RUTGERS
School of Health Professions

Judith Deutsch

IMMERSIVE VIRTUAL REALITY BICYCLING FOR PERSONS WITH PARKINSON'S DISEASE

INFORMED CONSENT FORM

NCT05160025

Newark, New Jersey, USA

October 24, 2023

RUTGERS
School of Health Professions

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Enhancing Exercise Intensity, Motivation and Enjoyment for Persons with PD (VCycle-Competition)

Principal Investigator: Dr. Judith Deutsch

This informed consent form provides information about a research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part in it, you should feel free to ask them and should expect to be given answers you completely understand. It is your choice whether to take part in the research. Your alternative to taking part is not to take part in the research.

After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this informed consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?
Dr. Deutsch is the Principal Investigator of this research study. Dr. Deutsch is a named inventor on a virtual reality system not related to this project. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Deutsch may be reached at: 65 Bergen Street SSB, Room # 912, phone # (973-972-2373)

Dr. Deutsch or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: National Institute of Aging

Why is this study being done?

The purpose of this study is to learn about how persons with Parkinson's Disease respond to different stimuli in virtual environments while bicycling.

Who may take part in this study and who may not?

You may take part in this study if you are a person who has mild to moderate Parkinson's Disease and are between the ages of 45 and 80 years old and are able to ride a bicycle.

You may not participate in this study if you:

- Have a recent history of severe heart disease, severe lung disease, uncontrolled diabetes, traumatic brain injury or neurological disorder other than Parkinson Disease.
- Are unable to follow directions or sign a consent form
- Do not have adequate vision or hearing ability to see or hear a television
- Have unstable medical condition or musculoskeletal disorder such as severe arthritis, recent knee surgery, hip surgery, or any other condition that the investigators determine would impair the ability to ride the bicycle
- Have any other medical condition that prevents bicycling.
- Have moderate depression.

Why have I been asked to take part in this study?

You are being asked to participate in this study because you are a person who has Parkinson's Disease and fit the inclusion requirements for this study.

How long will the study take and how many subjects will take part?
You will be one of 35 persons participating in this study. Participation will consist of one visit that will last approximately 3 hours.

What will I be asked to do if I take part in this study?

You will be asked about your exercise activity and to perform movements that will be scored. You will then be shown and given a chance to practice three bicycling activities. During each of the activities you will be wearing virtual reality goggles. Once you are familiar with each activity, you will be asked to participate in each activity for 8 minutes. After each activity, you will fill out a short survey about your experience. You will also be asked a few questions about each activity during which you will be audiotaped.

What are the risks and/or discomforts I might experience if I take part in this study?

There are no major risks associated with participation in this research study. However, there is minimal risk that you may experience mild fatigue, dizziness, or loss of balance; but, a clinician will be standing by you at all times to ensure your safety. You may also experience some minor redness or discomfort from wearing the goggles.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be:

Your input will contribute to building useful tools for rehabilitation for persons with Parkinson Disease. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take part in this study?

No there is no cost to you if you take part of this study.

Will I be paid to take part in this study?

You will receive $30.00 for taking part in this study according to this schedule
- $30.00 at the completion of the session

How will information about me be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Questionnaire responses will be coded and only identified by number. All data will be stored in SSB 736 & SSB 912 in a locked cabinet. The links to personal identifiers will be contained in a single file on the PIs password protected desktop. PHI will only be reported in aggregate.

Certificate of Confidentiality from the National Institute of Health:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state

government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen if you are injured during this study?

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: mild fatigue or loss of balance. In addition, it is possible that during the course of this study, new adverse effects of bicycling in a virtual environment may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, 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 otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Deutsch (deutsch@shp.rutgers.edu, 973-972-2373)

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

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

Who can I call if I have questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Judith Deutsch
Rehabilitation and Movement Science Department
973-972-2373

If you have any questions about your rights as a research subject, you can call:

IRB Director
973-972-3608 Newark
and
Human Subject Protection Program
973-972-1149

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- Name
- Age
- Diagnosis

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study

- Non-Rutgers investigators on this study team
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The National Institute of Aging

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Judith Deutsch, 65 Bergen Street SSB, Room # 912, phone # (973-972-2373)

How long will my permission last?

Your permission for the use and sharing of your health information will last until:
There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY IRB
AUDIO/VIDEOTAPE ADDENDUM TO CONSENT FORM

You have already agreed to participate in a research study conducted by **Judith Deutsch PT PhD**. We are asking for your permission to allow us to ***both audio and videotape*** as part of that research study. You do not have to agree to be recorded in order to participate in the main part of the study.

The recording(s) will be used for

1. ***possible use as a teaching tool to those who are not members of the research staff or may be members of the research staff in the future***
2. ***presented at a scientific conference to describe the study***

The recording(s) will include ***not include any personal identifier. whether the subjects Videotaping will block a participants' identity by covering the face and whenever possible videotaping from the back and side.***

The recording(s) will be stored ***on a secure computer with no link to the participants' identity*** **and will be *retained indefinitely.***

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

AGREEMENT TO VIDEO and RECORD

1. Subject consent:
I have read the consent to videotape and record or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form have been answered. I agree to allow video taping and recording during the research study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the videotaping and recording aspects of study. All questions of the research subject or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____