



# Comparison of the impact of two Nurofeedback 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 Nurofeedback 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 الألم. ومع ذلك، لا تزال الآليات 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 الآليات 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: Age minimum

18

### 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

### Trial scope

Therapy

### Study design: Allocation

Randomized controlled trial

### Study design: Control

Placebo

### Study design: Purpose

Treatment

### Key inclusion and exclusion criteria: Specify gender

### Key inclusion and exclusion criteria: Age maximum

30

### Type of intervention: Specify type

N/A

### Trial scope: Specify scope

N/A

### Study design: Masking

Blinded (masking used)

### Study phase

N/A

### 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



<b>Date of study closure: Type</b> Anticipated	<b>Date of study closure: Date</b> 01/07/2024
<b>Recruitment status</b> Recruiting	<b>Recruitment status: Specify</b>
<b>Date of completion</b> 21/12/2023	
<b>IPD sharing statement plan</b> No	<b>IPD sharing statement description</b> N/A
<b>Additional data URL</b> N/A	
<b>Admin comments</b>	
<b>Trial status</b> 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



## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
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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 Maarawi	neuroscience	Approved
Saint Joseph University of Beirut – Faculty of Medicine – Laboratory of Research in Neuroscience	Joseph Maarawi	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
efficacy 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
efficacy 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**