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Neurofeedback for treatment of post-COVID-19 complications

Submission date	Recruitment status	[_] Prospectively registered
08/04/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/10/2022	Infections and Infestations	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 administrated within 2 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Neurofeedback (Deymed Diagnostics, version 11)

Primary outcome measure
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

Secondary outcome measures

Measured using Visual Analogue Scales at baseline, immediately, one week and one month after neurofeedback:
1. Mood swings
2. Memory and attention problems

Overall study start date
01/06/2021

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
10

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

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Sponsor type
University/education

Website
http://www.cuni.cz/UKENG-1.html

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
06/06/2022

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?
Results article		27/07/2022	28/07/2022	Yes	No
Protocol file			06/10/2022	No	No