IRB APPROVED
Sep 05, 2018

RESEARCH SUBJECT CONSENT FORM

Title: Arm Motor Rehabilitation, Entertainment and Cognition System for the Elderly

Protocol No.: BCI-10-001

WIRB® Protocol #20101313

Sponsor: National Institutes of Health (NIH)

Investigator:
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North Brunswick, New Jersey 08902
United States

Daytime Phone Number: 1-732-640-0400

24-hour Phone Number: 1-908-420-7010 or 1-206-353-6054

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

In this consent form "you" generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

What should I know about this research?

This consent form may contain words that you do not understand. Please ask the study the study staff to explain any words or information that you do not clearly understand. You may have an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

You are being asked to be in a research study. This consent form is part of an informed consent process for a research study conducted by Bright Cloud International Corp and PowerBack (part of Genesis Rehabilitation). This form will give you information that will help you decide whether you wish to participate in this research study. It will help you understand what the study is about and what will happen during the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand. After all of your questions have been answered, you will be given time to think about participating. If you still wish to take part in the study, no later than the following day you will be asked to sign this consent form.

The study's principal investigator, Nam Kim, Ph.D., Co-Investigator Jonathan Tapia OT, as well as the Supervising Nurse, will also be asked to sign this consent form. You will be given a copy of the signed consent form to keep.

You understand that you are not giving up any of your legal rights by participating in this research study or by signing this consent form.

Why is this research being done?

The purpose of this research is to provide information about:

- Healthy volunteers: the usability of the BrightArm Compact (BAC) experimental systems for upper-body rehabilitation, improved cognition (attention, memory, decision making), and reduced depression. This usability targets healthy subjects, who are 50 to 80 years old and is aimed at design evaluation and possible improvement recommendations;

- Stroke survivors: the feasibility of BrightArm Compact experimental systems for improved arm function, strengthening of the arm and hand, better cognition (attention, memory, decision making), and reduced depression of early sub-acute stroke population. This targets those who suffered from stroke very recently (typically one week to 10 days prior) and who have been admitted at PowerBack Rehabilitation in Piscataway, NJ. The study aims at determining if adding a dose of virtual reality game rehabilitation to your usual care helps your upper body, mind and mood heal better and faster.

How long will I be in this research?

- Healthy subjects: We expect that your taking part in this research will last 2 weeks;

- Stroke survivors: Up to 4 weeks from admission to PowerBack Rehabilitation.

How many subjects will participate?

- Healthy Subjects: you will be one of the 4 volunteers;

- Stroke survivors: you will be one of the 6 subjects

What happens to me if I agree to take part in this research? And wat are my responsibilities if I take part in this research?

- Healthy subjects: You will be asked to play experimental games on the BrightArm™ Compact and give your opinion to the study staff. You will need to come on several days to complete the study. Your opinion will be provided using evaluation paper forms that will be given to you by the research staff after each evaluation session.

- Stroke survivors: You will be asked questions about your medical background, medications you are taking, your ability to use your arms/hands, your memory, problem solving, and attention. Your intake medical documents will be reviewed by the research team. You will also be asked about your ability to do activities of daily living**.**

- You will be examined by an Occupational Therapist to measure your arm abilities, and by a Psychologist/Researcher to measure you memory, focus, decision making and mood.

- While making sure there is no overlap with the standard sessions in PowerBack, you will be brought to the room where the experimental therapy takes place. This will happen every other day, up to 4 times per week, for about 3 weeks. You will spend less than 1 hour at each session (including set-up and rest periods). You will be told what time these sessions are, and it is important that you are ready for transport on time. If you miss a session for any reason, you will be given the opportunity for a makeup.

- While in the BrightArm study room, you will be asked to wear custom low-friction arm supports, which allow you rest your arms on a table and interact with games on a large TV. A picture of the forearm support is attached at the end of this consent form. You will rest your arms on a special low-friction table (BrightArm Compact picture at the end of the form) and sit in a wheelchair or chair, facing a TV screen. The table may tilt for some of the exercises, depending on your abilities. As you get stronger, the table may be tilted progressively upwards, to present more resistance to your arm movement and help you strengthen your hands, shoulder and trunk. First you will play games with your affected arm for one week, but starting with the second week you will be asked to play the games with both arms. An Occupational Therapist (OT) will be in the same room to help you, and you can ask for breaks if you are tired or feel pain. Sessions will progress from 15 minutes of play in the first week to 30 minutes of play towards the end of this experimental therapy.

- While at the table you will be asked to periodically grasp rubber pears, which are part of the forearm supports. This will allow you to train your grasp strength in games that require it and coordinate arm reach and grasp. It will also train your ability for split attention. You will also do memory games, which will have clues to help you solve them. You will also play games that require your fast thinking, problem solving and decision.

- It is important to understand that these games are medical games that will adapt to you. They will help you win, and provide a pleasant experience.

- At the start of each session ***you will have your blood pressure and pulse measured***. Then you will be asked to move your arms as far as you can reach comfortably, and without pain in all directions while supported by the table, and without leaning. You will look at the screen which will show where your arm went. You will then be asked to squeeze the rubber ball as much as you can, so the computer knows your grasp strength that day. You will look at the screen to see how hard you squeeze, and you will do so three times, while avoiding pain. You will also be asked to strengthen your fingers as much as you can. You will look at the screen to see how much you strengthened your fingers, and you will do so three times, while avoiding pain. The picture of the baseline screens is attached to this consent form.

- You will then be asked to play several types of "video game" exercises with one arm and then with both arms. In-between playing the games, you will rest your arm(s) to reduce fatigue. Pictures of some of the games are attached to the consent form.

- At the middle of the session you will have a mandatory break so your blood pressure and pulse are measured again.

- You will play more games, and at the end of each session you will again have your blood pressure and pulse measured.

- While you are exercising, the computer will automatically measure your performance (such as game scores, arm movements, grasps, hand strengthening), and these data will be stored in a special database, which is only accessible to the researchers in this study and does not store your name.

- At the end of every fourth session you will be asked to read and answer a questionnaire about your impression of the system. This questionnaire asks for your rating of the ease of use, usefulness, and other questions about the BrightArm Compact system. If you have any questions about the questionnaire, you can ask Grigore Burdea, Ph.D. to clarify them.

- All or part of the study sessions may be videotaped so that they can be studied. Furthermore, some pictures may be taken of you while using the study device. A video exit interview may be taken of you after completion of the study sessions to find out your impression of the system. These pictures or movies may be used in publications, presentations at scientific meetings, for grant proposals, company presentations, marketing publications and on the company website (www.brightcloudint.com). Your identity will be masked, your face will never appear fully in the photo/video, and/or will be blurred.

- The study staff may ask your spouse, care giver or legal representative for photos of things you do with your affected arm after you finished the therapy and went home. These pictures are for research purposes and may be used in the same way and with the same protection as those taken during your study sessions. Providing such photos is voluntary. These photos, if provided, will be processed to mask your face.

Could being in this research hurt me?

Likely

You may experience occasional fatigue in your shoulders/arms/fingers during the exercises. In such cases, or if you do not feel well, you need to promptly tell the study staff in the room. You may also feel discomfort when placing your arms in the firearm supports used by the BrightArm Compact. In such cases you should limit your movements to a range where pain is manageable. Gradually your range of movement may increase. The Senior Occupational Therapist in the room may perform some arm/finger stretching at the start of sessions, so to minimize your discomfort.

You may also feel frustrated during the study sessions if the study device does not work properly, or if the games seem too difficult. You should immediately tell the study staff, who will attempt to change things to make you feel better. If you become too upset or angry, and these feelings towards the experimental therapy persist, you have the right to stop your participation in this study.

Rare

There is a risk of increased blood pressure when exercises become too difficult or when the sessions become longer. Your blood pressure will be monitored three times at every session. If the trend continues over several sessions and reaches unsafe levels, you understand that your participation in the study may be stopped. In addition to the side-effects listed above there is always the risk of developing previously unknown side-effects.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

There is no cost to you to receive the experimental therapy on the BrightArm Compact system.

Costs related to your other care at PowerBack depend on your insurance coverage, and are not related to this study.

Will being in this research benefit me?

Benefits to you or others from your taking part in this research are not guaranteed. However, there may be an increased arm range, stronger grasp strength, straighter fingers, improved attention, improved decision making, improved memory, reduced pain, and reduced depression. However this is not guaranteed. Investigators may learn more about the way the brain controls movement, and how stroke disease affects cognition, or how virtual reality intervention soon after a stroke may improve recovery. This information may help to better treat elderly stroke survivors in the future.

What other choices do I have besides taking part in this research?

If you are a short-term resident of PowerBack who has experienced a stroke recently, your alternative is to continue with the treatment provided by the Rehabilitation Department, without the additional experimental game-based therapy. There are no alternative treatments available otherwise. Your only choice is not to take part in this study.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor,
- People who work with the research sponsor,
- Government agencies, such as the Food and Drug Administration,
- The Institutional Review Board (IRB) that reviewed this research.

In addition to the sponsor and study staff, the following people will be allowed to inspect parts of your medical record and your research record related to this study:

- The Western Institutional Review Board® (WIRB®). WIRB is a group of people who perform independent review and oversight of research.
- Research personnel at Bright Cloud Int'l Corp.
- Officials of PowerBack Rehabilitation.

There is a risk that your information could be given to others without your permission. By taking part in this study, you should understand that the study collects clinical data, your demographic and health information. This information will be stored and kept as long as the study is being conducted and for 5 years thereafter.

Your personal identity, that is name, address, and other identifiers, will be kept confidential. You will have a code number and your actual name will not be used in the study or in resulting publications. Only your study staff will be able to link the code number to your name and they will keep this information for 5 years.

Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential. The exception to this rule will be when there is a court order or when a law exists requiring the study investigators to report communicable diseases. In this case, you will be informed of the intent to disclose this information to the state agency. Such a law exists in New Jersey for diseases such as cancer, infectious diseases such as hepatitis, HIV, viruses and others.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by the Western Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If I take part in this study, I will be exposed to certain risks of physical injury. Medical treatment will be arranged for me by the Principal Investigator for any physical injury that occurs as a direct result of my taking part in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. I understand that I will be responsible for any part of the treatment cost not paid by my insurance or managed care provider. No financial payment is routinely offered in the event of physical injuries that happened as a direct result of my taking part in this study. I understand that I will exercise in sitting, so as to minimize injury from falls. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- If it is in your best interest;
- You have a side effect that requires stopping the research;
- You need a treatment not allowed in this research;

- You become pregnant;
- The research is canceled by the FDA or the sponsor;
- You are unable to keep your scheduled appointments.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

You understand that you may choose not to be in the study. If you do choose to take part, it is voluntary. You may refuse to take part or may change your mind at any time.

If you do not want to enter the study or decide to pull out of the study, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing.

If you decide to pull out of the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

At any time, the sponsor or study investigators can take you out of this study because it would not be in your best interest to stay in it, or for any other reason. Your study investigators can stop treatment even if you are willing to stay in the study.

Will I be paid for taking part in this research?

- Healthy subjects: You will receive a $25 money order at the end of each usability evaluation session; If you drop out of the study, you will be paid for the sessions you had completed.

- Stroke survivors: You will not be paid for participation in the study.

Statement of Consent:

If you have any questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
South Hill Business and Technology Center
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

If you have complaints about the research, you may contact:

Rachel Sheeran, CIP
Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2420
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

You or your Legally Authorized Representative should not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

Consent:

I have read the above information. Participation in this research study is voluntary. Involvement in this research is not a requirement and will not affect my treatment. Refusal to participate or a decision not to continue participation will involve no penalty or loss of benefit to which I am otherwise entitled. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the release of my medical records, including photos or video, for research or regulatory purposes to the sponsors, the FDA, DHHS agencies, and the WIRB®.

By signing this consent form, I have not given up any of my legal rights.

Consent and Assent Instructions:
Consent: Subjects able to provide consent must sign on the subject line below
Consent is provided by the Legally Authorized Representative for subjects unable to consent
Assent: Complete the assent signature block below, as applicable.

Subject Name (printed) Subject ID#

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CONSENT SIGNATURES:

_____ _____
Signature of Subject (if no Legally Authorized Representative is used) Date

OR

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Subject's Legally Authorized Representative or Relationship to Subject

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

New Jersey law requires the signature of an individual who can attest that the requirements for informed consent to the medical research have been satisfied. (The individual cannot be the subject, the subject's guardian or representative, or the researcher).

I confirm that the person obtaining consent verbally addressed each element included in the written consent form with the subject's Legally Authorized Representative (LAR). This verbal information was provided in non-technical terms and in a language in which the LAR is fluent.

Signature of Supervising Nurse (Witness)_____ Date:_____
(for dementia subjects)

ASSENT SIGNATURES, for Subjects with a Legally Authorized Representative:

Assent:

For subjects who have a legally authorized representative, I confirm that:

- I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.

OR

- The subject is not able to assent due to lack of mental capacity.

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Signature of Person Conducting Assent Discussion _____ Date _____

Subject ID #: _____

Investigator: _____

Signature: _____ Date: _____
(if different from above)

Figure 1 BrightArm system and BBG game controller

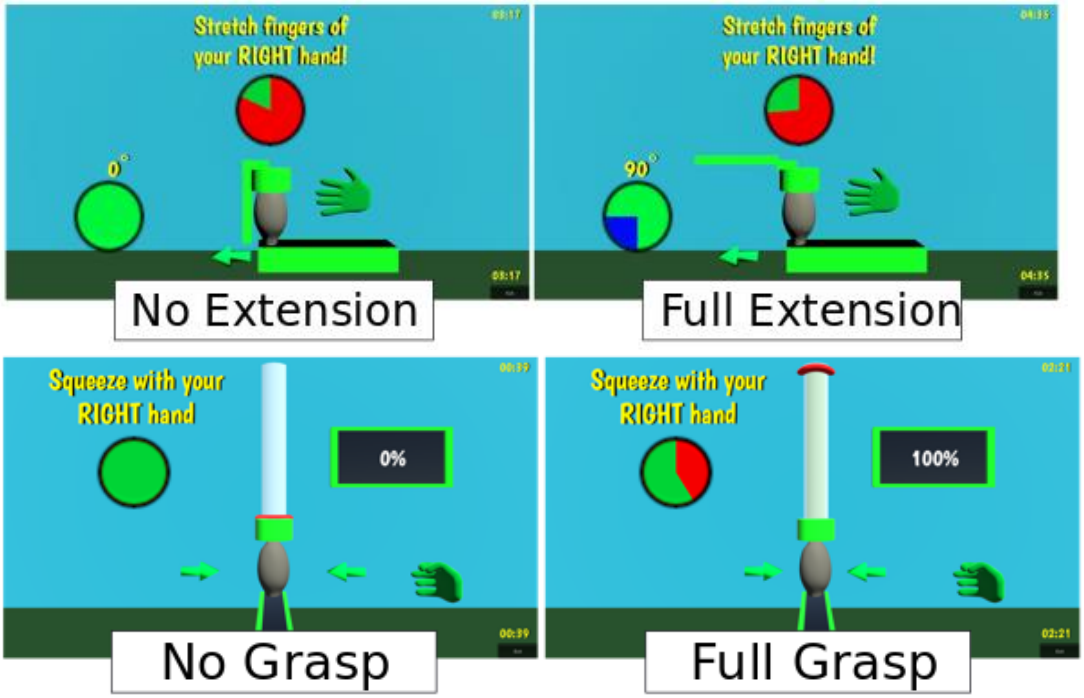

Figure 2: Baseline Screens for grasping and finger extension

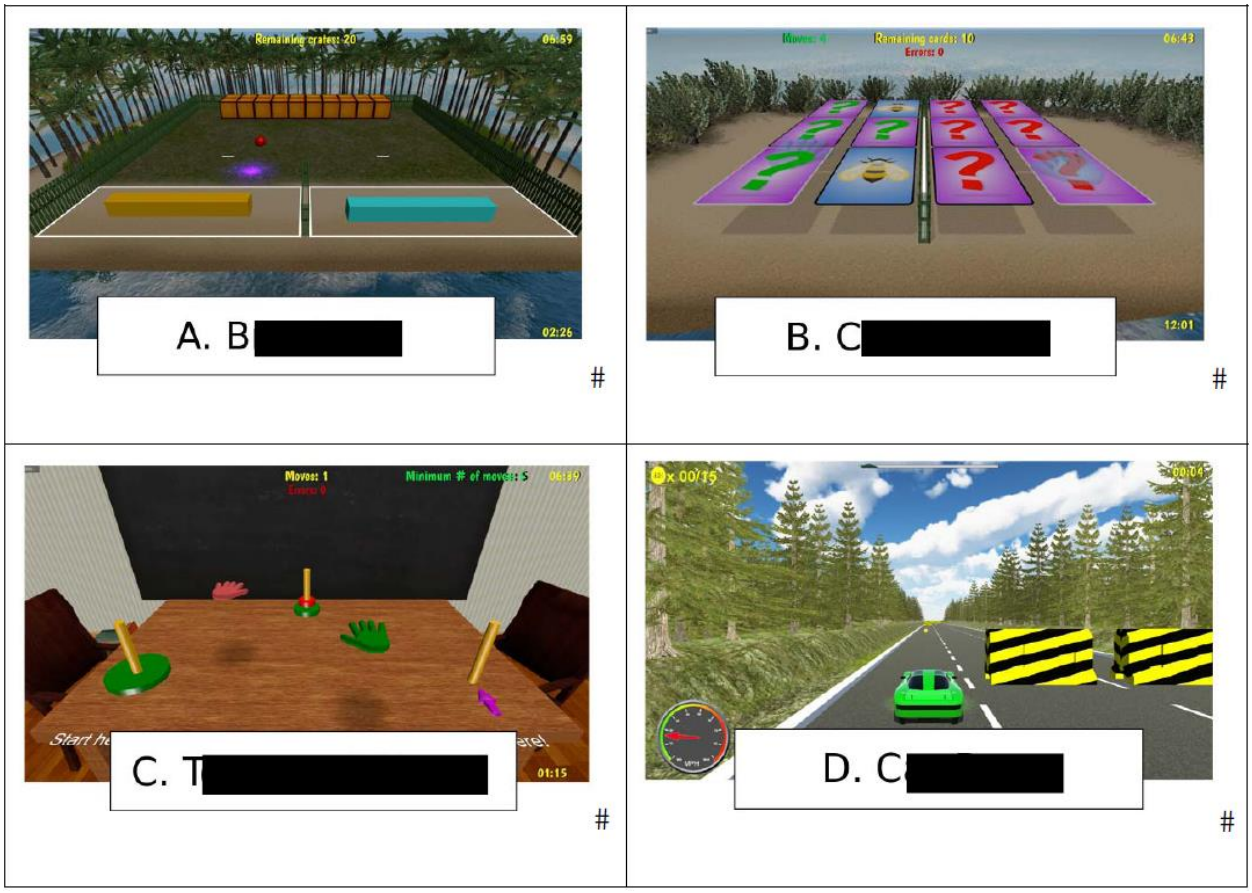

Figure 3: Example of therapeutic games