Mood, serotonin and social interaction

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON36285

Source
ToetsingOnline

Brief title
Mood, serotonin and social interaction

Condition

- Mood disorders and disturbances NEC

Synonym
Depression; Mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: NWO MAGW

Intervention

Keyword: Depression, Mood, Serotonin, Social interaction

Outcome measures

Primary outcome

Primary outcome is empathic accuracy measured with an empathic accuracy task (EAT).

Secondary outcome

Secondary outcome measures are the amount of behavioural mimicry, speech characteristics, heart rate variability (HRV), scores on the Positive and Negative Affect Schedule (PANAS) and Visual Analogue Scale (VAS). Finally, polymorphisms of genes thought to be related to MDD are analysed.

Study description

Background summary

Major depressive disorder (MDD) is a psychiatric disorder whose onset, severity, and duration are influenced by interpersonal factors. The serotonin system is known to influence MDD risk. Recent research has suggested that serotonin may also play a role in regulating social behaviour. Therefore, it would be interesting to study the role of serotonin in responses to social stimuli in individuals at risk for MDD.

Study objective

This project aims to study how changes in serotonin alter interpersonal functioning in adults with or without a first degree family member diagnosed with MDD. The primary goal is to investigate the effect of experimentally lowered brain serotonin levels on empathic accuracy. Secondary goals are to determine how this manipulation influences verbal and non-verbal communication, cardiovascular function in a social context, and mood. An exploratory goal is to investigate how these outcomes are related to genes thought to be involved in MDD.

Study design

A mixed design, with family history (FH+ and FH-) as between-subjects factor

and intervention (ATD or placebo) as within-subjects factor.

Intervention

Participants receive, in a randomized, counterbalanced order, and under double-bind conditions, tryptophan-deficient and balanced amino acid mixtures on the mornings of two non-consecutive test days.

Study burden and risks

There is no direct benefit to the participants. Participants are not allowed to eat on test days from 00:00 until 17:00. The greatest potential risk to the participants involves the possibility of transient occurrence of mild lowering of mood, especially in those with a family history of depression. In the past this effect on mood has always been mild and transient and did not require treatment. Previous studies have shown that mood returns to baseline levels within 24 hours. Side effects such as nausea or vomiting have also been observed in previous studies, and may occur in the present study. In addition, participants may develop bruising from the needle sticks performed to obtain blood for plasma tryptophan analyses.

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

Inclusion criteria: Age 18-65 years. At least one first-degree family member with MDD (FH+) or no first- and second-degree family members with MDD (FH-). Willingness to cooperate; to sign written informed consent.

Exclusion criteria

Exclusion criteria: Any current or past DSM-IV Axis I mood disorder, anxiety disorder, psychotic disorder, eating disorder, or somatoform disorder as determined by SCID-NP interview. Any current substance use disorder. Any past substance dependence. Ongoing medical treatment for a chronic disease, particularly cancer, gastrointestinal disease, phenylketonurea, diabetes, cardiovascular disease, or disease of the liver or kidneys. Not speaking Dutch fluently. Current or past use of neuroleptics, sedative drugs, antidepressants etc. On test days, a positive urine test for drugs of abuse. For women, initiation of hormonal contraceptive treatments <= 3 months prior to screening, or a positive urine test for pregnancy on test days

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	13-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20623
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34731.042.10
OMON	NL-OMON20623