Effects of light on emotional processing

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON47762

Source
ToetsingOnline

Brief title
Light and emotional processing

Condition

- Movement disorders (incl parkinsonism)
- Mood disorders and disturbances NEC

Synonym
Parkinsons's disease, symptoms of depression

Research involving
Human

Sponsors and support

Primary sponsor: VU Medisch Centrum, Amsterdam UMC
Source(s) of monetary or material Support: NWO National Initiative Brain & Cognition: Light Cognition Behavior & Health

Intervention

Keyword: Depressive symptoms, Emotions, Light, Parkinson

Outcome measures

Primary outcome

Our main study endpoints include 1) Blood Oxygenation Level Dependent Signal (BOLD) in people with PD and persons with symptoms of depression compared with controls

Secondary outcome

2) PD and depressive symptoms and their correlation to brain sensitivity to light; 3) Anatomical connectivity as measured with diffusion tensor imaging (DTI); 4) Daily subjective mood and its correlation to 24-hour ambient light exposure patterns and body temperature rhythm, the sleep wake cycle and brain sensitivity to light.

Study description

Background summary

Low or disorganised patterns of light exposure have been associated with both mood and sleep disturbances. In Parkinson*s disease (PD) which is traditionally treated with dopamine replacement and deep brain stimulation, neuro modulation through the visual system is becoming a viable non-invasive alternative for treating the non-motor (enhance mood and attenuate sleep disturbances) and motor symptoms of PD. Light ameliorates disturbances of mood, sleep and performance in elderly people with major depression. The neurobiological mechanisms underlying the positive effects of light in PD and depression remain poorly understood. Therefore, further work is required to better understand how light modulates brain activations in response to different emotional valence in persons with PD and in persons with symptoms of depression .

Study objective

Our primary objectives are to study: 1) differences in the brain*s sensitivity to the effects of light on emotional processing in people with PD and people with depressive symptoms compared with healthy controls 2) whether different spectrum of light modify emotional brain responses; 3) determine whether the magnitude of post-illumination pupil response and PD/depressionsymptoms severity correlates with the effects of blue light (as opposed to red light) on emotional brain responses. Secondary objective : 1) determine if the association between affective state, sleep and ambient light in the natural environment are mediated by the degree of sensitivity of the brain to light.

Study design

Case-control study involving 10-days of ambulatory monitoring, followed by an MRI session and pupillometry.

Study burden and risks

This study involves 2 site visits and 10 days of ambulatory monitoring. Total participation time is approximately 7 hours (including components done at home). Overall, the risk associated with participation can be considered negligible and the burden can be considered modest.
For the multi-parameter ambulatory recording, participants will wear thee small non-invasive and nonintrusive integrated sensors and recorders. Wearing of these ambulatory sensors is of negligible burden and without risk.
To avoid any risk during light stimulation, the maximum intensities of the light source in the set-up are well below the recommendations of the American National Standard (ANSI-2007) for red, blue and white illumination. These sub-threshold intensities, in combination with the limited exposure durations, and exclusion of participants with increased retinal sensitivity to light, will eliminate any risk associated with bright light exposure.
In the PD group the fMRI experiment is conducted while patients are at the end of their regular dopaminergic medication cycle (i.e., while experiencing the end-of-dose phenomenon), because this closely resembles the real-life clinical situation. As in their usual daily life participants are likely to experience increased PD symptoms end-of-dose which will directly resolve upon intake of their usual medication after the assessment. No risks are associated with a transient end-of-dose state and this is common practice in PD research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Depression:
- Age > 40 years
- Significant symptoms of depression (score > 13 on the Inventory of Depressive Symptomatology (IDS-SR))40
- Symptomatic on the depression part of the Composite International Diagnostic Interview * Short Form (CIDI-SF)41
- Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements.;PD:
- Age > 40 years
- Idiopathic PD, as diagnosed by the UK Brain Bank Criteria
- Mild PD stage 1-3, based on Hoehn & Yahr scale
- Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements
- MMSE 24;Control:
- Age > 40 years
- Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements.

Exclusion criteria

PD
- Early onset PD (< 40 years)
- Treatment with continuous apomorphine infusion, intestinal duodopa therapy or deep brain stimulation (DBS);- PD patients with excessive tremor.;Control:
- Current or past psychiatric diagnosis
- Significant symptoms of depression (score > 13 on the IDS-SR)
- Symptomatic on the CIDI-SF.;All groups
- Current diagnosis of bipolar disorder, psychotic disorder, alcohol or substance dependence, or any cognitive disorder
- Neurological disease (other than PD for the PD group) stroke or major head trauma, current or in history
- MRI contraindications such as metal implants, claustrophobia, left-handedness, pregnancy
- Self-reported inability or unease to cease smoking for 24 hours prior to testing
- Current treatment with tricyclic antidepressant or antipsychotic medication
- Ophthalmic disorder, color blindness, severe visual impairment or auditory impairment
- Travel to a different time zone within the last month
- Night work or rotating shift work.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2018
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	MR compatible light guide
Registration:	No

Ethics review

Approved WMO Date:	12-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL61308.029.17