

# Neurofeedback for treatment of post-COVID-19 complications

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<b>Registration date</b> 29/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/10/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Neurofeedback (EEG [electroencephalography] biofeedback) is a non-invasive method to regulate brain activity by biological feedback. In simple terms, the device monitors the EEG and gives the subject information (e.g. visual) about how "good" the EEG is. When the brain receives immediate and accurate information about the EEG, it can, after a short training, learn how to improve the EEG. Neurofeedback has been proven by a number of scientific studies to be a successful method for improving learning, attention, memory, motor function, sleep disorders, and other neurological conditions. Neurological post-COVID syndrome includes complications such as dizziness, seizures, fatigue, insomnia, depression, anxiety and migraines. The aim of this study is to determine if neurofeedback could be a treatment for the rehabilitation of neurological post-COVID symptoms.

### Who can participate?

Patients aged 18 years and over who have had COVID-19 and suffer from at least one of the following neurological symptoms: insomnia, migraines/headaches, dizziness, seizures, fatigue, depression and anxiety

### What does the study involve?

Participation involves an initial interview (medical history), completion of questionnaires about the medical condition of the participants, and five 30-minute neurofeedback sessions. Questionnaires are completed before neurofeedback and immediately after, 1 week after and 1 month after the neurofeedback sessions.

### What are the possible benefits and risks of participating?

Participants may improve their post-COVID symptoms. Regarding the potential risks of participation, participants might experience some temporary side effects of neurofeedback, such as headaches or fatigue, which may occur during neurofeedback training and/or several hours after termination of the neurofeedback session.

### Where is the study run from?

Charles University in Prague (Czech Republic)

When is the study starting and how long it is expected to run for?  
June 2021 to December 2021

Who is funding the study?  
Charles University in Prague (Czech Republic)

Who is the main contact?  
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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

In adults suffering from post-COVID complications is neurofeedback therapy effective, when comparing conditions before and after the intervention, in reducing the severity of these complications?

### Acronym

PCOVIDNE

### Study objectives

1. Five sessions of neurofeedback (NFB) will significantly reduce post-COVID-19 seizures, dizziness, insomnia, headaches/migraines, fatigue, anxiety, and depression
2. NFB-induced significant improvement in the above post-COVID-19 symptoms will be present 1 week after NFB
3. NFB-induced significant improvement in the above post-COVID-19 symptoms will persist after 1 month after NFB
4. There will be a positive correlation between post-COVID fatigue, anxiety and depression
5. Improvements in fatigue, anxiety and depression will be correlated

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 16/07/2021, Ethics Committee of Third Faculty of Medicine, Charles University (Prague 87 Ruská, Prague, 100 00, Czechia; +420 (0)26710 2915; marek.vacha@lf3.cuni), ref: none provided

### Study design

Single-center interventional open-label non-randomized clinical trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

## Post-COVID complications

### Interventions

The aim of this pilot control clinical trial is to investigate the effect of neurofeedback therapy (Othmer method) on fatigue, anxiety, and depression after COVID-19. For measuring the severity of post-COVID-19 fatigue, anxiety, and depression, standardized medical questionnaires are used before, immediately after, 1 week after and 1 month after termination of neurofeedback therapy. Five 25-minute sessions of neurofeedback therapy are administered within 2 weeks.

### Intervention Type

Device

### Phase

Not Applicable

### Drug/device/biological/vaccine name(s)

Neurofeedback (Deymed Diagnostics, version 11)

### Primary outcome(s)

1. Fatigue measured using the Fatigue Assessment Scale at baseline, immediately, 1 week and 1 month after neurofeedback
2. Anxiety measured using the Beck Anxiety Inventory at baseline, immediately, 1 week and 1 month after neurofeedback
3. Depression measured using the Beck Depression Inventory (version 2) at baseline, immediately, 1 week and 1 month after neurofeedback
4. Dizziness measured using the Dizziness Handicap Inventory at baseline, immediately, 1 week and 1 month after neurofeedback
5. Seizures are measured using the Seizure Severity Questionnaire at baseline, immediately, 1 week and 1 month after neurofeedback
6. Migraines/headaches measured using the Headache Disability Index at baseline, immediately, 1 week and 1 month after neurofeedback
7. Insomnia measured using the Insomnia Severity Index at baseline, immediately, 1 week and 1 month after neurofeedback

### Key secondary outcome(s)

Measured using Visual Analogue Scales at baseline, immediately, one week and one month after neurofeedback:

1. Mood swings
2. Memory and attention problems

### Completion date

22/12/2021

## Eligibility

### Key inclusion criteria

1. Age 18-65 years
2. A positive history of SARSCoV2 infection confirmed by a positive antigen/reverse transcription polymerase chain reaction (RT-PCR)/antibody test

3. At least one of the following symptoms: insomnia, headaches/migraines, dizziness, seizures, fatigue, depression, and anxiety that were not present prior to SARSCoV2 infection
4. The specific symptoms should have been present or persisted for at least 3 months after confirmed SARSCoV2 infection and should not have been attributable to any other neurological disease prior to COVID-19
5. Being free of neurological/systemic health problems prior to SARSCoV2
6. Being medication-free (or medically stable in type and dosage of the drug for at least 3 months prior to neurofeedback experiment)

**Participant type(s)**

Other

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

17

**Key exclusion criteria**

1. Younger than 18 years
2. No positive anamnesis of SARSCoV2 infection confirmed by positive antigen/RT-PCR/antibody test
3. Absence of post-COVID complications
4. The presence of neurological/systemic disorders prior to SARSCoV2 infection

**Date of first enrolment**

01/08/2021

**Date of final enrolment**

02/11/2021

**Locations****Countries of recruitment**

Czech Republic

**Study participating centre**

**Third Faculty of Medicine, Charles University in Prague,**  
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## Sponsor information

### Organisation

Charles University

### ROR

<https://ror.org/024d6js02>

## Funder(s)

### Funder type

University/education

### Funder Name

Univerzita Karlova v Praze

### Alternative Name(s)

Charles University, Charles University in Prague, Univerzita Karlova, Karls-Universität zu Prag, UK

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### Location

Czech Republic

## Results and Publications

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		27/07/2022	28/07/2022	Yes	No
<a href="#">Protocol file</a>			06/10/2022	No	No