



Title of Study¹ :

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

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

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

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1.0 Study Summary

Study Title	<i>NeuroGaze in Virtual Reality: Assessing EEG and Eye Tracking Interfaces Against Conventional VR Selection Methods</i>
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 and eye tracking. EEG – Electroencephalogram VE – Virtual Environment VR – Virtual Reality NASA-TLX – NASA Task Load Index HMD – Head Mounted Display PI – Principal Investigator

2.0 Objectives*

2.1 *We plan to evaluate the efficiency and accuracy of our new interaction technique against traditional approaches in a virtual environment.*

2.2 *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?

3.0 Background*

- 3.1 *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.*
- 3.2 *N/A.*
- 3.3 *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.*

4.0 Study Endpoints*

- 4.1 *N/A*
- 4.2 *N/A*

5.0 Study Intervention/Investigational Agent

N/A

6.0 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 randomly assigned one of three 3DUI techniques to be evaluated on 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. *We will greet the participant and administer a paper demographics survey recording age, gender, familiarity to using VR systems, familiarity playing video games, listing any video games they play, and listing any VR video games they play.*

2. *We will provide an overview of the EEG headset they will be using, the Emotiv Insight 2.0, and apply an electrode gel solution to each node on the headset before placing the headset on the user's head.*
3. *A silk headband will be used around the users head to keep the EEG headset in place and provide some comfort to the user.*
4. *We will provide an overview of the HMD device they will be using, the Meta Quest Pro with controllers. We will show participants how to handle the controllers as well as adjust the comfort via the adjustable straps on the HMD.*
5. *Participants will calibrate the eye tracking software built into the Meta Quest Pro.*
6. *Participants will be provided with an overview of the training scene.*
7. *Participants will be placed in the virtual environment and for ~8 seconds will be asked to look at the red cube and room they have been placed in. Meanwhile, a researcher will be starting the EmotivBCI "neutral state" training to gather a baseline for the users EEG waves.*
8. *Participants will then be asked to look at the red cube and imagine they are shrinking it. Meanwhile, a researcher will be starting the EmotivBCI "pull state" training and will click a button in Unity to shrink the cube giving the illusion that the participant is shrinking the cube.*
9. *Step 6 will be repeated 10 times to establish baseline (~80 seconds) and then step 7 will be repeated 10 times to establish a good reading of what a user's EEG signal looks like when they want to select a cube (~80 seconds).*
10. *Participants will be provided with an overview of the evaluation scene in which users will be placed in a black room surrounded by 4 arrays of white cubes (4 x 9) that grow when users eye looks at a cube (projects from eyes in NeuroGaze and Eye Gaze + Hand Gesture, and controller in VR controller) and shrinks when the ray stops intercepting. Cubes can be removed from the scene only when the ray is intercepting a cube and a secondary command is issues (NeuroGaze: a user's "pull command" is active, Eye Gaze + Hand Gesture: pinch gesture is active, VR Controllers: right trigger is active). Users will need to remove all the red cubes in the scene as quickly and accurately as possible.*
11. *A researcher will start the evaluation and after all red cubes have been removed from the scene, the evaluation will automatically stop, and users will be removed from the evaluation virtual environment. This is done for all three 3DUI techniques being evaluated.*
12. *A CSV file will be automatically exported including a randomly assigned participant id, the time (in seconds) it*

took for them to remove all the red cubes, the number of red cubes in the evaluation scene and the number of non-red cubes the user selected.

13. *We will administer a paper System Usability Scale (SUS) and a paper NASA Task-load index (NASA TLX) surveys to the participants.*
14. *After participants complete the tasks and fill out the surveys, they will be thanked and finished with the study.*
15. *After each participant, the EEG headset will be sanitized with saline on each of the code, the VR HMD will be cleaned with sanitized wipes, and the headbands will be discarded, and machine washed at the end of the day.*

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:*
 - a. *Demographics Survey*
 - b. *HRP 251 Form*
 - c. *HRP 502 Form (NeuroGaze Research Consent Form)*
 - d. *HRP 503 Form (this document)*
 - e. *NASA TLX Survey*
 - f. *SUS Survey*
 - g. *VR Recruitment Flyer*

6.3 *What data will be collected during the study and how that data will be obtained.*

6.4 *N/A*

6.5 *N/A*

7.0 Data and Specimen Banking*

- 7.1 *Performance data and demographics data of participants will be stored on a spreadsheet then will be immediately transferred to an ISUE Lab password protected computer in the ISUE lab as an encrypted file and only the PI and faculty supervisor will have access to it. This computer is password-protected and only accessible on this computer.*

7.2 *All data will be stored for a minimum of 5 years from study closure, per UCF IRB guidelines. We will codify all personal identifiers. We will do this by assigning unique numbers in place of identifiers and will store them on a linking sheet. We plan on storing the coded data for future research and do not plan on sharing any data with other researchers, identifiable nor deidentified. Coded data will be used to de-identify participants and goals for this study can be accomplished by only using de-identified data. The linking sheet will be kept to re-link participants to data if acquiring more data to represent more findings is necessary. We will not recontact participants for any reason.*

8.0 Sharing of Results with Subjects*

8.1 *Results will not be shared with subjects.*

9.0 Study Timelines*

9.1 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 “pull command” for about 5 minutes in total. Then participants will be evaluated on each 3DUI technique (NeuroGaze, Hand Tracking, VR Controller) for 3 rounds (~2min/round) which will take about 30 minutes. Afterwards, participants will complete the SUS and NASA TLX surveys which will take 10 minutes.

10.0 Inclusion and Exclusion Criteria*

10.1 *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.*

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).*

10.2 *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.*

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

11.0 Vulnerable Populations*

11.1 *N/A*

12.0 Local Number of Subjects

12.1 *We anticipate on recruiting 30 participants for the Field Study.*

12.2 *N/A*

13.0 Recruitment Methods

13.1 *Subjects will be recruited via an email blast until we have recruited our designated number of subjects. The email blast will be disseminated to the UCF CECS student body by Charlese Hilton-Brown; academic advisor for UCF CECS in charge of sending emails to students in the department.*

13.2 *We plan on targeting the UCF student body for subjects.*

13.3 *An email blast will be sent by Charlese Hilton-Brown (academic advisor for UCF CECS as previously mentioned).*

13.4 *Check "NeuroGazeFlyerPDF.pdf" for material that will be used for subject recruitment.*

13.5 *For the study, compensation in the form of \$15 in cash and will be given to each participant at the end of each session. The only circumstance in which a participant will not be paid is if they voluntarily leave the research prior to completing all study activities and they will not receive any compensation.*

14.0 Withdrawal of Subjects*

14.1 *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 and dismissed.*

14.2 *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.*

14.3 *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 being stored for 5 years after study closure.

15.0 Risks to Subjects*

15.1 Some 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.

15.2 N/A

15.3 N/A

15.4 N/A

16.0 Potential Benefits to Subjects*

16.1 N/A

16.2 N/A

17.0 Data Management* and Confidentiality

17.1 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.

17.2 Data will be password-protected and stored on an ISUE Lab Computer. Only the Principal Investigator and faculty advisor will have access to the data.

17.3 Study data and metrics from the VR simulation will be stored on a private password protected ISUE Lab computer. Consent forms will be stored in a separate location in a file cabinet from other study data to keep identifiable data in a different location, and the linking sheet will be stored in a different location in a file cabinet than the consent forms and other study data.

17.4 Data will be retained for at a minimum of 5 years from the time the study closes.

17.5 We will verify that participants complete all questionnaires immediately after them filling the forms out, to ensure that data collection is complete, and no data is missing or lost. Questionnaires will be stored in an envelope in a locked file cabinet in the PI's research lab.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 PI conducting the research will be present during the study to monitor the safety of the participants involved in the study.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 PI will be responsible for securing, formatting and uploading task data to a password protected computer in the ISUE Lab.

19.2 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.

19.3 The research team will only be allowed access to information regarding the user if further information is needed to draw conclusions. Otherwise, the data collected will be anonymous and unlinked from the participants. All researchers looking to gain access to the data should contact Wanyea Barbel (lead researcher) and elaborate on why they need access to the data.

20.0 Compensation for Research-Related Injury

20.1 N/A.

21.0 Economic Burden to Subjects

21.1 N/A.

22.0 Consent Process

22.1 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 and sign the form. Additionally, the experimenter will ask for verbal consent.

22.2 We will provide the consent documentation via email when the participant is recruited, and we will also ask the participant to review the form and sign the consent in person. Participants will have time to ask questions prior to the start of the study.

22.3 We will follow SOP 090

23.0 Process to Document Consent in Writing

23.1 *We will provide the consent documentation via email when the participant is recruited, and we will also ask the participant to review the form and sign the consent in person. Participants will have time to ask questions prior to the start of the study. Participants will receive a blank copy of the consent form.*

23.2 *We will follow SOP 091.*

24.0 Setting

24.1 *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.*

25.0 Resources Available

25.1 *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.*

26.0 Multi-Site Research*

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