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**Title of Study[[1]](#footnote-2)** **:**

*NeuroGaze in Virtual Reality: Assessing EEG and Eye Tracking Interfaces Against Conventional VR Selection Methods*

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**VERSION NUMBER/DATE:**

*V2 3.11.2024*

**REVISION HISTORY**

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| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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# Study Summary

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| --- | --- |
| **Study Title** | *NeuroGaze in Virtual Reality: Assessing EEG and Eye Tracking Interfaces Against Conventional VR Selection Methods* |
| **Study Design** | 1x3 Mixed mode design |
| **Primary Objective** | Evaluate the efficiency and accuracy of our new 3DUI interaction technique against traditional approaches in a virtual environment. |
| **Secondary Objective(s)** | Evaluate which 3DUI technique do participants prefer when in a virtual environment. |
| **Research Intervention(s)/ Investigational Agent(s)** | N/A |
| **IND/IDE #** | N/A |
| **Study Population** | General |
| **Sample Size** | 30 |
| **Study Duration for individual participants** | ~60min |
| **Study Specific Abbreviations/ Definitions** | **NeuroGaze** – our new 3D User Interface technique using electroencephalogram combined eye tracking to select objects from a virtual environment.  **EEG** – Electroencephalogram  **VE** – Virtual Environment  **VR** – Virtual Reality  **NASA-TLX** – NASA Task Load Index  **HMD** – Head Mounted Display  **PI** – Principal Investigator |

# Objectives\*

* 1. We plan to evaluate the efficiency and accuracy of our new interaction technique against traditional approaches in a virtual environment.
  2. Research Questions:

How efficient and accurate is our ‘NeuroGaze’ technique when compared hand tracking and VR controllers in a virtual environment?

How much cognitive load does ‘NeuroGaze’ demand when compared to hand tracking and VR controllers in a virtual environment?

What interaction technique do participants prefer when in a virtual environment?

# Background\*

* 1. Research studies involving VR and EEG focus on using VR as a medium to simulate environments to gather EEG readings. Research involving VR do not attempt to use EEG as a medium to interact with the VE.
  2. N/A.
  3. The research is significant because there are currently many VR studies that use traditional interaction methods (e.g. controllers or eye + hand-tracking) when evaluating a user’s ability to perform various tasks in a VR. The introduction to our technique in this space could yield results that suggest there are techniques that surpass mainstream approaches. Additionally, our technique allows for those with certain physical disabilities to interact with VE’s and possibly participate in VR studies that previously would not be possible.

# Study Endpoints\*

* 1. N/A
  2. N/A

# Study Intervention/Investigational Agent

*N/A*

# Procedures Involved\*

6.1 We plan on conducting a 1 (task complexity; within subject) x 3 (available 3D user interfaces; between subject) mixed design study in which participants will be evaluated on all three 3DUI techniques in virtual reality (**NeuroGaze**: eye gaze for highlighting, EEG for intent to interact with object. **VR controller**: ray from controller to highlight, right trigger button to select. **Eye +** **Hand Tracking**: eye gaze for highlighting, pinch gesture to interact with object). Users will have to select all the red cubes out of the white ones in the scene where task performance and accuracy will be evaluated by determining the time taken to select all the red cubes and how many were selected correctly. The study will take place at HEC 208 on the UCF campus. Below are the details participants will be asked to complete as part of this study:

1. The participant will first complete a demographics survey recording age, gender, familiarity to using VR systems, familiarity playing video games, listing any video games they play, listing any VR video games they play and if the participant is allergic to any of ingredients found in our saline solution.
2. We will provide an overview of the electroencephalogram (EEG) headset the participant will be wearing (the Emotiv Epoc X) and the VR headset (the Meta Quest Pro) and demonstrate to participants how to put both headsets on.
3. The participant will put the EEG headset on, and we will assist moving the nodes around to ensure the best contact quality and comfort for participants. Saline solution will be applied to each node on the EEG headset to help establish a higher contact quality between the EEG headset and the participant’s scalp. Some participants may be asked to put their hair in a higher position to accommodate for EEG node placement.
   * 1. At this time, the EmotivBCI software used to collect user EEG data should be running and connected to the Emotiv Epoc X EEG headset.
     2. The EmotivBCI program displays the contact quality of each node on the participants head and this is the time to make sure every node has a high contact quality.
     3. More saline solution may be applied to a node on the EEG if the EmotivBCI program is showing that the contact quality of that node is low.
4. A new-unused silk headband will be put around the participants head to keep the EEG headset in place and provide more comfort to the participant.
5. We will put the VR headset on the participants head and help the participant adjust it for their comfort.
6. We will calibrate the eye trackers in the VR headset by asking the participant to look at a target while it is moving in VR.
7. We will load the training game in VR and explain what participant will need to do.
   * 1. At this time, the EmotivBCI software should be ready to begin collecting data.
8. The participant will perform tasks in VR within the training game that we will use to gather their EEG data.
   * 1. The training game within the VE consists of a black room with a singular red cube in the middle of the room.
     2. Participants are told to look around the room over 8 seconds intervals. These 8 second intervals are repeated 10 times (80 seconds in total).
     3. Over these 8 second intervals, the PI will start the EEG data collection within the EmotivBCI program for the “neutral” state. This is the baseline state for the participants EEG data.
     4. Participants are then told to look at the red cube in the black room and over 8 second intervals, attempt to shrink the cube by imagining themselves shrinking it. This 8 second interval is repeated 10 times (80 seconds in total).
     5. During these 8 second intervals, the PI will start the EEG data collection within the EmotivBCI program for the “shrink” state. Additionally, the PI will force the red cube to shrink over this 8 second interval to give the illusion that the participant is shrinking the cube for the EEG training data to be as accurate as possible. This is the data used to classify when the participant wants to shrink an object.
9. *Once the training sessions are over, we will load the evaluation game in VR and participants will be told what to do.*
   * 1. *The evaluation game puts participants in the same black box within the VE as they were in during the training game. Now, instead of one red cube, each wall has a 4x9 array of white cubes (36 per wall, 144 in total).*
     2. *When participants look at the cubes, they will grow to a set size to let the participant know they are interacting with the cube.*
     3. *When the participant is ready, the PI will start the evaluation game and start the link between the evaluation game and the EmotivBCI program.*
     4. *Once the evaluation game has started, one cube on each wall will be randomly chosen to turn red (4 red cubes in total).*
     5. *Participants will need to look at these red cubes and imagine they are shrinking it. Once these conditions have been met, the red cube in the game will disappear.*
     6. *Participants are tasked with making all the red cubes in the game disappear as quickly and accurately as they can to complete the evaluation game.*
     7. *This evaluation game is run for three rounds.*
10. We will remove the EEG headset, the silk headband, and VR headset from the participant’s head.
11. Participants will complete one Qualtrics NASA-TLX survey on a laptop that gives feedback on the NeuroGaze interaction technique. After completion of this survey, this will conclude the NeuroGaze evaluation section of the experiment.
12. We will put the VR headset back on he participant and help adjust the headset for their comfort. We will load the evaluation game in VR and the participant will perform a task using their eyes and hands.
    * 1. Similar to NeuroGaze evaluation, participants are placed in the same black box with the same 4x9 array of cubes that change size when the users look at them.
      2. When the PI starts the assessment, 4 cubes will randomly turn red and participants must as quickly and accurately as possible, look at a red cube and perform a “pinch gesture” with their hands to make all the red cubes disappear.
      3. *This evaluation game is run for three rounds.*
13. We will remove the VR headset from the participants head and participants will complete one Qualtrics NASA-TLX survey on a laptop that gives feedback on the Eye Tracking combined with Hand Tracking interaction technique. After completion of this survey, this concludes the Eye Tracking combined with Hand Tracking evaluation section of the experiment.
14. We will put the VR headset back on the participant and help adjust the headset for their comfort. We will put the participant in the evaluation game in VR and the participant will perform a task using VR controllers.
    * 1. Participants are placed in the same black box with the same 4x9 array of cubes.
      2. These cubes will change size when the user points their controller at them.
      3. When the PI starts the assessment, 4 cubes will randomly turn red and participants must as quickly and accurately as possible, point their controller at a red cube and click the trigger to make all the red cubes disappear.
      4. *This evaluation game is run for three rounds.*
15. We will remove the VR headset from the participants head and gather the VR controllers from the participant. Participants will complete one Qualtrics NASA-TLX survey on a laptop that gives feedback on the VR controller interaction technique. After completion of this survey, this concludes the VR controller evaluation section of the experiment.
16. The VR headset will be removed, and we will gather the VR controllers.
17. Participants will complete one Post Evaluation survey giving their feedback about the entire experiment and all three interaction techniques evaluated.
18. Participants will be paid $15 in cash and are free to leave. If at any point the participant withdraws themselves or the researcher withdraws them, participants will be paid $5 for every selection technique they have completed.
19. After participants leave, the EEG headset will be sanitized with saline on each of the nodes, the VR headset will be cleaned with sanitized wipes, and the headband will be thrown away.

6.2 Safety measures and documentation:

1. Participants will be placed in object-free spaces while using Meta Quest Pro HMD for the study and a virtual boundary will pop up indicating that they are almost out of the allotted space.
2. Document list:
   1. NeuroGaze VR Demographics Survey
   2. NeuroGaze VR NASA TLX Survey
   3. NeuroGaze VR Post Evaluation Survey
   4. HRP 251 Form
   5. HRP 502 Form (NeuroGaze Research Consent Form)
   6. HRP 503 Form (this document)
   7. VR Recruitment Flyer

# 6.Data and Specimen Banking\*

* 1. All data will be stored for a minimum of 5 years from study closure, per UCF IRB guidelines. We do not share any data with other researchers, identifiable nor deidentified. We do not plan to use the data for future research.

# Sharing of Results with Subjects\*

* 1. Results will not be shared with subjects.

# Study Timelines\*

* 1. We anticipate each session to elapse 60 minutes. Participants will first fill out the demographics survey, learn how to use the headset, and will be given an overview of what they will be doing in the first 15 minutes. Then, users will be training their EmotivBCI Profile on the “neutral command” and the “shrink command” for about 5 minutes in total. Then participants will be evaluated on each 3DUI technique (NeuroGaze, Eye Tracking combined with Hand Tracking, VR Controller) for 3 rounds (~2min/round) which will take about 30 minutes. In between each 3DUI technique evaluation, the participant will complete a NASA TLX survey which will take 2 minutes each. After all 3DUI techniques have been evaluated, participants will complete the Post Evaluation survey which will take about 5 minutes.

# Inclusion and Exclusion Criteria\*

* 1. *For the**study, we will screen individuals based for eligibility based on the following criteria:*

1. *Participants must be 18 years or older.*
2. *Normal (20/20) or corrected-to-normal vision and hearing.*
3. *Must speak and understand English.*
4. *Has the ability to walk, extend both arms, and use both hands.*
5. *No previous history of simulator sickness.*

*Exclusion criteria:*

1. *Do not have any visual, hearing, conditions affecting the nervous system, or physical disabilities (e.g. injuries to the arms and legs preventing someone from completing the task).*
   1. *Participants will be required to self-report that they meet each of the*

*above criteria. On the day of the study session, we will verify that*

*the participants can continue by going over the consent with*

*them.*

* 1. *We will not be recruiting any special populations.*

# Vulnerable Populations\*

* 1. N/A

# Local Number of Subjects

* 1. *We anticipate on recruiting 30 participants for the Field*

*Study.*

# Recruitment Methods

* 1. *After our A&F Communications Request form (See A&FCommunicationRequestForm.pdf) is approved by UCF, participants will be recruited via bulk email until we have reached our designated number of subjects. The email blast will be disseminated to UCF students and faculty through the UCF mass email system. This email will have a flyer attached (See NeuroGazeFlyerPDF.pdf ) to it for participants to view. This flyer includes a QR code that links to a Google Form and the email itself will include this Google Form link as well. (See GoogleFormExplained.pdf) We do not have access to the users email when they complete the Google Form and Doodle calendar invite. Additionally, we do not have access to the individual emails that are a part of the bulk email, this is all handled by UCF. We do not send out individual emails to participants. These emails are the same for every student they are sent to and include the PI and the faculty advisors contact information.*
  2. *We plan on targeting the UCF student body for subjects.*
  3. *Check “NeuroGazeFlyerPDF.pdf”*

*for material that will be used for subject recruitment.*

* 1. *For the study, compensation in the form of $15 in cash will be*

*given to each participant at the end of each session. Participants will be paid in $5 increments for each selection technique they complete. Completion of a selection technique means the participant completed the evaluation game in VR for that technique and completed the corresponding NASA-TLX survey for that technique as well. If participants voluntarily leave the research prior to completing all study activities or the researcher removes the participant due to observed simulation sickness or observed reaction to saline solution, participants will still receive $5 for each technique successful completed.*

# Withdrawal of Subjects\*

# *We do not anticipate needing to terminate subjects early. If*

# *participants experience simulator sickness, they will be withdrawn from the research without their consent and will be allowed to sit to ensure they are fine and to let simulator sickness symptoms subside, after which they will be thanked for their participation, paid $5 for every technique successfully completed until that point, and dismissed.*

# *If participants need to be withdrawn while they have study*

# *equipment in their possession such as the HMD, they will be required to return the equipment back to the experimenter.*

# *If subjects withdraw from the research, the session will*

# *conclude with the procedures described in 14.1 and 14.2 being done along with any data collected up to that point will be stored for five years after study closure in a separate location, per FL law.*

# Risks to Subjects\*

* 1. Participants may experience simulator sickness due to using VR, which can cause physical risks including general discomfort, fatigue, headaches, eye strain, difficulty focusing, increased salivation, seating, nausea, fullness of head, blurred vision, dizziness with eyes open, dizziness with eyes closed, vertigo, stomach awareness, and burping. For increased safety, a virtual boundary will pop up indicating that they are almost out of the allotted space.

Participants may experience skin irritation from the felt nodes on the EEG headset if worn for a long period of time. Additionally, the EEG headset may cause participants feel discomfort or pressure on the scalp. During the entire time participants are wearing the EGG headset, they will be asked if the EEG headset nodes feel comfortable on their scalp and participants are encouraged to let any researcher know if they start to feel discomfort. To reduce the amount of the time the EEG headset in on your head the headset will be removed if it isn’t actively being used.

We are using a saline solution (Opti-Free PureMoist Solution) with the following ingredients:

Sodium Citrate, Sodium Chloride, Boric Acid, Sorbitol, Aminomethyl Propanol, Disodium EDTA, Two Wetting Agents (Tetronic 1304 and HydraGlyde Moisture Matrix [EOBO-41- polyoxyethylenepolyoxybutylene]) with Polyquad (Polyquaternium-1) 0.001% and Aldox (Myristamidopropyl Dimethylamine) 0.0006% Preservatives. HydraGlyde Moisture Matrix is a Proprietary Multi-functional Block Copolymer that is Primarily Designed for Wetting and Lubricating Silicone Hydrogel Lenses.

There is a small risk that this saline solution may cause redness, itchiness, and discomfort if participants are allergic to any of the solutions ingredients.

If participants experience any of these symptoms, they may choose to stop participating or they will be withdrawn by the researcher. Additionally, if during the demographic survey a participant marks “Yes” to being allergic to any of the ingredients found in the saline solution they will not be permitted to continue with the study. If participants begin to show signs of being allergic during any point in the experiment, they may choose to stop participating or they will be withdrawn by the researcher. There are no foreseeable psychological, social, legal, or economic risks involved with participating.

* 1. N/A
  2. N/A
  3. N/A

# Potential Benefits to Subjects\*

* 1. There are no benefits associated with participating in this study.

# Data Management\* and Confidentiality

# *For our study, we will utilize analyses of variances (ANOVAs) to*

# *determine if there are any significant differences between 3DUI techniques being evaluated in a single session of the study.*

# *Performance data collected during the evaluation game (participant number, how many cubes were available for selection, how many cubes participants incorrectly selected, and time participants took to correctly select all cubes) will be password-protected and stored on an ISUE Lab*

# *Computer. Only the Principal Investigator and faculty advisor will have access to the data Survey data collected from participants.* *(one Demographics survey per participant, three NASA TLX surveys per participant, one Post Evaluation Survey) collected via Qualtrics is stored in a Qualtrics password protected server that is General Data Protection Regulation (GDPR) compliant. Only the PI (Wanyea Barbel), has the username and password to access this data. When the Qualtrics survey data is viewed, connection to the Qualtrics server is protected by Transport Layer Security (TLS). A linking sheet listing the participants participant number and name will only be accessible by the PI and will be stored on a password protected computer in the ISUE Lab. This linking sheet is only used to identify participant data if a participant wants to remove their data from the study.*

# *We will verify that participants complete all Qualtrics surveys*

# *completely to ensure that data collection is complete, and no data is missing or lost.*

# *All data will be retained for at a minimum of 5 years from the time*

# *the study closes.*

# Provisions to Monitor the Data to Ensure the Safety of Subjects\*

* 1. NA.

# Provisions to Protect the Privacy Interests of Subjects

* 1. PI will be responsible for collecting, task data and verifying it is stored to a password protected computer in the ISUE Lab. The study will be conducted in the ISUE Lab (HEC 208) and only the PI and faculty advisor will be permitted to enter the space until the study has finished. This will be enforced by putting a sign outside the door stating “Study in session. Do not enter” and locking the doors to the room. Additionally, no video or audio recording of any kind will be permitted in the room during the study.
  2. Participants will be made aware before the study begins that we are evaluating the performance of the VR 3DUI techniques, not the user themselves. They will be made aware that at any point in time they can remove themselves from the study and any data collected will be immediately discarded. Participants will also be made aware that their data will be anonymized and stored on a secure device where only the research team can access.
  3. Only the PI will be allowed access to anonymous and unlinked data associated with each participant. No other researchers looking to gain access to the data will be permitted access to the data. If participants want to remove their data at any point following the study, only the PI will have access to the linking sheet to determine what participant data should be removed.

# Compensation for Research-Related Injury

* 1. N/A.

# Economic Burden to Subjects

* 1. N/A.

# Consent Process

* 1. When the participant meets with the experimenters at the ISUE Lab (HEC 208), they will be explained the study and its relevant procedures and then the participant will be provided with the consent form. The participant will be asked to read the form. Additionally, the experimenter will ask for verbal consent.
  2. We will provide the consent documentation in the Google Form included in the email sent to potential participants (See Recruitment Methods) so they can understand what they will be consenting to during the study before they even sign up for the study. Additionally, we will also ask the participant to review the form in person. Participants will have time to ask questions prior to the start of the study.
  3. We will follow SOP 090

# Process to Document Consent in Writing

* 1. We are requesting a waiver of written documentation of consent. Signatures will not be required, but all participants will receive a copy of the consent.

# Setting

* 1. Participants will be completing the study in the ISUE Lab (HEC 208) All study-related procedures will be carried out in this location. Potential subjects’ recruitment will be done on the UCF campus.

# Resources Available

* 1. The University of Central Florida campus is a public university. Adequate time is allotted to complete the study. We have access to the UCF population of students for the study.3 weeks will be devoted to conducting and completing the research. Enough supplies and team members are available to carry out this study. The principal investigator is the person leading the study and has completed CITI training.

# Multi-Site Research\*

# 26.1 *This is not a multi-site study; N/A*

1. This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D [↑](#footnote-ref-2)