"LET'S TALK ABOUT COLLEGE STUDENT SLEEP: AN INNOVATIVE NON-INVASIVE NEUROMODULATION TREATMENT TO IMPROVE SLEEP QUALITY AND ACADEMIC PERFORMANCE: RANDOMIZED CLINICAL TRIAL" (USLEEP)

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TITLE OF THE PROJECT

"Let's talk about sleep in college student: an innovative treatment based on non-invasive neuromodulation to enhance the sleep quality and academic efficiency: Randomized controlled trial" (USLEEP)

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ABSTRACT

Currently, disorders such as insomnia, narcolepsy or circadian rhythm disturbances are the most common among college students. The concern about the quality of sleep of university students, future professionals of the world, must be crucial for the scientific community, as well as for university professors and professors. Innovative electrotherapy technologies such as non-invasive neuromodulation NESA are showing effects on improving sleep quality, concentration and stress, so the objective of this project is to carry out a triple-blind randomized clinical trial with first-year science science students. health from three universities. The design was made up of an intervention group with NESA technology and another control group in each of the centers. Where the quality of sleep will be analyzed,

This multicenter project hopes to demonstrate that non-invasive NESA neuromodulation can be a preventive treatment for the maintenance of sleep quality during stressful periods such as university exams, as well as being able to modulate perceived stress and translate into an improvement in student performance.

STUDY JUSTIFICATION:

INTRODUCTION:

The university student population has never been considered as possible affected by sleep problems. However, they are very susceptible to sleep disorders due to their pace of life, exams and their social life. Students also have a tendency to use exciting substances such as caffeine, tobacco, or heavy alcohol consumption. Consequently, sleep disorders that are closely related to academic performance can be generated. Identifying the most common and prevalent disorders in this population, as well as studying the most effective possible treatments should be one of the objectives of today's sleep medicine professionals. Currently, disorders such as insomnia, narcolepsy or circadian rhythm disturbances are the most common among college students. The concern about the quality of sleep of university students, future professionals of the world, must be crucial for the scientific community, as well as for university professors and professors(Al Salmani et al., 2020) .

Fortunately, new emerging technologies such as non-invasive neuromodulation NESA, manage to neuromodulate the autonomic nervous system through electrotherapy and this has shown positive changes in the quality of sleep(Medina-Ramírez et al., 2021) and performance in young athletes, which can be extrapolated to young students who also require performance for their studies.

It is for this reason that with this study we want to deepen the responses generated by students to stimuli and stress generated throughout an exam period.

NESA NEUROMODULATION NON-INVASIVE TECHNOLOGY.

Non-invasive neuromodulation NESA was invented in Japan in 1989 by Dr. Seikai et Al and their team at the Odawara Neurological Hospital, with the aim of improving the functionality of electrotherapy in the nervous system.

Currently its main quality is that it is its main therapeutic quality is based on its pleasant nature for the patient, in addition to being a non-invasive procedure it is used in various Hospitals, clinics and football clubs in Spain and the United Arab Emirates. The central manufacturing plant is based in the Basque Country, Spain, directed by the son of Dr. Seikai.

The objective of the NESA microcurrents generated by the XSIGNAL® device is none other than to introduce, by means of a non-invasive technique, electrical energy to normalize the nervous stimulus. This makes it an excellent complementary treatment to the activity of the doctor or physiotherapist.(Medina-Ramírez et al., 2021).

Its effects are achieved by establishing various input nerve pathways corresponding to the body dermis, through which the signals are intellectualized in time-space. These signals are the basis for achieving a normalization of the nerve impulse through microcurrents. Although the information transmittable through this force has a limit, rationalizing the signal creates a possibility to modulate the nervous system.

Noninvasive neuromodulation NESA occupies an independent position separate from classical electrotherapy. In this sense, it will act against any affection that causes excitement and tension in the cerebral nervous systems, osteoarticular muscular, and visceral vascular.

In this sense, sleep takes on special importance, the workhorse of any physical therapy.

Non-invasive neuromodulation NESA proposes a methodology with which it is possible to significantly reduce the biological energy costs of treatment with an electrical current supply. If several input routes of the stimulus are ensured, the intensity of the input energy can be reduced to levels typical of the physiological environment, allowing treatments that involve the whole organism.

If we also manage to translate the input pulse of each sensory stimulation into information in the form of data with polar, temporal and spatial properties, it can interfere more significantly in the transmission and processing of information from the central nervous system and, therefore, Consequently, intervene in the possible existing anomalies. The condition for obtaining effects is not the intensity, but the informational nature of the medium that is introduced and the input method of said medium.

Conventional analog-type electrical stimulation treatments subject the human body to an excessively inefficient energy output compared to the information processing system deployed by the body itself.

The NESA XSIGNAL® device is a bioelectrical interface designed to enter, by affinity, in contact with the body, and bind to it through a series of "signals" previously converted into information. Starting from this premise, non-invasive neuromodulation NESA proposes the foundation of the science of electrophysiological information, that is, a procedure designed to calm and stabilize the excess activity of all related systems.

In many diseases, the central nervous system is subjected to excess activity of an interactive nature (eg, with the sympathetic nervous system or its reticular formation). There are a few effective treatment methods that inhibit excess activity without resorting to intense stimulation. This allows them not to cause pain or any other unpleasant effect, such as secondary or some type of dependency. By supplying imperceptible electrical signals, NESA microcurrents deepen the development of an original methodology that calms and stabilizes excess activity from all related systems. This process will be called normalized topographic stimulation generated by the NESA XSIGNAL®, basic conditions for an energy of weak intensity to be effective.

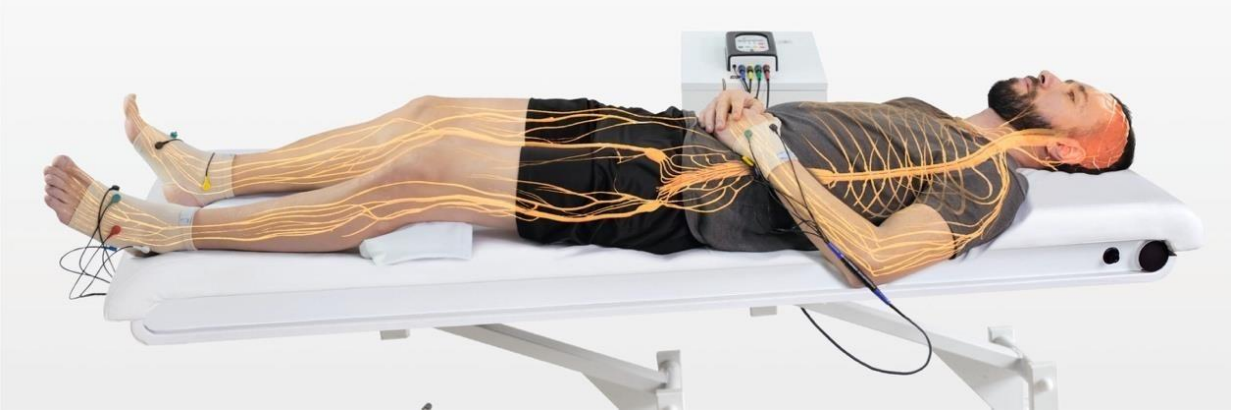


Figure 1. Example of NESA stimulation (NESA DRIVE).

Therefore, the NESA XSIGNAL® is a treatment system for the supply of electrical current, which converts information, temporally and spatially, and controls it automatically, modulating the processing and transmission of information carried out by the human body.

NESA technology also acts on this parameter, including a coordinated stimulation through 24 electrodes, modulating the nervous system through low-frequency bioelectric signals. The action on the different areas of the body is carried out through the current that circulates between them. Since each person has different conductivity and frequencies, and these can vary depending on multiple factors (age, physical constitution, sweating, etc.) there are different programs (transmission protocol of the impulse sequences) and disposition of the electrode mass. that address these situations.

The system is minimally invasive; superficial application, with electrodes connected by cable in gloves and anklets (or adaptations to amputated limbs), with 24 electrical access points. The characteristics of the current model are:

1. Emit low frequency pulses from 1.3 Hz to 14.28 Hz oscillating.

    1. Pulse emission at an intensity of 0.5 milliamps with a potential difference of ± 3 V and ± 6 V.

    2. Emission of impulses in a coordinated manner between 24 electrodes (6 electrodes per limb) that are stimulated simultaneously. 6 electrodes per limb are placed at different points of the peripheral nerve with lower impedance.

    3. Focusing of the impulses to a ground electrode, with the function of conductive wire.

    4. Stochastic algorithm emission in each pulse emission cycle. The signals are programmed in time and space.

To obtain the different therapeutic effects, the combination of up to 9 different programs is assigned. The electrical stimulation between the points follows a certain order, stimulus time and polarity change, generated automatically by means of a patented algorithm.

The impact of this ultra-weak electrical signal, practically imperceptible, is amplified thanks to its input through multiple routes and the phenomenon of stochastic resonance, configuring a circuit that encompasses the nervous system with related physiological functions. Has shown in preliminarystudies, effects on improving concentration(Rico & Aranguren, 2016, 2017)neuralgic pain (Molina et al., 2020) and sleep quality (Contreras & Medina-Ramírez, 2021; Lledó-Amat et al., 2021)

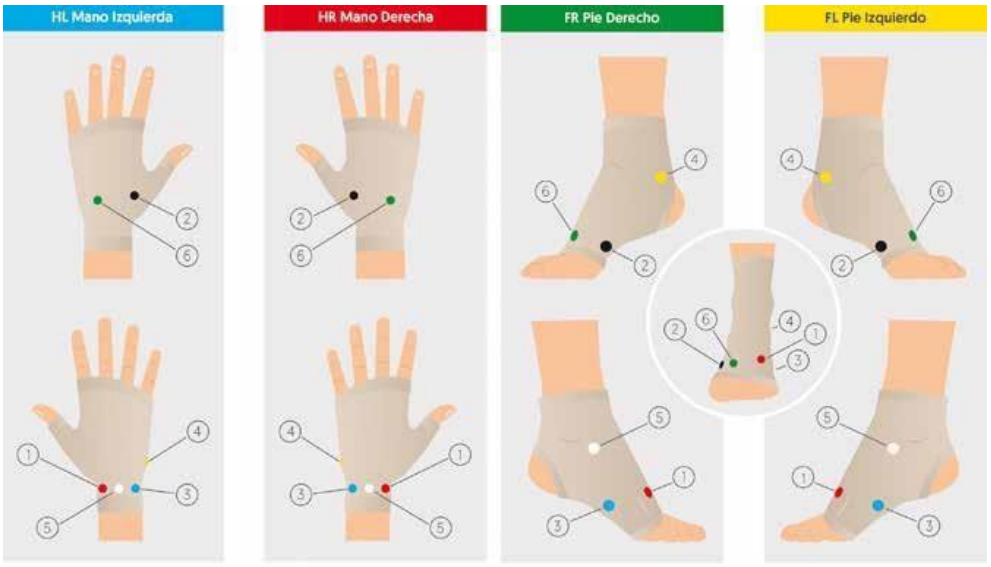
NXSIGNAL® DEVICE COMPONENTS

The device consists of the following elements:

- Control console and device management. It consists of the connections for the cables to the electrodes, battery and configuration panel (Figure 2).

Figure 2. NXSIGNAL® Device Console

- Gloves for both hands and anklets for the feet. They incorporate fixed electrodes, connected by cable to the control console, positioned at the points of least resistance and greater connectivity with the peripheral nerves (Figure 3).



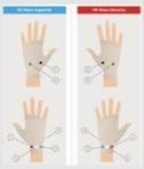
ZONA	COLOR	NERVIO
TOBILLERA 	ROJO	N. Peroneo superficial
	NEGRO	N. Safeno
	AZUL	N. sensitivo Sural
	AMARILLO	N. Tibial y ramas calcáneas
	BLANCO	N. Peroneo (rama superficial)
	VERDE	N. Peroneo profundo
GUANTE 	ROJO	N. Radial (rama anterior)
	NEGRO	N. Radial (rama posterior)
	AZUL	N. Cubital (rama anterior)
	AMARILLO	N. Cubital (rama cutánea dorsal)
	BLANCO	N. Mediano (rama cutánea palmar)
	VERDE	N. Cubital (rama dorsal)

Figure 3. Location of the electrodes according to the corresponding anatomical region (upper and lower image).

OBJECTIVES OF THE STUDY:

MAIN GOAL:

- To analyze the effects on the quality of sleep and student performance through the application of non-invasive neuromodulation NESA.

SECONDARY OBJECTIVES:

- Analyze if there is a correlation in the improvement of stress perception.
- To assess the influence between non-invasive neuromodulation and academic performance.

METHODOLOGY:

DESIGN:

Randomized clinical trial with passive control, triple blind (for the patient, the physiotherapist applying the technique and evaluator), with a parallel and multicenter design. The study will have two arms, the intervention group will undergo neuromodulation treatment with the NESA XSIGNAL® device and the control group will not carry out any intervention, but both will be evaluated for the same variables at the same times.

SCOPE AND STUDY POPULATION:

Multicenter study whose collaborating entities correspond to the University of Las Palmas de Gran Canaria, Alfonso X el Sabio University, the Pontifical University of Salamanca and the University of Alcalá de Henares. The study population will be students from the collaborating universities, corresponding to first-year health sciences degrees. For the selection of the sample, a non-probabilistic convenience sampling will be carried out, which allows selecting those accessible cases that agree to be included.

CALCULATION OF THE SAMPLE:

The present study is proposed as a pilot study due to the absence of similar studies in this field that allow a

calculation of the adjusted sample size. For this, 80 participants will be included, who must meet the established selection criteria.

CRITERIA FOR SELECTING THE PARTICIPANTS

INCLUSION CRITERIA.

- Healthy people
- Be enrolled in a degree in health sciences at the partner universities in the study in the first year.
- Optimal cognitive abilities and mentally competent to participate in the study.
- In cognitive conditions to complete the study questionnaires
- Have an optimal command of the Spanish language to complete the questionnaires.
- Signing of the informed consent for participation

EXCLUSION CRITERIA.

- Present some of the contraindications for a treatment with NESA XSIGNAL®: Pacemaker or other electrical surgical device, internal bleeding, do not apply electrodes on skin in poor condition, with ulcerations or wounds, acute febrile processes, pregnancy, acute thrombophlebitis and / or phobia of electricity, and pregnant.
- Combine another pharmacological treatment that influences the variables to be evaluated during the study.

ELIMINATION CRITERIA.

- Missing an intervention session of the 10 scheduled sessions.

RECRUITMENT OF PARTICIPANTS AND EVALUATION PROCESS.

Phase 1. Dissemination of the study
The dissemination of the participation of the subjects in the study will consist of making an initial contact through the teachers responsible for each center. Once informed, the students will receive an email with the complete information sheet containing the description of the study, the objective, the justification, the risks and benefits derived from participation, everything related to the protection of their personal data and the way of contacting the researcher in charge of each center (ANNEX 01). In the same actions, the established selection criteria will be reported.

Phase 2. Call for anamnesis of those interested in participating in the study and selection of study subjects.

Phase 3. Acceptance of participation in the study by signing the informed consent (ANNEX 02)

Once the consent is signed, the participant will fill in the participant's demographic characteristics questionnaire (ANNEX 03) and measures of baseline variables.

Next, the participant will be summoned to the laboratory of the corresponding university for the application of the evaluation intervention within the corresponding deadlines and indicated in the information sheet of the study.

RANDOM ASSIGNMENT:

Patients who agree to participate will be randomly assigned to one of the 2 arms of the study (real device or control), using a fixed-size block design generated by the data manager to guarantee balanced randomization for each of the arms and in each of the participating universities. The assignment process will be carried out hidden and will be carried out by the support researcher in the Unit indicated for this study. Each research subject will be assigned an identification code corresponding to correlative numbers from 1 to 80, with 1-20 subjects from the UPSA, from 21-40 students from the Alfonso X el Sabio University, from 41 to 60 students from the University of Las Palmas and from 61 to 80 from the University of Alcalá.

BLINDING:

The intervention to which the subjects have been assigned, the specialist and the researcher who collects the information and performs the follow-ups will be blinded. Data analysis will also be performed in a blinded fashion.

INTERVENTION PROTOCOLS

For neuromodulation:

Group 1: Application of Nesa microcurrents through the NXSIGNAL® generator twice a week.

The volunteer subjects of the study are treated with the NXSIGNAL® device in sessions of 60 minutes, twice a week and for 5 weeks (10 sessions).

The correct application of the NXSIGNAL® device, as well as an adequate programming, is of vital importance for the fulfillment of the objective. General guidelines will be established, which must always be followed with the application of NESA microcurrents, and specific guidelines for this particular study, in order to obtain a sample as homogeneous as possible and bring the programming of the device closer to the objective to be pursued. in the clinical trial. General guidelines for the application of NXSIGNAL®.

- The skin must be clean, free of creams and grease, so it will be necessary to clean with alcohol or similar. The device's gloves and socks will be placed in accordance with the established protocols, paying attention to the location of each semi-electrode in its anatomical position. The device has a color system to determine the location of each cable.
- The directing electrode will be located with the skin equally clean, and will be essential for the operation of the technology.
- The use of electronic devices by the patient, less than one meter away, is contraindicated in order to optimize their use. The electrodes are connected to the control console and the targeting electrode located on the intervertebral area between C7 and T1 (cervical area) and will follow the central treatment pattern with the following combination:

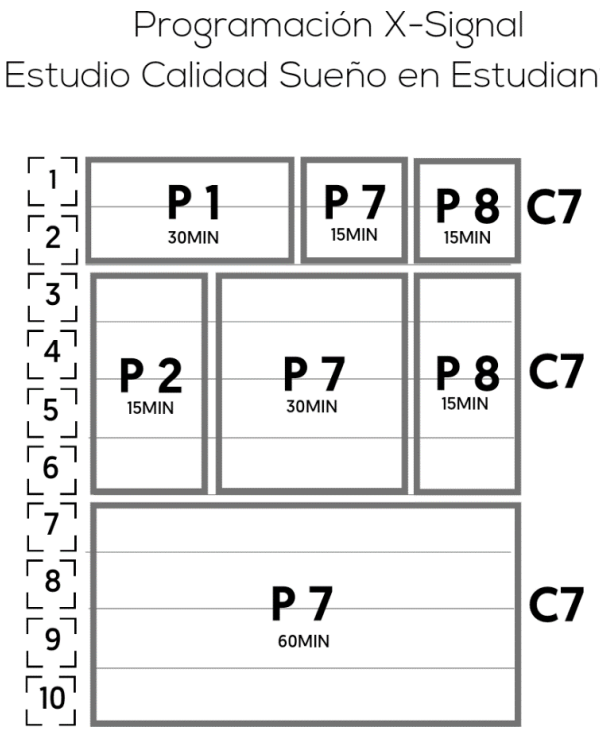


Figure 4. The numbers located vertically to the left of the image represent the number of sessions. The central blocks refer to the programs and the application time and in the vertical right column the type of central application of the targeting electrode is defined, located in the cervical area C7.

The default schedule is based on the goals set in this study. The main objective is to improve the quality of sleep. The secondary objectives are to correlate with improving perception of stress and academic performance.

Group 2: Control group without NESA XSIGNAL® application

The same protocol for the analysis of variables is followed, but without performing any type of treatment with the NESA XSIGNAL device.

DEFINITION OF THE STUDY VARIABLES AND MEASUREMENT INDICATORS:

The variables will be measured before the start of the intervention (PRE), at the end of the intervention (POST) and one month after the end of the study.

1. SLEEP VARIABLES

1.1 Perceived sleep quality: through a validated sleep quality perception questionnaire, Pittsburgh questionnaire(Escobar Córdoba & Eslava Schmalbach, 2005) (ANNEX 04)

1.2 Salivary cortisol measurement: Through the Soma OFC II cube. The analysis will be performed in real time through the collection of saliva, it is not affected by recent food and drink; Once the swab is in the buffer, your sample is stable for months. It is a validated instrument (Fisher, 2015).

2. STRESS VARIABLES

2.1 Academic stress questionnaire at university (CEAU).

This questionnaire prepared by García - Ros & Pérez - González (2012), (ANNEX 05) assesses possible stressful

situations in the university environment and consists of a total of
21 items. The participants' responses indicate the level of perceived stress in each situation using a Likert-type response scale with 5 options ranging from “no stress” (1) to “a lot of stress” (5). The internal consistency of this instrument, in this study, has a .819 once Cronbach's α has been analyzed.
This questionnaire is divided into 4 subscales, which are:
• Academic obligations (OA): consists of 8 items (1, 5, 7, 9, 10, 11, 14 and 15) that assess the level of stress generated in students by carrying out academic work and exams, the lack of time to develop activities, academic overload, performing required work, excess responsibilities and study-related activities. Its internal consistency is .675 using Cronbach's α.
• Record and future prospects (EF): provided with 6 items (16, 17, 18, 19, 20, 21) that, like the previous one, measure the stress generated by the anticipation of problematic situations or future academic situations, such as completing the studies within the stipulated deadlines, obtaining high grades, maintaining or obtaining a scholarship, the choice of subjects and itineraries during the career and family pressure to obtain good results. Its internal consistency in this study is .691 using Cronbach's α.
• Interpersonal difficulties (ID): using 4 items (6, 8, 12, 13) determines the level of stress that can produce problems or conflicts with classmates and teachers, as well as that related to competitiveness with peers. Its internal consistency is .758 through the analysis of Cronbach's α.
• Expression and communication of own ideas (EC): through 3 items (2, 3, 4) stress is evaluated in the moments that students are required to present and express their own ideas in the classroom in the presence of all their colleagues. Its internal consistency is .725 according to Cronbach's α.

2.2 Academic Stress Coping Scale (A-CEA)

The coping scale, known as A-CEA(González Cabanach et al., 2010), is a subscale of the CEA questionnaire, an instrument made up of three scales, which is used to assess academic stressors (E-CEA), stress responses (R-CEA) and stress coping strategies (A-CEA). (ANNEX 06).
The A-CEA scale is made up of 23 items, formulated to evaluate the cognitive and behavioral strategies used by the student when facing situations of academic stress. It is a scale with Likert-type responses to each item, in which the student can choose between five options: Never (1), Sometime (2), Many times (3), Many times (4) and Always (5). The reliability of the A-CEA scale has a general Cronbach coefficient for this study of .885. In turn, this coping scale is divided into 3 factors that are specified below:
• Factor 1. Positive Reevaluation: This dimension groups nine items (1, 3, 4, 5, 6, 14, 17, 18 and 19) that present different ways of coping aimed at creating a new positive meaning about the problem or academic difficulty . This factor underlines its active and positive character in propositions such as “When I face a problematic situation the night before the exam I try to think that I am prepared to do it well” or “When I face a complicated situation, in general, I try not to give it importance to the problems ”. Its internal consistency according to Cronbach's α is .668.
• Factor 2. Search for Social Support: It includes seven items (2, 8, 10, 13, 20, 21 and 23) to evaluate an active and behavioral type of coping, based on the student's search for information and advice, as social support to the problem, and also of understanding on the part of other people, as emotional support with what he experiences. Its internal consistency according to Cronbach's α is .727.
• Factor 3. Planning and management of personal resources: It includes seven items (7, 9, 11, 12, 15, 16 and 22) that refer to the activation of strategies based on analysis and reasoning to change the problem situation , and that denote a type of behavioral and active coping. Its internal consistency according to Cronbach's α is .741 for this study.

2.3 Sociodemographic variables questionnaire

A third questionnaire (ANNEX 03) to collect necessary information on sociodemographic variables such as age, gender, place of residence and type of home. This questionnaire also aims to collect some data referring to their academic life, such as the average grade for access to the university and the degree completed. The ad-

hoc questionnaire consists of a total of 11 items and all questions are made in a clear and concise manner so that the answer is free from ambiguity.

3. ACADEMIC PERFORMANCE

The final average grade of the first academic semester will be analyzed comparing by groups.

To dispense the questionnaires, a computer tool will be designed through the Google Forms platform, which will allow the creation and distribution of said questionnaires digitally, which will facilitate their dissemination and subsequent coding. The link to said questionnaire will be sent to the participants by email, which will be completed electronically without the need to contact the researcher. Once completed, the results will be automatically sent to the main researcher, subsequently being encoded in a statistical database.
In order to compare the individual results of the PRE and POST intervention questionnaires, they will be identified with the identification code of the participants, without thus making it possible to identify the subjects.

STATISTICAL ANALYSIS PLAN OF THE RESULTS

For the coding and analysis of the data, the statistical program IBM® SPSS Statistics version 22 will be used. For the treatment of categorical variables, tables of absolute and relative frequencies will be made, which will be analyzed using Pearson's Chi-square.
In the case of quantitative variables, the mean and standard deviation will be obtained as the measures of central tendency and dispersion index. The Kolmogorov-Smirnov test will be performed to check the normality of the distribution in the event that the sample obtained is the expected one (greater than 30 individuals). If the distribution is normal, parametric tests will be performed to assess differences between groups. Statistically significant differences will be sought between the quantitative variables of the groups by means of a student's t test for independent measures. and repeated measures ANOVA to compare the measures collected at different times in the same group. If the population does not follow a normal distribution of the variable under study, non-parametric tests will be performed to determine the differences between groups. Friedman's test for paired samples and Kruskal Wallis's test for independent samples. In all cases, a 95% confidence interval and a significance level less than or equal to 0.05 will be established.

FORECAST OF POSSIBLE SIDE EFFECTS THAT MAY OCCUR

Anticipation of possible risks / damages and mechanisms to reduce harm or distress to a minimum

No risk is foreseen during the performance of the technique. The study will meet the ethical requirements of the Helsinki Declaration of the World Medical Assembly (WMA) on ethical principles for medical research involving human beings.

Provision of measures to minimize pain, stress, physical or emotional risk.

Study participation does not have harmful risks to health. No study complications and no adverse effects of the applied techniques are anticipated. They will be warned in advance that during the first two sessions of the treatment they could perceive slight alterations of the sleep phases, exceptionally.

Forecast of remuneration or gratification for participation in the study

The study subjects have as a common link their own health or that of the future patient, therefore, all of them can benefit from knowing the applicability of the proposed technique in improving the quality of life. No economic remuneration is foreseen, however, the student will be rewarded with a special recognition in the subjects that he / she takes related to research methodology.

Sensitivity to the needs and perspectives of the people participating in the project
No long-term benefit or harm is anticipated, as the technique is safe and tested in healthy patients.

Provision of contracting liability insurance
The different Faculties have civil liability insurance that will cover possible liabilities.

SCHEDULE

The total duration of the project is estimated to be 8 months.

A. Project design.
B. Authorization of the Center and request for approval by the Ethics Committee for Clinical Research.
C. Recruitment of Personnel and Users.
D. Therapeutic intervention and data collection.
E. Statistic analysis.
F. Evaluation and interpretation of results.
G. Drafting of results report and dissemination of results.

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QA

1.- Identification of collectors:

Each collector will be assigned a code that will be included as the first digit in the patient's identification code in the 1-xxxx format. Each collector is responsible for the data dump so the collector digit matches the data dump.

Recorder	Code
Person I	1
Person II	2

Person III	3
Person IV	4

2.- Quality audits:

Since it is estimated that the total sample will be registered during the first month, a quality audit will be carried out on a weekly basis. In them, the following will be carried out:

a) Ascending ordering of the data: revision of the variable date of inclusion and time of exposure.

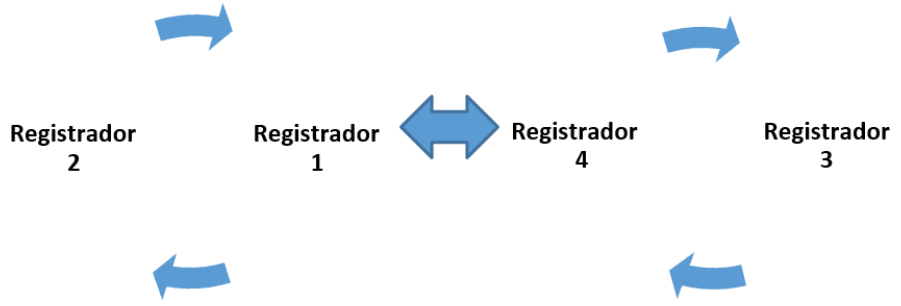
b) Exploration of the variable.

c) List of Frequencies for the variables: age, sex, marital status, use of drugs and perception of health.

According to this procedure, we could detect inconsistencies in the data dump, as well as identify the person who executed it, guided by the code assigned to the registrar already mentioned in the first section. In addition, the code could be associated with the name of the document when it is edited and saved, so that it would be known who last entered or evaluated the document. In both situations, in the event of detecting an error, the person in charge would be notified immediately to correct it.

3.- Audit mechanism: Cross Audit

Each logger, weekly the first month, and biweekly the following months, will review the data dumped from another logger in the team from the last review to date, according to a random sequence established by the principal investigator. The scheme to follow would be the following:



4- Ethical and legal considerations. Procedures to keep information and comply with legal considerations regarding data protection.

All data will be collected by computer in an encrypted Excel document (Microsoft Office Excel 2019 MSO 64-bit program). They will be downloaded in electronic format from the Google Forms platform, and a database will be created whose access will be encrypted, which will make it only accessible through a key known

exclusively to the researchers responsible for each project center.

The pseudonymization used in completing the questionnaires will make the personal data collected in no case identifying a natural person.

The estimated time for the coding and analysis of the results is estimated at 2 months, after which time the database will be erased, keeping only the statistical data. The destruction will be done by means of computer erasure by means of a program that allows deleting specific folders, eliminating hard drives and filling in empty spaces on the disk, so that the elimination technique is safe and the deleted information is not allowed to be recovered again. Statistical data will be kept for the time necessary for the adequate dissemination of the results.

During this processing time, the owners of the data may exercise the right of access, rectification, cancellation, portability, etc. going to the email addressRaquel.medina@ulpgc.es.

Researchers will be solely responsible for the introduction, modification and deletion of data as well as for imposing the limitations and restrictions on the properties of the file.

There is no assignment, transfer or communication of data to third parties.

Everything is collected in accordance with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights and by virtue of the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data.

Forecast of dissemination of research results:
There are no restrictions on publishing the research results.
Regarding the expected communication of the results to the participants, informative talks will be held to the group of students to present the results, as well as the methodology as a didactic class on research methods.

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