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Understanding the impact of multisensory immersive experiences on the heart rate variability and cognitive functioning in patients with post-traumatic stress disorder

Submission date
04/08/2022

Recruitment status
No longer recruiting

Registration date
15/08/2022

Overall study status
Completed

Last Edited
23/07/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Several studies showed that being in nature reduces stress levels and increases positive emotions and well-being. Forest-bathing and outdoor recreational interventions have been associated with positive outcomes in people suffering from depression, anxiety, bipolar disorder and post-traumatic stress disorder (PTSD). In parallel, the psychological effects of virtual nature have been found to be comparable to real immersion in nature. Olfactive stimulation in virtual experiences has also been shown to reduce stress levels and promote relaxation. Few studies have examined the effects of virtual nature on patients with PTSD. This pilot study aims to assess the impact of virtual nature on heart rate variability and cognitive functioning in PTSD patients. With this information, we want to determine if this intervention could be combined with psychotherapy and pharmacotherapy to increase the quality of life of PTSD patients.

Who can participate?
Adults who live in the Sept-Rivières area (Quebec, Canada) with a confirmed PTSD diagnosis

What does the study involve?
Their physician must also confirm that their PTSD is unrelated to nature and that they don’t meet any exclusion criteria. It is expected that recruitment and data collection will be conducted over the next year considering that the research lasts 20 weeks. If PTSD diagnosis is confirmed, the participant will try the olfactive and the virtual reality headset in order to see if they can tolerate it, as it can trigger sickness and nausea in some people. If the participant adapts well to the virtual environment, the research protocol may start. It contains six steps, distributed over a 20-week period. Four of those steps are identical cognitive, emotional, and psychological assessments, along with physiological measures of stress (HRV), performed at weeks 1, 5, 8 and 20.

Between weeks 2 and 4, no intervention will be conducted with participants. This period is used to compensate for the absence of a control group, as the sample of this study is relatively small, and it would be impossible to declare two comparable groups of PTSD patients.

Virtual exposure to nature will take place between the 5th and the 8th week, four times/ week for three weeks. Each visit will last 30 minutes, as the multisensorial virtual scenes last 15 minutes. Three different natural environments lasting 5 minutes each will be presented to participants: one with the sounds of nature only; one with a cardiac coherence exercise; one with an auditory guided meditation. During each session, physiological measures of brain activity, eyes and facial movements and heart rate variability will be recorded. After each session, participants will rate their experience in terms of presence and cybersickness. When all twelve sessions will be completed, cognitive, emotional, and psychological assessments, as well as physiological measurements (HRV) will be redone. A follow-up assessment of the same variables and measures will be done 3 months after the post-test (week 20) to see if the effects of repeated exposure to nature using multisensorial virtual reality, if any, lasts over time. As PTSD is a complex and long-lasting condition, it was deemed more likely that the virtual exposure to nature will have positive short-term effects rather than long-term effects.

Dr Roberge will conduct each evaluation and the virtual exposure to nature at her clinic (Traumas Côte-Nord) in Sept-Îles aided by a psychology trainee, in regards to the data collection, literature reviews and statistical analyses. Professor Falk and his students (INRS) will offer their expertise with virtual reality equipment and protocols, data collection, and statistical analyses. They will also analyze the biometric signals recorded from the VR headset.

What are the possible benefits and risks of participating?
Benefits for participants may include reduced stress levels and increased well-being. Benefits for the scientific community include a better understanding of the impact of repeated exposure to nature using multisensory virtual reality on PTSD patients and may guide future studies toward similar or other interventions to help this population. However, since this population is mentally vulnerable, risks are inherent to any intervention, and safety nets were put into place to prevent substantial negative impacts on participants. PTSD is an anxiety condition, and patients may worry that answering questions about their traumatic experiences will cause psychological distress. Thus, before the signing of consent participants will be informed that the questions about their traumatic event(s) will be asked many times during the assessments so that they understand the emotional implications of this study. They will have access to free psychological support if they feel psychological distress. It is also made clear that they are free to revoke their consent at any given time during the experiment, without explanation or consequence. Participants will also be informed of the possible physical effects of virtual reality, such as headaches, disorientation, and fatigue, but those effects, if any, should not last. Participants can choose to take a break or terminate the exposure if they feel unwell. There are no known negative effects of using sensors to measure physiological activity. If any problem should arise during exposure to virtual reality (i.e., the participant has an epileptic episode), they will receive medical attention quickly. Participants must attend in person every session at the clinic. No compensation is offered for this study, as it is not funded; however, the study is free for the participant. All collected data will stay anonymous. Participants will be informed that this study might be published as a scientific article once the results are analysed and that if they give their consent to promote open science, their data might be shared with other researchers while staying anonymous.

Where is the study run from?
Traumas Côte-Nord (Trauma North Shore) (Canada)

When is the study starting and how long is it expected to run for?
May 2022 to July 2023

Who is funding the study?
1. Investigator initiated and co-funded
2. Natural Sciences and Engineering Research Council of Canada (NSERC) Discovery Grant

Who is the main contact?
1. Prof Tiago Falk, tiago.falk@inrs.ca (Canada)
2. Dr Marie-Claude Roberge, mcroberge@traumascotenord.ca (Canada)

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Additional identifiers

Protocol serial number
CER-22-669

Study information

Scientific Title
The effects of a 3-week exposure to nature using multisensorial virtual reality on heart rate variability and cognitive functioning of patients with post-traumatic stress disorder: A pilot study

Study objectives
1. Repeated exposure to nature using multisensorial virtual reality improves the root mean square of successive differences between normal heartbeats (RMSSD), a measure of heart rate variability, which represents the strength of someone's autonomic nervous system (specifically the parasympathetic branch).
2. Repeated exposure to nature using multisensorial virtual reality improves cognitive functions, more specifically attention (simple, complex and sustained), processing speed and memory (verbal and visual)
3. Higher RMSSD score is correlated with better scores on neurocognitive computerized testing
4. Improved RMSSD score and cognitive functions following repeated exposure to nature using multisensorial virtural reality are maintained over a three-month period

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/07/2022, Ethics Committee of the Institut National de la Recherche Scientifique (490 rue de la Couronne Québec (Québec) G1K 9A9, Canada; +1 418 650-7434; cer@inrs.ca), ref: CER-22-669

Primary study design
Interventional

Study design
Single-centre longitudinal interventional pretest-post-test study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-traumatic stress disorder

Interventions
Week 1: Pretest-1
Administration of psychological measures of PTSD and mood, a 1-minute HRV test, and CNS Vital signs (computerized neurocognitive assessment).

Weeks 2 to 4: Each participant undergoes a 3-week period without treatment (being their own control).

Week 5: Pretest-2
Administration of psychological measures of PTSD and mood, a 1-minute HRV test, and CNS Vital signs (computerized neurocognitive assessment).

Weeks 5 to 7: Exposure to nature using multisensorial virtual reality
In this phase, consenting participants will be exposed to multisensorial virtual reality 4 times per

week for 3 weeks. During each session, each participant will be seated in a chair and wearing an instrumented virtual reality headset combined with an olfactive device, and headphones. They will be exposed each session to three 5-minute scenarios presented with multisensorial virtual reality, for a duration of 15 minutes. The first scene consists of a 360° nature video without instruction. The second scene consists of a second 360° nature video combined with a cardiac coherence exercise. The last scene consists of a third 360° nature video combined with auditory guided meditation. During each scene, the olfactive device will activate nature scents. Simultaneously, the instrumented virtual reality headset will record EEG, EOG, ECG and EMG signals. After each session, the participants will fill out two questionnaires regarding the presence and cybersickness. Also, the three scenes will be presented randomly each time (n=12) for all participants.

Week 8: Post-test
Administration of psychological measures of PTSD and mood, a 1-minute HRV test, and CNS Vital signs (computerized neurocognitive assessment).

Follow-up 1: Retesting at 3 months after post-test
Administration of psychological measures of PTSD and mood, a 1-minute HRV test, and CNS Vital signs (computerized neurocognitive assessment).

Intervention Type
Other

Primary outcome(s)
Attention, processing speed and memory measured using CNS Vital Signs (computerized neurocognitive testing) at baseline 1 and 2, and at post-test and 3-month follow-up

Key secondary outcome(s)
Root mean square of successive differences between normal heartbeats (RMSSD) measured using a 1-minute test with Emwave Pro + software at baseline 1 and 2, and at post-test and 3-month follow-up

Completion date
09/07/2023

Eligibility

Key inclusion criteria
1. Aged 18 years old and older
2. Understanding, speaking and reading French
3. Being diagnosed with post-traumatic stress disorder by a physician
4. Living in the area of Sept-Rivières, Québec, Canada
5. Being able to come to Traumas Côte-Nord 1 to 4 times per week during the research period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Post-traumatic stress disorder related to nature
2. Severe substance use disorder
3. Uncontrolled epilepsy

Date of first enrolment
11/07/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Canada

Study participating centre
Traumas Côte-Nord
140 Père-Divet
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Sponsor information

Organisation
Institut National de la Recherche Scientifique

ROR
https://ror.org/04td37d32

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Natural Sciences and Engineering Research Council of Canada Discovery Grant (RGPIN-2021-03246)

Alternative Name(s)
The Natural Sciences and Engineering Research Council of Canada, nserc_crsng, Conseil de Recherches en Sciences Naturelles et en Génie du Canada, NSERC, CRSNG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Raw data from consenting participants will be anonymized and made available via Professor Falk's laboratory website hosted at INRS (https://musaelab.ca).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/10/2023	23/07/2024	Yes	No