Comparison of the impact of two NEurofeedback EEG protocols on the perception and threshold of experimental pain in healthy subjects

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Main Information

Primary registry identifying number
LBCTR2023065392

Protocol number
CEHDF2110

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
18/06/2023

Primary sponsor
Saint Joseph University of Beirut – Dr Sandra Kobaiter Maarrawi

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
26/03/2024

Date of registration in national regulatory agency
18/06/2023

Public title
Comparison of the impact of two NEurofeedback EEG protocols on the perception and threshold of experimental pain in healthy subjects

Acronym

Scientific title
Physiological and validation study in healthy subjects of the effect of two Neurofeedback protocols on acute pain - clinical trial.

Acronym

Brief summary of the study: English

Neuropathic pain is difficult to treat. Studies show that Neurofeedback, a way to voluntarily modulate brain activity, has shown significant results in pain relief. However, the mechanisms and the specificity of the treatment are still not sufficiently investigated. From there, we are interested in passing two protocols of opposite principles (one aimed at the synchronization of the alpha band and the other its desynchronization) aimed at improving the perception and tolerance of pain, in order to understand more meticulously the mechanisms of action of this technique to propose optimal protocols for the management of pain..

Brief summary of the study: Arabic

* من الصعب علاج آلام الأعصاب. تشير الدراسات إلى أن الارتجاع العصبي ، وهي طريقة لتعديل نشاط الدماغ بشكل طوعي ، أظهرت نتائج مهمة في تخفيف الآلام. ومع ذلك ، لا تزال آليات وخصوصية العلاج لم يتم التحقيق فيها بشكل كافٍ. من هناك ، نحن مهتمون بتمرير بروتوكولين لمبادئ متناقضة (أحدهما يهدف إلى مزامنة نطاق ألفا والآخر إلغاء التزامن) يهدف إلى تحسين الإدراك والتسامح مع الألم ، من أجل فهم آليات عمل بدقة أكبر. هذه التقنية لاقتراح البروتوكولات المثلى لإدارة الألم.

Health conditions/problem studied: Specify

neuropathic pain results from damage or disease of the somatosensory nervous system, which affects the central and/or peripheral nervous system . This pain directly interferes with the well-being of sufferers. Indeed, it significantly reduces the quality of life, causes emotional distress

and negatively affects the sleep cycle in the affected population, in comparison with the general population and even sufferers of non-neuropathic chronic pain. Consequently, a lack of adaptation to the level of daily life is noted (absences at work, social withdrawal, etc.) . Therefore, appropriate treatment is essential to improve their lives.

Interventions: Specify

1- Neurofeedback + schultz relaxation group : this group will undergo a n autogenic relaxation before the neurofeedback training that aims to increase alpha amplitude over C4.

2- Neurofeedback + Motor imagery training group: this group will undergo a Motor imagery training in which he will visualize his hand moving and then undergo a neurofeedback training to decrease the alpha amplitude over C4.

3 -Two groups Neurofeedback alone: one group will do a neurofeedback training with the target of increasing alpha amplitude and the second group will do a neurofeedback training that will decrease the alpha amplitude.

4- Scham group : this group will not do a neurofeedback training to modify his brainwave instead random values will be displayed during training

Key inclusion and exclusion criteria: Inclusion criteria

- The inclusion criteria are:
-Young and healthy subject, aged between 18 and 30 years old
-Male and female sex
-Right handed
- Absence of urticaria reactions to cold
-No analgesics 6 hours before visits/tests
-Regular sleep cycle (Bergen insomnia scale Ar-Fr)
- Perceived stress within the norms(PSS10 Ar-Fr)

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

30

Key inclusion and exclusion criteria: Exclusion criteria

-Chronic Pain
-Psychiatric and/or neurological pathologies
- Post-traumatic stress disorder (PCL-S) (see appendix 4)
-Anxiety or depression (HAD Ar-Fr) (see appendix 5)
-Amputations
-Uncorrected visual or hearing impairment
-History of cardiovascular disorders
-History of fainting or seizures
-History of frostbite
-Open cut of the arm to immerse in the cold pressor test
-Fracture of the limb to be immersed
-History of Reynaud's phenomenon

Type of study

Interventional

Type of intervention

Complementary therapies

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

N/A

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment
Parallel

Study design: Specify assignment
N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class
N/A

Therapeutic indication
The training suggested, if proved to be beneficial, could be eventually applied in the context of neuropathic pain diseases

Therapeutic benefit
reduce neuropathic pain perception

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention
Samples without DNA

Biospecimen description
Saliva

Target sample size
100

Actual enrollment target size
100

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
15/07/2019

Date of study closure: Type
Anticipated

Date of study closure: Date
01/07/2024

Recruitment status
Recruiting

Recruitment status: Specify

Date of completion
21/12/2023

IPD sharing statement plan
No

IPD sharing statement description
N/A

Additional data URL
N/A

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Full name of issuing authority Saint Joseph University of Beirut (USJ) – Faculty of Medicine	Secondary identifying number - FM444

Sources of Monetary or Material Support

Name
Saint Joseph University of Beirut (USJ) - Research Council and Faculty of Medicine

Secondary Sponsors

No Sponsors

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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Saint Joseph University of Beirut – Faculty of Medicine – Laboratory of Research in Neuroscience	Sandra Kobaiter Maarrawi	neuroscience	Approved
Saint Joseph University of Beirut – Faculty of Medicine – Laboratory of Research in Neuroscience	Joseph Maarrawi	neurosurgery	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	13/12/2022	Pr Michel Scheuer	michel.scheuer@usj.edu.lb	00961 1 421 000 ext 2228

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Chronic pain	2-Propanol (T51.2)	pain

Interventions

Intervention	Description	Keyword
Neurofeedback	a methode of voluntarily brain modulatioin activity for therapeutic purposes	neurofeedback
schultz relaxation	a technique that involves deep breathing and progressive muscle relaxation to induce a state of calm and reduce stress and anxiety.	Schultz Relaxation
Motor imagery	a cognitive practice that involves mentally rehearsing and visualizing specific motor movements to enhance physical performance and improve motor skills.	Motor Imagery
TENS	electrical stimuli on the skin for inducing pain	TENS
Cold Pressor Test	putting the hand in cold water for inducing pain	CPT

Primary Outcomes

Name	Time Points	Measure
Reduction of pain perception with TENS after treatment.	before and after each session. And the start and end of experiment.	pain perception using Verbal Rating scale
increase of pain tolerance with CPT after treatment	before and after each session. And the start and end of experiment. Measure 2: maximum time of hand submersion.	maximum time of hand submersion

Key Secondary Outcomes

Name	Time Points	Measure
efficacity of schultz relaxation to increase alpha amplitude during training.	before and after each session. And the start and end of experiment	mean alpha wave amplitude using an eeg
efficacity of Motor imagery to decrease alpha amplitude during training	before and after each session. And the start and end of experiment.	mean alpha wave amplitude using an eeg

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files