Cognitive-based Rehabilitation Platform of Hand Grasp after Spinal Cord Injury using Virtual Reality and Instrumented Wearables

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VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM

Version Date [Date of submission]: June, 22, 2023	**Page: 1 of 11**
Subject Name:	**Informed Consent Date:**
Protocol #: 1591774 **Principal Investigator: Noam Y. Harel, MD, PhD**	**VAMC: James J Peters**

Title of Study: Cognitive-based Rehabilitation Platform of Hand Grasp after Spinal Cord Injury using Virtual Reality and Instrumented Wearables

You are being asked to participate in a research study. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely and take your time to decide. You may discuss it with family and friends if you wish. If there is anything that is not clear or if you would like more details, please inform the study staff. If you do decide to take part, your signature on this consent form will show that you received and understood all of the information below and discussed any questions and concerns with the study staff.

INTRODUCTION

Currently there are no effective treatments for people living with paralysis or profound weakness after spinal cord injury (SCI). The goal of this project is to test a new 'cognition glove' and 'sensory brace' to improve reaching and grasping function in people with hand weakness after cervical SCI. The system uses a combination of virtual reality and enhanced sensory feedback to enhance your sense of control ("agency") over your hand and arm actions. While wearing these devices, we will measure device comfort and usability, hand/arm movement and performance, muscle activity, and brain activity.

1. Purpose of study and how long it will last:

You are being asked to participate in a research study. The purpose of this study is to test the ability of the 'cognition glove' and 'sensory brace' to improve reaching and grasping function. You are being asked to participate in this research study because you are between the ages of 18 and 65 and you have a cervical SCI that happened more than 12 months ago.

You will undergo a series of research tests that are not part of usual medical care. There is **no** drug treatment given.

All procedures will take place at James J. Peters Veterans Affairs Medical Center (JJPVAMC), Spinal Cord Injury Research Center (SCIRC), 7th floor, Suite A-13. Your participation will require two visits – one short visit (roughly 2 hours) to perform a 'screening' evaluation, and one longer visit (roughly 8 hours) to perform the glove and brace testing. You will be required to participate in both visits. We plan to enroll 18 participants with SCI over a 2-year period.

This study is funded by the VA's Rehabilitation Research and Development Service.

2. Description of the Study Including Procedures to be Used:

If you consent to participate in this research study:

General: All participants will undergo the same procedures. You will come to our research center in Suite 7A-13 of the JJPVAMC main hospital building for all your visits. You will be seated in an adjustable reclining chair in our testing room within the research center. Alternatively, the experiment can be performed in a manual/powered wheelchair.

Clothing: During the clinical examination, we need access to your arms and legs. You will be asked to wear light loose-fitting clothing such as a short-sleeved t-shirt or shorts. Alternatively, a sleeved top or pant that can be lifted/rolled up will be okay. A surgical gown can be provided if inappropriate clothing is worn. During your visits, a blanket can be provided if you are ever cold.

Visit 1 (Screening; approximately two hours)

Screening Intake: A review of your demographics, medical and SCI history will be conducted. This will determine if you have a history of any condition(s) that would make you ineligible to participate in this study. Furthermore, an upper extremity questionnaire will be administered to find out how well you are able to use your arms and hands.

Clinical Examination: A routine physical and neurological exam will be performed. This examination should take about 30-40 minutes to complete and will include:

A test of your sensory function and strength at key levels above and below your spinal injury. This test is called the International Standards for Neurological Classification of Spinal Cord Injury. If we are unable to detect some ability to partially move your fingers voluntarily during this visit, you will not be eligible for further participation in the study.

Force production: The forces exerted by your fingers onto an object will be measured using force sensors containing 6 degree-of-freedom load-cells.

Muscle activity recording: Activity within your muscles will be measured using several surface electrodes attached to the skin overlaying key muscles of your hands and arms. These electrodes are only used to record muscle activity and do not stimulate. If we are unable to detect enough responses in your hand or wrist muscles with the following test procedures, you will not be eligible for further participation in the study.

Visit 2 (Testing; approximately eight hours)

This visit will not include the neurological exam or the demographic intake questions. It will focus on measuring your movements, muscle responses, brain responses, and comfort while using the cognition glove and sensory brace.

Set-up: As described above in Visit 1, you will be seated in an adjustable reclining chair. Alternatively, the experiment can be performed in a manual/powered wheelchair. You will be asked to wear light loose-fitting clothing such as a short-sleeved t-shirt or a sleeved top that can be lifted/rolled up.

Motor tasks: You will be asked to perform simple hand reach and grasp tasks involving moving your hand from location to location and/or applying pinch grasp force onto small sensor objects. Some examples of motor tasks will include: donning and doffing the 'cognition glove'; manipulating small hand-held devices (mouse, joystick); reaching to various locations according to experimental cues; and applying grip to a force sensor.

Virtual reality: Part of the session will be conducted while wearing goggles displaying a virtual-reality environment with a computer hand. You will have partial control over the computer ('avatar') hand. The amount of control over the avatar hand will vary during the course of the session. Using a combination of virtual reality visual feedback, audio feedback, and touch-feedback from the cognition glove and sensory brace, we will measure how different amounts of feedback and control affect performance.

"Agency": We will ask you to estimate the time-interval between an action taken by your hand (either your own hand or the computer avatar hand) and an audio tone/beep that occurs after each motor task action.

Motion trajectories: Motion data will be collected using camera-based motion capture that tracks reflective markers placed on the skin surface.

Muscle activity recording: Activity within your muscles will be measured using several surface sensors attached to the skin overlaying key muscles of your hands and arms. These sensors are only used to record muscle activity and do not stimulate.

Brain activity recording: Just like an electrocardiogram (ECG) measures heart muscle activity, an electroencephalogram (EEG) measures brain wave activity. We will place a cap over your scalp that has EEG sensors able to record your brain's own electrical activity. We will analyze how your brain's activity changes while performing the various tasks during the session. Just like the muscle activity recording, these sensors are only used to record brain activity, not to stimulate.

Force production: The forces exerted by your fingers onto an object will be measured using force sensors containing 6 degree-of-freedom load-cells.

Your opinions: You will give us your impression of how well you believed you could control the computer hand within the VR environment, and how easy the system was to use. We will also ask you a series of questions during and after the session to determine if you have any discomfort from the procedures.

NOTE: If during your visit we see something wrong that requires you to be checked by your primary care doctor, we will let you know at that time. The tests performed in this study are for specific research purposes and are not set up to find medical abnormalities. These tests are not the same as regular medical care. However,

on occasion we may notice a finding that should be followed up by your primary care doctor. If you are a Veteran, we will arrange for a visit with your VA primary doctor. If you are a veteran and you do not have a primary care doctor, we will refer you to one within the VA system. If you are not a veteran, we will advise you to follow up with your primary care doctor. You can decide at any time not to continue participating in the Study. Your future care or privacy at the VA will not be affected by dropping out of the Study.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:

You are being asked to participate in a study that requires a time commitment of two visits. This may be an inconvenience.

Skin irritation: The tapes or adhesives used to secure sensors and reflective markers onto your skin may cause mild irritation or inflammation. This could cause temporary redness or itchiness or pain under the skin contact points. We will carefully monitor your skin during each session. Areas with too much hair will be shaved prior to adhesive application. Any open skin wounds will be avoided and may prevent you from participating in the study.

Abrasions: There is a low risk of scrapes and blisters associated with wearing the glove, brace, or goggles, or from handling the various objects during the session. All objects have been machined to smooth any exposed sharp corners and the straps used to wear the VR goggles have been padded to reduce risk of irritation. A first-aid kit and/or related treatment materials (e.g., bandages, ointment) will be available to treat abrasions if they were to occur.

Visual fatigue: There is a possibility that you will feel strained or tired from tracking visual cues with and without virtual reality goggles during the session. To avoid this, you will be given a dedicated visual-rest period of 2 minutes every 20 minutes of experiment time.

Neck fatigue: Likewise, there is a possibility that you may experience some fatigue in the neck and shoulders with prolonged wearing of the virtual reality goggles. To avoid this, you will be given a goggles-off rest period at least every 20 minutes. In addition, we will be periodically ask you about your comfort level wearing the goggles. If you experience discomfort at a frequency greater than every 20 minutes, you will be allowed to stop wearing the goggles whenever discomfort arises.

The devices used in this study are for research only. In the future, versions of these devices may be available for home use, but not at this time. Therefore, the devices used in this study will not be available for your use after study participation is completed.

4. Expected Risks of Study:

In addition to the small risk of mild discomforts noted in Section 3, there are several other risks:

Falling: There is a small risk of falling during transfers between different chairs; with the risk of falling is the risk of bone fracture. The risk of falling during transfer in our lab is the same as the risk of falling during any transfer you do in the course of your daily activities. The study staff are trained and experienced in the care and rehabilitation of participants with limited mobility, including extensive safety experience in preventing falls. You will never be left unattended during a test session.

Burns and electrical hazards: There is a possibility of electrical shock, including electrical burn whenever electricity is used to power the nearby instruments necessary to record test results. The 'cognition glove' is powered by a USB port (5 V), not a wall socket (110 V). All other instruments used in our research have already passed commercial safety standards for electrical safety and are specifically designed to prevent any current flow at levels that could produce tissue damage or shock – we and labs around the world have used these recording devices for years without electrical shocks.

Unknown and unanticipated risks: There may be yet unknown, delayed risks that may occur months or years after participating in this research. The investigators will tell volunteers of any new information learned during the study that might cause them to consider future participation or possible effects from previous participation. This research may have unknown effects on an unborn child. For female born participants, the study should not be performed during pregnancy. A pregnancy test may be requested. You also agree to avoid becoming pregnant during the study.

Loss of privacy: There always exists the potential for loss of private information; there are procedures in place to minimize this risk.

Please note, all procedures take place within the JJPVAMC, where there is access to all forms of life-support equipment, medications, and medical personnel.

5. Expected Benefits of the Study:

It is important for you to know that you may not get any benefit from taking part in this research study. However, any information we get from this study can help others with SCI (including you if you have SCI) in future studies.

6. Other Treatments Available:

This study is being done for research purposes. No routine clinical care or medications that you are scheduled for will be withheld from you.

7. Use of Research Results:

Only the study staff will have access to the research materials obtained from you during this study. The materials will be secured in a locked file cabinet in SCIRC (7A-13) as well as on a password-protected file on the VA server. Your identifiable and personal health information (PHI) will be protected by coding your identity. Only IRB-approved research personnel will enter data into the repository. Only research personnel approved by IRB, R&D, PO, and ISO, as applicable, will have access to identifiable repository data. The code is kept in a locked cabinet and secured on password-protected electronic servers. The code will not be used to link the information back to you without your permission, unless the law requires it.

There is minimal risk of a breach of confidentiality or data security. In the case that the Repository is terminated, the data will be destroyed or transferred according to the most current VA Research Standards set out by the IRB and R&D. Other resources that may be consulted include the ACOS-R&D (Section 13), VA ethics officials, and Regional Counsel.

An important part of this research is to save your data in a secure data repository for other research studies in the future. The repository would be held to the same privacy protection standards as described above.

We will let you and your physician know of any significant new findings made during this study that are clinically relevant or which may affect your willingness to participate in this Study. Your medical records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1.

Photography, audio and video consent (optional)

We may ask to photograph or video record you during study procedures for the purposes of academic presentations, publications, or study advertising. Any media will be stored on a password-protected secure VA network drive, coded by subject number. No other identifying information is attached to recordings. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

The purpose of this section is to document your consent to the Department of Veterans Affairs' (VA) request to obtain, produce, and/or use a verbal or written statement or a photograph, digital image, video and/or audio recording containing your likeness or voice. By signing this optional section below, you are authorizing the production or use only as specified below. You may rescind your consent at any time prior to, during production of a photograph, digital image, or video or audio recording, or before or during your provision of a verbal or written statement. You may rescind your consent after production is complete if the burden on VA of complying

with that request is not unreasonable considering the financial and administrative costs, the ease of compliance, and the number of parties involved.

I hereby give my permission to Dr. Harel to use any photography, digital image, video and/or audio recording material taken of myself while enrolled and undergoing study procedures for current protocol, entitled, "Cognitive-based Rehabilitation Platform of Hand Grasp after Spinal Cord Injury using Virtual Reality and Instrumented Wearables".

I have read and understood the foregoing, and I consent to the use of a verbal or written statement from me, and/or of my likeness and/or voice as specified for the above-described purpose(s). I understand that no royalty, fee, or other compensation of any kind will be made to me by the United States for such use. I understand that consent to obtain, produce, and/or use a verbal or written statement, photograph, digital image, and video or audio recording containing my likeness or voice is voluntary, and my refusal will not adversely affect my access to any present or future VA benefits for which I am eligible. I further understand that I may, at any time, rescind my consent prior to or during production of a photograph, digital image, or video or audio recording. I also understand that I may rescind my consent after production is complete if the burden on VA of complying with that request is not unreasonable considering the financial and administrative costs, the ease of compliance, and the number of parties involved.

The following requests apply. Select all that apply (tick or cross box):

- ☐ I request my face not to be in view
- ☐ I request my face to be blurred / barred
- ☐ I do not mind my face being seen
- ☐ I permit use for presentations
- ☐ I permit use for publications
- ☐ I permit use for the Laboratory's website

_____ _____ _____

Subject Signature Date Time

None of your research results involves whole genome sequencing. We are not collecting specimens in this study. Therefore, no specimens will be used for commercial profit.

• _____ By checking and initialing this box, you agree to be contacted by the Principal Investigator or his investigative team at a future date for additional studies being conducted at SCIRC.

In order to comply with federal regulations, research records identifying you may be reviewed by the following:

- Representatives of the sponsor [VA Rehabilitation Research and Development service] of this study,
- Authorized representatives of the JJPVAMC (e.g. Institutional Review Board, Research Compliance Officer), including the Office of Research Oversight, and similarly authorized representatives of the Mount Sinai Medical Center,
- Federal Agencies such as the Government Accounting Office (GAO), Food and Drug Administration (FDA), and
- The Office for Human Research Protections (OHRP)
- Office of Inspector General (OIG)

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research subjects.

A description of this study will be available on www.ClinicalTrials.gov. This website site will not include information that can identify you. At most, the website site will include a summary of the results. You can search this site at any time.

8. Special Circumstances:

Your participation in this study will be included in the VHA health record. A copy of the signed informed consent form and signed HIPAA authorization for participation in the study will be in your health record.

The study staff has no real or apparent conflicts of interest involving this study.

9. Compensation and/or Treatment in the Event of Injury:

The VA must provide necessary medical treatment to a research volunteer injured by participating in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA Medical Center.

10. Voluntary Participation:

You are not required to take part in this study. Your participation is entirely voluntary. You can refuse to participate, or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment if you are a veteran.

11. Termination of Participation:

If you decide to withdraw from this study, please notify one of the study staff. This will not interfere with your regular medical treatment at the VA. Alternatively, your participation may be terminated by the investigator without regard to your consent under certain conditions, such as if you suffer a seizure at any time during your involvement.

12. Costs and Reimbursements:

As a Veteran or non-Veteran, you will not be charged for any treatments or procedures that are part of this study. For Veterans who are required to pay co-payments for medical care and services provided by the VA, these co-payments will continue to apply for medical care and services provided by the VA that are not part of this study.

You will be reimbursed to offset any travel expenses and inconvenience you may incur due to participation in this study. You will be reimbursed $40 for the screening visit and $300 for the testing visit. The total amount for participating in all sessions adds up to $340. You will be reimbursed according to the number of visits that you complete. You will receive payments in approximately 4-6 weeks after completing participation.

13. Contact Person(s):

To obtain answers to questions about the research, report medical problems, or seek treatment for a research-related injury, or to voice concerns or complaints about the research, contact the following (investigator/research team):

- **During the Day:** **Dr. Noam Y. Harel, M.D. Ph.D.:** [redacted]
- **After Hours:** **Dr. Harel can be reached at:** [redacted]

To voice concerns or complaints about the research to someone, or discuss your participation in this study with a doctor or layperson outside of the research team, you can contact **Mary Sano, Ph.D,** ACOS-R&D Program by requesting an appointment at [redacted], 1st floor in the research building, room **1F-01.**

*If I have questions, concerns, or complaints concerning the research and research Participant's rights, I can ask one of the researchers listed above or contact **Dr. Sano**, who is not affiliated with this research study, to obtain information or to offer input. Medical problems during the course of the study should be addressed to the investigator at the phone listed above.*

To obtain answers to questions about your rights as a research participant, provide input about the research process, or to check whether this study is being conducted at the James J Peters VAMC and whether study staff is permitted to represent the study, contact the following: **Mary Sano, Ph.D.** [redacted]

RESEARCH SUBJECTS' RIGHTS

I have read or have had read to me all of the above information. **Dr. Harel** or his research delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. Furthermore, I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law. This study has been explained to me. I have had a chance to ask questions. I voluntarily consentto participate in this study. I will receive a signed copy of this consent form.

I voluntarily consent to participate in this study:

_____	_____	_____
Printed name	Signature	Date

Investigator or Delegate obtaining informed consent (as indicated on Assurance Page)

_____	_____	_____	_____
Printed name	Signature	Date	Time

VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTIONS TO COMFORTABLY WRITE

_____ is unable to sign the consent form due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.

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Protocol #: 1591774 **Principal Investigator: Noam Y. Harel, MD, PhD**	**VAMC: James J Peters**

Title of Study: Cognitive-based Rehabilitation Platform of Hand Grasp after Spinal Cord Injury using Virtual Reality and Instrumented Wearables

Person obtaining informed consent

Printed name	Signature	Date

Witness to consent

Printed name	Signature	Date	Time

Please ensure that the following regulations for a legally authorized representative are met (38 CFR 17.32(e)):

- A legally authorized representative is an individual or body authorized under applicable Federal law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- A legally authorized representative includes:
  - Health care agent (i.e., an individual named by the individual in a Durable Power of Attorney for Health Care (38 CFR.17.32 (a)(iii))
  - Legal guardian or special guardian;
  - Next of kin in this order: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or
  - Close friend.

NOTE: An individual who is qualified as a LAR to provide informed consent on behalf of a prospective research subject may not always qualify as a personal representative for purposes of consent to use or disclose a human subject's PHI (i.e., signing a HIPAA authorization). Therefore, in circumstances involving authorization for use or disclosure of a human subject's PHI, the investigator must ensure the LAR meets the requirements of a personal representative (legal guardian or power of attorney) in HIPAA and the Privacy Act of 1974 prior to the LAR's signing a HIPAA authorization (see VHA Handbook 1605.1).