Cover page

Official Title of the study: Individualized Vestibular Rehabilitation for Elderly With Self-Management and Gaming Elements

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RESEARCH CONSENT FORM

Individualized Vestibular Rehabilitation for Elderly with Self-Management and Gaming Elements

Investigator: Linda D'Silva
3901 Rainbow Blvd. Mail Stop 2002
University of Kansas Medical Center
Kansas City, KS 66062
913-588-4343

- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Linda D'Silva as the researcher. Forty people with dizziness due to an inner ear disorder between 60 to 75 years of age will be in the study at KUMC.

Why is this study being done?
People who have an inner ear disorder often complain of dizziness and imbalance. Physical therapists routinely prescribe repetitive head-eye exercises and balance exercises to overcome these problems. However, the exercises can increase symptoms and people usually stop doing the exercises because they can be boring. Using a game environment can be stimulating and can encourage people to adhere to their exercise program.

Researchers hope to develop a game on the computer that is engaging and easy to use.

How long will I be in the study?

We expect your participation for one session that will last about 90 minutes. Additionally, you will be invited to join a zoom focus group that will last 30 minutes where we will ask you questions about the exercise experience. This is an optional part of the study.

What will I be asked to do?

During the 90-minute session, you will be asked to:

- Complete 2 questionnaires one, is the Dizziness Handicap Inventory and the second is the Activities Specific Balance Confidence to assess how much you are affected by the dizziness.
- Wear a small sensor on your head and sit/stand in front of a tablet that contains the game. You will play a game on the tablet which involves moving your head from side-to-side or up-and-down to avoid obstacles in the game. Next the sensor will be placed on your waist, and you will play games for balance. As you are playing the game, you will be videotaped, any errors made will be flagged so that the app developers can work on the software to make it adaptive to change when errors occur. The exercises will be repeated without the app.
- Complete questionnaires about the user interface with the app, motivation and enjoyment using the app, and ease of use.

You will be invited to join a focus group in zoom later. During this session, we will ask open-ended questions. You can join the zoom session either through your computer or phone.

What are the possible risks or discomforts?

The head and eye exercises may be challenging in standing and you may be unsteady. We will have a gait belt around your waist and an assistant standing beside you if you lose your balance. Likewise, the balance exercises may be challenging, and we will take the same safety measures.

Are there benefits to being in this study?

You will not benefit from this study.
Results of this study may help people with dizziness due to vestibular disorders to perform their exercises correctly and regularly, by using a gaming environment that is fun and engaging.

Will it cost anything to be in the study?

You will not be charged for being in the study.

Will I get paid to participate in the study?

You will receive $50 for completing the study session. You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795. The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you

and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.
Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What happens if I am hurt by the study?

If you have any problem during this study, please contact Dr. Linda D'Silva at 913-588-4343 or in the evening at 913-634-3835. If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program at (913) 588-1240 or IRBhelp@kumc.edu.

What other choices do I have?
You can choose not to be in the study.

How will my confidentiality and privacy be protected?
The researchers will keep your identity confidential, as required by law. Your head movement and balance data will be shared with the app developers in deidentified form. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPAA. If you sign this consent form, you give permission for KUMC to use and share your health information. You can decide not to sign this form and not be part of the study.

Dr. Linda D'Silva and members of the research team will only use and share information that is needed for the study. They will collect health information from the study activities. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your study information will be labeled with your research ID number. The KUMC study team will keep the list that matches your name to the research ID number, but they won't share it outside KUMC. By taking these steps, there is less risk that your personal identity and information will be seen by others who shouldn't have it. Researchers plan to use your information indefinitely unless you cancel your permission. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

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.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you for legal proceedings. This does not stop you from voluntarily releasing information about yourself or your participation in this research.

One exception to the Certificate is if you agree that we can give out research information that identifies you. Your information will be shared for the purposes listed in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

Information about your research participation may be included in your medical record. The Certificate of Confidentiality does not prevent releases of information in your medical record for routine purposes such as treatment or billing purposes. Any research information in your medical record might be included when copies are sent for routine purposes.

How will my research information be used in the future?
Results from this study might be used in the future. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Can I stop being in the study?
You may stop being in the study at any time. Stopping will not prevent you from getting treatment or services at KUMC. You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Linda D'Silva using the contact information on the first page of this document. If you cancel permission to use your health information, you will be withdrawn from the study. They are permitted to use and share information that was gathered before they received your cancellation.

Could my participation be stopped early?
This study might be stopped, without your consent, by the investigator. Your participation also might be stopped by the investigator if it is in no longer safe for you or if you do not follow the study requirements.

Who can I talk to about the study?
Dr. Linda D'Silva or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or IRBhelp@kumc.edu.

CONSENT
Dr. Linda D'Silva or the research team has given you information about this research

study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.
By signing this form, you say that you freely and voluntarily agree to be in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Time Date