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# A virtual environment-based training system for the blind wheelchair user through use of 3D audio supported by EEG

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 14/08/2017 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 06/09/2017 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 06/09/2017 | Other | [_] Record updated in last year |

## Plain English summary of protocol

Background and study aims
People with physical and visual disability sometimes are not able to do tasks independently. Wheelchair users sometimes have difficulty moving around in their wheelchair, especially if they have visual problems. According to the Brazilian Association of Physical Medicine and Rehabilitation (2012), the use of wheelchairs for daily activities can be helpful for rehabilitation and the training is done using wheelchairs. These devices can be adapted using technology to improve the quality of life of the users. Virtual Reality can be used to create an artificial (fake) environment that can be helpful for training blind wheelchair users. The aim of this study is to see if virtual technology and EEG technology, applies to the training context of blind wheelchair users, has the potential to assist them in mobility and to evaluate the behavior of people when using the system.

Who can participate?
Adults aged 18 and older who are blind and use wheelchairs.

What does the study involve?
Participants are told about the study and provide consent. They then fill out a questionnaire in order to get information about the virtual reality system. Participant then use the system for around 30 and 60 minutes. They then complete another questionnaire about the use of the system and their behaviour in order to see if there are any improvements or errors that need to be addressed.

What are the possible benefits and risks of participating?
Participants may benefit from facilitating mobility and accessibility of people who have physical and visual disability through assisted technology. There are risks that participants may have their identity revealed without their authorization.

Where is the study run from?
Associacao de Apoio a Crianca Deficiente (AACD) (Brazil)

When is the study starting and how long is it expected to run for?
May 2017 to August 2017

Who is funding the study?
Universidade Federal de Uberlandia (Brazil)

Who is the main contact?
Mr Everton Silva de Souza

# Contact information

### Type(s)
Scientific

### Contact name
Mr Everton Silva de Souza

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
BrainChair2017

# Study information

### Scientific Title
A virtual environment-based training system for the blind wheelchair user through use of 3D audio supported by EEG

### Study objectives
The aim of this study is to investigate whether Virtual Reality and EEG technology, applied to the training context of blind wheelchair users, has the potential to assist them in mobility, and to evaluate the behavior of people when using the system.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
University Federal of Uberlandia, 09/05/2017, ref: CAAE: 68117717.0.0000.5152

## Study design
Non-randomised study

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Community

## Study type(s)
Quality of life

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
User BCI Emotiv Epoc with adapted wheelchair

## Interventions
The proposed path for the research will be:
1. Presentation of the research proposal, clarification as to its importance, and the invitation to the individuals and the responsible ones so that the people are collaborators, in the first moment
2. Read and explain the Term of Free and Informed Consent, together with the collection of signatures of the responsible and the individuals, in the second meeting
3. Application of a questionnaire with the purpose of knowing the profile of individuals and collecting information relevant to the development of the system
4. Use of the system in the association. The user will the System Virtual Brain Chair between 30 and 60 minutes. The system is composed of wheelchair adapted and integrated with Emotiv Epoc and Virtual Environment for replicated the movements.
5. Application of the questionnaire after use of the system
6. Analysis of the evaluation of the results obtained. It is important to point out that the individual can detect possible errors or needs for improvement of the tool which will feed back the process of analysis and development of the tool.

## Intervention Type
Other

## Primary outcome measure
1. The patient satisfaction is measured using the experience of patient and doctors that participate in the sessions with questionnaires and feedback as well as validation of time for execution of movements, percentage of correct movements and the quality of experience control
2. The viability of project is measured by assessing the validity of movements using EEG and

Facial expressions, use of stereo sound for orientation and commands of movememnts, if the Virtual Environment support the doctors for validiting the movements and the immersion of blind users with Sound 3D

### Secondary outcome measures
Sync between 3D interface, hardware and real movements with patients is assessed using the wheelchair adaopted integrated with Emotiv Epoch, trying to move the wheelchair with brainwaves (EEG), check if the movement is correct and examining the movements if they are oriented by sound and sync between Virtual Environment, Brainwaves and Wheelchair integration.

### Overall study start date
01/05/2017

### Completion date
13/08/2017

## Eligibility

### Key inclusion criteria
Blind wheelchair users aged over 18

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### Target number of participants
10

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
20/06/2017

### Date of final enrolment
01/07/2017

## Locations

### Countries of recruitment
Brazil

**Study participating centre**
**Associação de Apoio a Criança Deficiente (AACD)**
Brazil
02037-001

# Sponsor information

**Organisation**
Universidade Federal de Uberlândia

**Sponsor details**
Campus Santa Mônica Bloco 3N – Sala114
Av. João Naves de Ávila 2121
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Brazil
+55 (0)38408 100
3239-4707
copel@ufu.br

**Sponsor type**
University/education

**Website**
www.ufu.br

**ROR**
https://ror.org/04x3wvr31

# Funder(s)

**Funder type**
University/education

**Funder Name**
Universidade Federal de Uberlândia

**Alternative Name(s)**
Federal University of Uberlandia, UFU

**Funding Body Type**
Government organisation

### Funding Body Subtype
Local government

### Location
Brazil

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

### Intention to publish date
13/08/2017

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository at www.ufu.br digital library for 10 years for free. The data will be anonymised based on legal restriction.

### IPD sharing plan summary
Stored in repository