44cm2 post Exergame intervention (Cohen¿s effect size d=0.83). Assuming a pairwise comparison using t-test, 80% power, alpha of 5%, 14 subjects should be sufficient to observed significant difference in balance compared to baseline. Our preliminary study has also suggested that FES-I was significantly improved post exercise compared to baseline with an effect size of 1.14, suggesting a sample size of 9 to

observe benefit for fear of falling. Finally, effect size for improvement in TMT A post exercise was 0.42. Thus using similar assumptions described above, the needed sample size for observing benefit for cognitive function is 46. Assuming approximately 10% drop out, we plan to recruit 50 subjects per group, for a total of 100 subjects.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

(For both phases) We will used paired t-test (for normally distributed outcomes) and Mann-Whitney U-tests (for non-parametric outcomes) to determine the effect of intervention at 6 weeks. To examine whether the benefit of exercise is dependent on sex (sex as biological factor), we will compare the gain in balance improvement between male and female using Mann-Whitney U-test. We recognize that the study is under power for assessing the effect of confounders (e.g. age, baseline cognitive performance, baseline motor performance, BMI, etc). However, we determine whether the magnitude of gain is correlated with any of these confounders using Spearman correlation of coefficient change. During Phase II, these confounders will be controlled as covariant and between and within group comparisons will be adjusted.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

The measuring systems including LEGSys (for assessing gait and balance), BalanSens (for assessing balance), and PAMSys (for monitoring spontaneous daily physical activities) , as well as the iTMT platform are battery-powered, self-contained units and used in many clinical studies including patients with MCI and AD, and no adverse report were reported. Except activity monitoring, the rest of assessments including gait and balance will be performed in a control environment. As these devices are attached using elastic straps, research staff will ensure these are comfortably tight on the participant to avoid any pain or poor blood flow.

For home assessment, PAMSys (will be used for daily physical activity monitoring and daily motor performance such as postural transition) is worn in a shirt or vest pocket and does not rest directly against subjects¿ skin. Thus, wearing the PAMSys¿ poses no risks to subjects. All wearable sensors, which will be used in this study meet the requirements for IDE exemption under 21 CFR 812.2(c), Category 3.

This is a longitudinal study of 'care-as-usual' with supplementary minimum risk virtually guided foot and ankle motor-cognitive exercises. We believe that there are no significant psychological, legal, or social risks. Participation is entirely voluntary and the participants could stop/leave the study at any time. All exercise programs are administered while standing but the subject will have a research staff member or caregiver (during Phase II, remote intervention arm) and thus potential risk of fall is minimum. However, like any exercise, some may feel joint pain associated with consecutive foot and ankle joint rotation. To minimize the fatigue and risk of joint pain, exercises are divided to several blocks of maximum 5 min. Subjects will have enough rest before initiating the next block of exercise. There may be some concerns or stress due to potential "failure" to successfully complete an exercise task. To minimize the risk, the first few sessions include simple motor-cognitive tasks and the complexity level increases as the exercise progresses. In our pilot program, in which 7 subjects participated in the Exergame intervention program (twice per week for 4 weeks), only one subject was dropped out due to travelling difficulties, while all other participants completed all exercise sessions. No adverse events or concerns about difficulties of the exergame tasks were reported.

Please note that there is also the possibility for loss of confidentiality. The PI and the research team will minimize the possibility of for loss of confidentiality by keeping all the physical data locked in cabinets only accessible to the research team. The electronic data will be kept on network password protected institutional computers. . Data collected during the study may be published and made publicly available. Data may also be shared with other research groups. However, data that could in any way identify the subject will not be made public or shared. And, subject PHI will be coded as much as possible to minimize the potential for loss of confidentiality.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Phase I: There is no direct benefit to participating subjects as this is a pilot study and their participation will help improve further research in this population.

Phase II: We cannot promise any benefit to you or to others from joining this research. However, possible benefits include enhancing the subject's balance and walking ability. In addition, what the researchers find out from this study may help other people with poor balance as well as those suffering from MCI and mild dementia.

Describe potential benefit(s) to society of the planned work.

The main benefit to subjects is the positive feeling that they will have by participating in a study that will potentially help other people by developing new technology that could assist them to maintain mobility, preserve their cognitive, and promote aging in place and independency. They might eventually directly benefit from this technology if they purchase it in the future. In addition, all participants will provide validated exercise interventions, which have been showed to be effective to improve balance and mobility in people with dementia and MCI. The subjects will be compensated for their time ($50 per visit either in clinic for baseline assessment or at home when study investigators will visit them at home). In the Phase II, participant will be compensated $10 per exercise session as well. During Phase II for the control group, who needed face-to-face exercise, their parking fee and/or transport (up to $50) would be compensated. Except baseline screening and post exercise evaluation, no any clinic visit is needed for the intervention group. At the end of the study, a research investigator will collect the teleexergame platform from the intervention group.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

While the risk is anticipated to be minimal as described above, the gained knowledge is significant and may assist us to translate a practical, low cost, and personalized game-based exercise platform in a secure and remote setting to enhance balance, mobility, and quality of life of patients with MCI and mild dementia.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

We will review our patient charts to determine and verify patient eligibility.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

A plan exists such that only the PI and clinical database administrator have access to these passwords protected identifiers, which are subsequently removed when sharing data with co-investigators, analyzing data, and reporting or disseminating aggregate outcome data (often reported as rates) in scholarly publications and scientific presentations. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

Subjects will receive the same standard regardless of their participation in the trial.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

If we are not allowed to search the patient's records, we cannot identify and recruit the patients that are eligible for the study. Patients will receive the same standard of care whether or not they participate in the research.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

The PI and his designated research coordinator have both received training in the protection of confidential patient information. All study information obtained will be coded. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals. As there is a possibility of a loss of confidentiality in this study, the PI and his team will employ ample measures such as coding as much of the data as possible. In addition all physical information will be kept in locked file cabinets. All electronic data will be stored on our network password protected computers.

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

Protected health information will be kept in physical regulatory binders under double lock. Only the PI and the PI's staff will have access to the regulatory binders. All study non-identifiable data will be kept in the iCAMP server, with address \\discovery1.ad.bcm.edu\bcm-dept-icamp which is password protected. Protected health information will not be disclosed to any other person or entity except if required by law or for an authorized oversight of the research study.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

We will destroy identifiers at the earliest opportunity consistent with conduct of the research absent a health or research justification for retaining them or a legal requirement to do so. The use or disclose of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals. PHI is not disclosed to any other person or entity except for the authorized oversight of the research study. The Division uniformly adheres to all patient and patient data security and confidentiality rules and regulation set forth by the College.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) 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 or disclosure of the PHI would be permitted under the Privacy Rule.

The PHI 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 disclose of the PHI would be permitted under the Privacy Rule.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

No

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

Yes

Other:

No

Will additional pertinent information be provided to subjects after participation?

No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.

If the patient was screened and was not enrolled, they will not receive any study information. Those patients who were enrolled will have access to that information once the study has been completed.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Research Staff will allocate several days of the week at Baylor Clinic in order to recruit participants. Research Staff will be using referrals from specialist (PI's colleague in the same practice) indicating the patients that meet the criteria for the study. All participants will be existing clinic population.

All participants will be given enough time to read over consent forms and ask questions to Research Staff members. Consent processes will be performed in private and once signed, participants will be provided with a signed copy prior to enrollment of the study.

Spanish speaking subjects will be consented using a SPA ICF. The Spanish consent form will be submitted in an amendment once the English version is approved. In the meantime, no Spanish speaking subjects will be recruited.

For patients who are not coming to clinic, the investigator/designee may explain the study to the subject by phone or email. The discussion will be documented in the subject's medical record or research chart. Two copies of the unsigned consent form will be sent to the subject/legal representative with instructions for completion of the signature page and assent (if applicable). Signatures will be obtained according to standard Baylor IRB regulations. The subject will be told to keep one form and returned the other to the investigator by mail, email, or fax. The Baylor investigator/designee will sign the consent form when returned from the subject. The signed consent form will be maintained in research records.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

A full-length informed consent document

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Other:
Yes, as described:
Patient contact information Admission/Discharge dates

At what institution will the physical research data be kept?
The physical research will be kept in our BCM offices housed in the McNair Building room B10.401.

How will such physical research data be secured?
Data will be kept in locked file cabinets that only the research team has access to.

At what institution will the electronic research data be kept?
Data will be kept locked on network computers in our BCM offices, under the password protected server. Address: \\discovery1.ad.bcm.edu\bcm-dept-icamp

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
No

Such electronic research data will be secured via Other:
No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
Yes, identify the classes of the persons:
People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
Each participant will be given a number that will correlate with their gathered data. Sponsors and collaborators will have no knowledge of any participant identifiable information.

Will you obtain a Certificate of Confidentiality for this study?
Yes

Please further discuss any potential confidentiality issues related to this study.
NA

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

Participants will not charged for any procedures in this study.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

270

Distribution Plan:

Participants will be paid $50 for every completed baseline and follow up visits. They will be paid $10 per exercise session. Payments will be processed through a ClinCard, which will work as a debit card. The balance will increase by input of the research coordinator. Further documentation has been attached to section S.

We will be asking participants for their SSN as it is necessary in order to issue their cards.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

Yes

Device 1: legsys

Device 2: balansens

Device 3: pamsys

Section Q: Consent Form(s)

Tele-exergaming Phase II: 12 Month Program

Tele-exergaming Phase I: 6 Week Program

Section R: Advertisements

None