STUDY PROTOCOL

NEUROPSYCHOLOGICAL AND ELECTROPHYSIOLOGICAL EFFECTS OF DANCE THERAPY WITH SEVERELY MENTALLY DISORDERED PEOPLE

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RESEARCH PROJECT PROTOCOL

TITLE OF THE STUDY	NEUROPSYCHOLOGICAL AND ELECTROPHYSIOLOGICAL EFFECTS OF DANCE THERAPY WITH PEOPLE WITH SEVERE MENTAL DISORDER
STUDY CODE	TFM_03_DANCE
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CENTER	*Canarian Association of Creative Therapies (ASCATEC)*

INTRODUCTION

Although the severity of symptoms varies from one subject to another (Joyce & Roiser, 2007), 75% of people with schizophrenia present cognitive dysfunctions (Heinrichs et.al, 2013), even before the first expression of symptoms (Brewer et al., 2005; Sheffield et al., 2018), being a basic characteristic (Green et al., 2019) in all phases of the disease (Rajji et. Al, 2014). These deficits in brain areas involved in attention, memory, social cognition, executive functions, and metacognition have a great impact on the daily functionality of affected people, often preventing them from enjoying a satisfying and full life.

Due to the limitation observed with pharmacological treatments to improve cognitive deficits in people with Severe Mental Disorder (SMD) (Ciceri , Ocampo & Franco, 2008) , it is essential to offer alternative treatments to work in this area. Although most of the research in relation to cognitive training is frequently linked to schizophrenia, in recent years it has been developed for other disorders, showing its great benefit in improving cognitive processes (Keshavan et al., 2014). Taking advantage of brain neuroplasticity to influence the cognitive capacity of affected people, many interventions have been developed. In the present study, we will focus on dance

therapy as a vehicle for the modulation of the neural system, achieving improvement in cognitive areas such as executive functions.

The concept of Dance Movement Therapy (DMT) is a psychotherapeutic technique that allows the person to engage in a creative and relational process (Association for Dance Movement Psychotherapy UK (ADMP UK), 2023) providing emotional, social, cognitive and physical integration (American Dance Therapy Association (ADTA), 2020) and personal growth (Panhofer & Rodríguez, 2005) seeking an improvement in their health and well-being. DMT is considered an intervention with the potential to prevent and treat physical and cognitive decline (Verghese, 2003). In terms of cognition, a study with a quasi-experimental design of matched controls that proposed a 60-minute group aerobic dance class, 3 times a week for 3 months, showed that DMT can be a technique that allows significant improvements in processing speed, memory and executive function, in people with schizophrenia (Chen et al., 2016). However, research related to DMT lacks data on the neurophysiological mechanisms that are possibly affected by the application of these types of interventions. The use of the electroencephalogram (EEG) allows us to obtain additional measurements on possible changes in brain connectivity that can contribute to a detailed quantification of the therapeutic effects of DMT (Ventouras et al., 2015).

These therapeutic approaches differ from cognitive, behavioral and other usual therapies based mainly on interaction, as well as communication and verbal expression. As has been previously reported, DMT suggests cognitive benefits (Tan et al., 2016), symptomatological (Lee et al., 2015), as well as functional remission (Gökcen et al., 2020) and quality of life (Kaltsatou, 2015) for people with SMD. However, there are major limitations in the previous literature regarding the study of this program. Therefore, further analysis is needed to determine the benefit of DMT on cognition (memory and executive functions) in people with SMD. For these reasons, it becomes critical to conduct research with a consistent theoretical framework and experimental design; that demonstrates the effectiveness of DMT. For all of the above reasons, this study proposes to analyze the effects of dance therapy on the cognition of people with SMD, using psychometric and neurophysiological techniques. These findings would allow us to modulate the interventions currently

offered, towards more effective protocols, improving the quality of life of people with SMD and thus report significant impacts on their interpersonal relationships and functionality.

HYPOTHESIS AND OBJECTIVES

1. Hypothesis

According to the evidence from the literature, it is proposed that participation in a therapeutic dance therapy program will have a significant positive effect on the scores of neurocognitive tests and on the electroencephalographic activity patterns of patients diagnosed with severe mental disorder (SMD). Specifically, it is expected that after the intervention, participants will show significant improvements in memory and executive functions compared to the control group without intervention.

From a more theoretical perspective, our null and alternative hypotheses are:

- Null Hypothesis (H0): there is no significant difference between the neurocognitive test scores and the electroencephalographic activity patterns of people with SMD who participate in a dance therapy therapeutic program and those who do not.
- Alternative Hypothesis (H1): Participation in a therapeutic dance therapy program will have a significant positive effect on neurocognitive test scores and electroencephalographic activity patterns of people diagnosed with SMD.

Specifically, it is expected that after the intervention:

- H1a: People participating in the dance therapy program show significant improvements in memory test scores compared to the control group.
- H1b: People participating in the dance therapy program show significant improvements in executive functions compared to the control group.

Our hypothesis is based on a solid theoretical foundation, which suggests that dance therapy could promote neuroplasticity and improve cognition through body movement. To this end, we will conduct this carefully controlled study, collecting pre and post intervention data in both groups and using appropriate statistical analyses.

To test this hypothesis, a controlled study will be carried out with an experimental group participating in the dance therapy program and a control group that will not. Neuropsychological test scores and electroencephalography data will be compared before and after the intervention to assess any significant changes in cognitive function and brain activity.

A valuable contribution of this research is the possibility of improving the quality of life of people with SMD through novel interventions such as dance therapy. Furthermore, it is worth highlighting the relevance of this study for the scientific and clinical community, where health personnel in hospitals, detention centers and shelters for patients with SMD are completely overwhelmed in a society where the number of people with mental disorders continues to increase.

In this study, we will also ensure that we address ethical issues such as informed consent of participants and consideration of their well-being throughout the study. Our priority is that research in the field of mental health and therapy is conducted in an ethical, rigorous and respectful manner.

2. Main objective

- To evaluate the impact of a therapeutic dance therapy program on cognitive functions, specifically on memory and executive functions, in patients diagnosed with severe mental disorder by measuring scores on neurocognitive tests such as the BACS and MOCA (subsequently defined in the section on data collection) and by analysing electroencephalographic activity.

3. Secondary objectives

1) To compare the scores obtained from the neurocognitive test battery between the experimental group and the control group.
2) To compare the changes in brain activity patterns recorded by electroencephalography between the experimental group and the control group.
3) To analyze the changes generated in both groups in order to be able to identify the

possible correlations between the improvement in cognitive functions and the alterations in brain activity.

4) To evaluate the effects of a 20-session dance therapy program on the symptomatology of people with SMD using the PANSS (later presented in the section on data collection).

STUDY METHODOLOGY

1. Design

A single-centre prospective randomised controlled trial will be conducted with a minimum of 47 patients with severe mental disorder (SMD) who will be randomly assigned into two groups, 1 intervention group receiving dance therapy (n=26) and 1 control group who will not receive any intervention or added treatment apart from continuing with their usual treatment (pharmacological), but will not receive intervention with dance therapy (n=21).

In summary, the groups are:

- Experimental group (n=26): people with SMD receiving dance therapy.
- Control group (n=21): people with SMD who do not receive the dance therapy intervention but do receive their usual pharmacological treatment.

Tests will be administered before the start of the study and at the end of the study, as well as 3 months after the end of the study in order to compare the results between groups.

2. Study population.

a. Population characteristics

Patients who will participate in the dance therapy program will be referred to the Canarian Association of Creative Therapies (ASCATEC) through the Mental Health Units of the Canary Islands according to a referral program of the Government of the Canary Islands. They will be selected according to the criteria listed below without distinction of age, sex, gender or type of diagnosis, as long as they meet the main diagnosis of SMD.

The assignment will be made randomly, as they will be referred by the Government of the Canary Islands (see point 6.4.1.2. Coordination between devices in the mental health network of the Mental Health Plan in the Canary Islands 2019-2023, p.179-180).[1]

b. Inclusion criteria

[1] https://www3.gobiernodecanarias.org/sanidad/scs/content/d7a0d910-4973-11e9-910b-f705e6f363c5/PSMC_completo.pdf

The inclusion criteria are the following:

- People diagnosed with a SMD according to the DSM-V.
- Have the capacity to decide and consent.
- Be in the age range between 18 and 65 years old.
- Do not present active consumption of toxic substances (except nicotine).
- Commitment to attendance during the entire study period from December 2023 to December 2024.

c. Exclusion criteria

The exclusion criteria are the following:

- Not having given their free consent to participate in the study
- Present a serious comorbid mental disorder, associated intellectual disability, history of severe brain damage or neurological disorder that may function as a confounding factor (Associated organic type disorder, borderline or lower intellectual IQ)
- Active substance abuse (except nicotine)
- Have a cochlear implant, fixed hearing aids or head plates.
- Having suffered a concussion to the head with loss of consciousness that subsequently triggered symptoms related to the pathology.
- Suffering from epileptic seizures.
- Not having the desire to participate in dance therapy sessions for any reason or to undergo EEG-type tests.
- Be currently involved and participating in another cognitive rehabilitation program.

d. Criteria provided for the withdrawal of subjects from the study

These criteria are:

- Explicit request from the person to stop participating in the study.
- Change of place of residence, outside the autonomous community in which the study will be carried out.
- Death of the person.
- Worsening of pathological symptoms or hospital admission during the

study.

- Medical findings, such as epilepsy, during the EEG.

e. Sample size calculation.

The present study aims to determine the number of participants needed to determine the effect of a dance therapy program administered to patients with severe mental disorders. Preliminary studies cited in the literature have determined that dance therapy has the potential to influence aspects such as emotional state, memory or executive functions, being observable through neuropsychological and EEG tests. The working hypothesis is that dance therapy will produce a statistical effect, involving cognitive improvement, observable in subsequent assessments of neuropsychological test scores and electroencephalographic activity patterns in those diagnosed with severe mental disorder. Therefore, in this study we tried to determine two independent sample means.

The calculation of statistical power was performed by means of two independent ("unilateral") means, based on the variance of a control group and the reference group with a minimum of 13 study subjects, in accordance with systematic reviews of previous scientific studies such as Jiménez et al. (2019). The probability of the degree of statistical significance was based on values of $p<0.05$ with the statistical tests applied, with a 95% confidence interval.

The sample was calculated using GRANMO software (Marrugat et al., 1998). In this line, in order to estimate the probability that the observed phenomenon is true and not due to chance with the calculated sample size, the alpha risk was determined. Specifically, an $\alpha=0.05$ was chosen, which assumes a 95% confidence level. To control for the potential of the analysis, a power of 80% was selected, with a beta of 0.2. To define the ratio between two groups (control and experimental), the ratio between group 1 and group 2 was indicated, the ratio being a value of 1, as these are two groups with equal sample sizes. In addition, as we are calculating on the basis of means, the standard deviation has been included. Since we do not have a pilot project with previous data before and after the dance therapy program proposed in the current project, the following process was used to find the standard deviation:

1. Review of previous literature on mental health and dance therapy; 2. Screening of dance therapy manuscripts with patients presenting with a pathology encompassed

within severe mental disorder (see Ren & Xia, 2013); 3. Selection of the manuscript by Röhricht & Priebe (2006) to estimate the standard deviation of the sample needed for the dance therapy intervention group. Specifically, this manuscript details a controlled trial with body-oriented psychological therapy similar to that performed in dance therapy with a group of patients framed within severe mental disorder. For standard deviation we took the means before and after dance therapy. Specifically, we have selected the values of the measures obtained in the negative symptoms of the PANSS scale, since they are one of the mental health values mainly suggested for statistical significance post-intervention with dance therapy in severe mental disorder. In this case, since in our study we also consider a follow-up of the success of the intervention after the implementation of the program, we have selected the mean of the negative symptoms of the PANSS before the intervention with dance therapy (23.4), the mean of these symptoms after finishing a program similar to the dance therapy program proposed in this project, also of 20 sessions for 10 weeks (18.9) and, as in our proposal, the mean of a follow-up after -after several months- the intervention program with dance therapy (18.2). Considering these means as a data set, they were entered into the Calcuvio software (www.calcuvio.com) which runs as a statistical calculator returning mean, sample and population standard deviation values. Specifically, the standard deviation of the set of numbers was found according to the study segment using the following equation:

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}} = \sqrt{\frac{(x_1 - \bar{x})^2 + (x_2 - \bar{x})^2 + \cdots + (x_n - \bar{x})^2}{n-1}}$$

A sample standard deviation of 2.822 was obtained for the intervention group; 4. Selection of the manuscript by Chao & Xiaolin (2022) to estimate the sample standard deviation needed for the control group without dance therapy. Specifically, this manuscript details an evaluation of the application of the effect of dance therapy in the rehabilitation process of patients whose pathology is framed within severe mental disorder. For the standard deviation, the means of the sample of participants in the control group of the study were taken before and after the parallel development of the

intervention program with dance therapy with the experimental group. In particular, to find the standard deviation of our control group sample with severe mental disorder, the mean values of the negative symptoms of the PANSS scale were chosen again (as they show significant statistical differences in scores between the control group and the experimental group in the manuscript of Chao & Xiaolin, 2022). In this case, the control group presented a mean of 14.98 on negative symptoms before the parallel start of the dance therapy intervention program, and a mean of 11.32 after the conclusion of the dance therapy intervention stage in the experimental group. Considering these means, we proceeded to calculate the sample standard deviation with the same procedure and software previously used to find the standard deviation of the intervention group in the previous point. Here we obtained a value for the sample standard deviation of our control group of 2.588.

In addition to the above, as the starting hypothesis is that the dance therapy program will improve emotional management and increase cognitive performance, it can be assumed that the minimum response to the program will be double (2).

After performing the mathematical calculation, accepting an alpha risk of 0.05 and a beta risk of 0.2 in a unilateral contrast, 28 participants in the intervention group are required to detect a difference equal to or greater than 2,822 units, as well as 28 participants in the control group to detect a difference equal to or greater than 2,588 units.

In addition, an expected rate or proportion of loss to follow-up of 10% (10/100=0.1) due to experimental errors, drop-out, etc., has been estimated in the intervention group, with participants engaged in the dance therapy intervention. On the other hand, a loss-to-follow-up rate or proportion of 25% (25/100=0.25) has been estimated in the control group with participants not engaged in the dance therapy intervention. This expected increase in losses in the control group is based on the hypothesis that the patient who does not receive the intervention may not be as involved in the experiment or, eventually, debut with pathological manifestations associated with their medical condition leading to absenteeism or indisposition during the data collection stage.

Therefore, considering the respective loss to follow-up rates in both the experimental group and the control group, the final (n) for each group would be as follows:
experimental group with an N=28, after expected loss to follow-up of 10% out of 28

equals 2.8 participants, would be left with a final (n) of 26 participants; control group with an N=28, after expected loss to follow-up of 25% out of 28 equals 7, would be left with a final (n) of 21 participants.

In conclusion, for this project we need 47 participants (21 participants for the control group and 26 participants for the experimental group receiving intervention with dance therapy). It is also worth mentioning that each participant will sign a pre-test consent to participate in data acquisition and, if applicable, intervention in the dance therapy program as part of the research project. These consents will inform them of the aims of the study, risks if applicable, and answer any questions or queries they may have.

PROCEDURE or DESCRIPTION OF THE STUDY

1. Workplan

All the tests (BASC, MoCA, PANSS and EEG) will be carried out with the 47 patients with SMD to find out their baseline status. The people with SMD will be randomly assigned to an experimental group (dance therapy program) or a control group (without intervention in dance therapy but with regular pharmacological treatment). The study will last approximately 1 year between the administration of tests, the program and the analysis of results. The dance therapy program will last 20 sessions over 10 weeks. The sessions will take place at the headquarters of the Asociación Canaria de Terapias Creativas (ASCATEC) in the Siglo XXI space in Santa Cruz de Tenerife.

The 26 people with SMD in the experimental group will participate in a 10-week intervention program with 2 sessions per week in which they will work for 1 hour on memory, attention and executive functions through dance and movement, ending with 10 minutes of Mindfulness.

The 21 people in the control group will not receive any type of dance therapy intervention, but will continue with their usual pharmacological treatment.

The effects will be measured after a treatment of 20 sessions (twice a week). Results will be obtained by analyzing EEG parameters (EEG amplitude and frequency) and cognitive functions (BACS and MoCA). On the other hand, at the end of the 20-session program, tests will also be administered to assess the symptomatology of the severe mental disorder suffered by the person (PANSS) to assess the effects of the program on these variables.

2. Study variables (primary and secondary)

All the data that the neuropsychological tests allow us will be collected in the intervention and control group. For the data analysis of the tests that will be administered, a series of parameters related to the objective of our study will be analyzed. In relation to the main variables, the following will be evaluated: cognitive functions, especially memory and executive functions.

An analysis of personal and sociodemographic data (age, diagnosis, medication and duration of the disease) will also be carried out.

In relation to the electroencephalogram (EEG), the following variables will be considered:

1) Dominant frequency: It can be analyzed whether the dominant frequency of the brain waves recorded in the EEG, such as alpha frequency (8-13 Hz) and beta frequency (12-25 Hz), show significant changes before and after the dance therapy.

2) Wave amplitude: the amplitude of the waves in the different regions can be observed to identify if delta, theta, alpha and beta vary with dance therapy.

In relation to the secondary variables, the PANSS tool will be administered to evaluate the impact of the program on the positive, negative and general symptoms presented by the participants, related to the disorder they suffer from.

Collecting data on these variables before and after the dance therapy intervention will allow us to assess in more detail whether the therapy has a positive impact on brain activity, cognitive functions, as well as symptoms related to the disorder.

3. Data Collection

The tests will be administered after randomization and before starting the intervention to measure the basal state of each participant and after the completion of the dance therapy program in order to determine the changes generated with the dance therapy program. The tests will also be repeated after 3 months as a follow-up of the results obtained.

All registrations will be done anonymously, assigning each person an identification number. All data will be kept for 5 years.

- **Brief assessment of cognition in schizophrenia (BACS)** (Keefe et al., 2004): serves to quantify cognitive impairment in schizophrenia and/or psychosis. The BACS includes assessments of verbal memory, working memory (Digit Stream), motor speed (Token Motor), verbal fluency, attention and processing speed (Symbol

Coding), and executive function (Tower of London). The minimum and maximum scores on the BACS for each subtest are:

1. Token Motor Task (TMT): The minimum score is 0, and the maximum is 100.
2. List Learning: The minimum score is 0, and the maximum is 50.
3. Digital Sequencing Task: The minimum score is 0, and the maximum is 21.
4. Semantic Fluency: The minimum score is 0, and the maximum is 40.
5. Symbol Coding: The minimum score is 0, and the maximum is 50.
6. Tower of London: The minimum score is 0, and the maximum is 21.
7. Verbal Memory: The minimum score is 0, and the maximum is 20.

These scores are used to evaluate performance on each of the BACS subtests. Subsequently, it is common to calculate a composite score that summarizes the individual's overall cognitive performance. For the interpretation of results, see the **attached technical sheet**. In our case, all patients in the intervention group will be patients with a diagnosis of psychosis without comorbidities.

- **Montreal Cognitive Assessment (MoCA)** (Ramírez et al., 2014): it is a 30-question test that evaluates mild cognitive dysfunctions by assessing executive function and visuospatial ability, identification, short-term memory, delayed recovery, attention, language, abstraction, animal naming and orientation. The ratings range from 0 to 30 and the cut-off value to determine a normal score is >26 points. The test is administered in about 10-12 minutes.

- **The electroencephalogram (EEG):** brain wave signals will be recorded by the 14-channel Emotiv EPOC®, whose electrodes (saline sensors) are arranged at positions AF3, F7, F3, FC5, T7, P7, O1, O2, P8, T8, FC6, F4, F8 and AF4, according to the international 10-20 system. The device also has 2 reference points at positions P3 and P4.

It should be noted that EEG data collection will be carried out in the patients' resting state. The process will be detailed as follows: First, a baseline will be carried out with the EMOTIV software of 1 minute eyes open with a fixation point of some eyes on the computer screen, followed by a gap for the participant to close their eyes. and,

continued by 1 minute of data collection in resting state where the participant keeps his eyes closed.

In addition, patients will always be given the following instructions: not to speak, not to move, try to leave the mind relaxed, as well as the same room with the same lighting and tranquility conditions will be used. To finish, the following task will be carried out: a 4-minute EEG collection will be carried out in resting state with eyes open and cross fixation point on white background, followed by 4 minutes of resting state with eyes closed.

In our case, the EEG tests will be carried out at the ASCATEC headquarters and will be carried out by Laura Ezama [2].

- **Positive and Negative Symptom Scale (PANSS)** (Kay et al., 1987): allows monitoring the progress of symptoms in severe mental disorders through 30 items that are grouped into three main dimensions: positive symptoms, negative symptoms and general symptoms. Each item is scored from 0 (absence of symptoms) to 7 (extreme severity) points. For the Positive Scale and the Negative Scale, the results can range from 7 to 49 and for the General Psychopathology section from 16 to 112, with the lowest total score being 30 and the highest being 210. For data interpretation, refer to the **attached technical sheet**.

ETHICAL AND CONFIDENTIALITY ASPECTS

The study will be conducted in accordance with the principles of the Declaration of Helsinki adopted by the 18th World Medical Assembly, Helsinki, Finland in 1964 and amended in Tokyo (1975), Venice (1983), Hong Kong (1989), South Africa (1996) , Edinburgh (2000), Washington (2002), Tokyo (2004), Seoul (2008), Brazil (2013); and the Laws and Regulations in force in Europe and Spain. On the other hand, with the objective of regulating, with full respect for human dignity and identity and the rights inherent to the person, biomedical research and, in particular, research related

[2]PhD in Health Sciences, Neuroscience. University of La Laguna, Spain. Master's Degree in Cognitive Neuroscience and Specific Needs for Educational Support. University of La Laguna, Spain.

to human health that involves invasive procedures, the study is will be in accordance with Law 14/2007, of July 3, on Biomedical Research.

The patient must provide consent before being admitted to the clinical study. The doctor must explain the nature, purposes and possible consequences of the study, in a way that is understandable to the patient. The information provided by the doctor must also be recorded.

For the acquisition of electroencephalography (EEG) data, informed consent will also be provided with meticulousness and rigor, both in the intervention group and in the control group, in order to guarantee the ethics and legality of the study, as well as to respect the rights and integrity of the participants. To this end, prior to inclusion in the EEG study, each participant will be given an informed consent document that exhaustively details the following aspects:

Purpose of the EEG: a clear and precise explanation will be provided about what an electroencephalogram is and its usefulness in research, in this case, to understand the influence of dance therapy on cognitive functions.

Voluntariness: it is highlighted that participation in the study is completely voluntary and that the EEG data will be collected confidentially (code instead of name in the generated database).

Right to interrupt: participants will be made aware that, at any time during the EEG, they have the right to interrupt the test if they wish.

EEG Procedure: A detailed description of the test procedure will be given, including how the electrodes will be applied to the scalp, hygiene and safety regulations and standards, and the estimated duration of the test.

Prior recommendations: Recommendations will be provided before undergoing the EEG, such as informing about the use of cochlear implants, ensuring that you have rested adequately the night before, and disclosing taking medications, especially anticonvulsants, that may affect brain activity.

Crucial Test Day Communications: Collect any relevant information on the day of the test, such as changes in health, taking additional medications, or any other circumstances that may influence the quality of the data collected.

In order to guarantee the confidentiality of the data of the patients participating in the study, only the researcher and his team of collaborators, the representative of the promoter who will carry out the monitoring tasks, the auditor in case the study was subject to an audit, the CEIm and the Health Authorities.

Rigorous application of EEG informed consent ensures that participants are properly informed and that their participation in research is carried out ethically, respecting their rights and well-being.

The study participant will give his or her consent by signing the corresponding model, which must also bear the signature of the researcher.

A copy of the informed consent model is attached.

The researcher will not initiate any investigation corresponding to the study until the patient's consent has been obtained.

The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD).

ANALYSIS STATISTICAL

A descriptive analysis of the data will be carried out. The qualitative variables will be presented with their absolute frequency and percentage. Gaussian quantitative variables will be presented with their mean and standard deviation (SD) and non-Gaussian variables as median [minimum-maximum]. For the comparison of two qualitative variables, the McNemar and Chi-square tests will be used; For the comparison of quantitative variables, and due to the small sample size, the non-parametric Mann-Whitney U, Kruskal-Wallis, Wilcoxon and Friedman tests will be used. Subsequently, a regression analysis will be carried out using Mixed Models (since although the sample size is very small, mixed models allow the data to be analyzed, correcting this problem with multiple measurements per individual). The accepted α risk for all hypothesis tests will be 0.05. The data will be analyzed with the SPSS 15.0 statistical package and the free R software.

For the analysis of EEG data, a Power will be used. Spectrum Analysis (PSA) with the EEGLAB toolbox or similar. This technique will allow us to evaluate the energy distribution in different frequency bands of brain signals. EEG signals are decomposed into their frequency components using mathematical transforms, such as the Fourier transform, and the power in each specific frequency band is calculated.

PSA focuses on the decomposition of EEG signals into different frequencies. This will allow us to understand the distribution of energy in the frequency domain. Some of the main variables that can be analyzed are:

- Frecuencias: aquí se analizarán diferentes bandas de frecuencia, donde por las características del EMOTIV se pueden incluir algunas como:
- Theta (4-8 Hz)
- Alfa (8-13 Hz)
- Low Beta (12-16 Hz)
- High Beta (16-25 Hz)
- Gamma (25-45 Hz)

Each of these bands is related to specific mental states and cognitive functions. For example, the delta band (0.5-4 Hz) is associated with deep sleep, while the alpha band (8-13 Hz) is associated with states of relaxation or non-stressful alertness.

PSA will allow quantification of electrical activity in these bands, which provides crucial information for understanding brain activity.

- Amplitudes: we will be able to quantify the amplitude of the waves in each frequency band. This involves measuring the magnitude of EEG signals in each specific frequency range.
  In general, these variables provide critical information about the brain's electrical activity. This will allow us to assess associated neurological disorders and the study of the patient's cognition

Therefore, this technique will allow us to identify abnormal patterns of brain activity, evaluate brain responses during resting-state EEG data acquisition, and examine the relationship between activity in different frequency bands and specific cognitive functions. and will allow us to deepen our understanding of brain electrical activity and its correlation with cognitive processes and mental states.

INSURANCE

To carry out the research project, the ASCATEC center as well as the promoter have an insurance policy 036352408/00000 with the company ALLIANZ SEGUROS Y REASEGUROS, SA through the contract 140622278, which complies with current legislation (Royal Decree 1090/2015) and will provide participants with compensation and compensation in the event of impairment of their health or injuries that may occur in relation to their participation in the study. , as long as they are not a consequence of the disease being studied or of the evolution of the disease as a consequence of the ineffectiveness of the treatment .

EXPENSES AND ECONOMIC COMPENSATION

Due to the characteristics of the study, it is not proposed that the researcher receives financial compensation for carrying out the study.

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