Mood, serotonin and social interaction.

Published: 25-11-2010
Last updated: 13-01-2025

The present study will investigate how serotonin (manipulation via ATD) modulates psychological and physiological reactions to interpersonal stimuli in individuals at risk for MDD. This is relevant for several reasons:1. The onset, severity, and...

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20623

Source
NTR

Health condition

Depression; social interaction

Sponsors and support

Primary sponsor: Sponsor is NWO-MAGW

Perfomer: University of Groningen in collaboration with University Medical Center Groningen
Source(s) of monetary or material Support: NWO-MAGW

Intervention

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 Scales (VAS). Finally, polymorphisms of genes thought to be related to MDD are analysed.

Study description

Background summary

Rationale:
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.

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.

Study population:
Healthy volunteers, 18 – 65 yr old, with (FH+) or without (FH-) a first degree family member diagnosed with MDD are selected for participation in the present study. First degree family members may include children, siblings or parents.

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.

Main study parameters/endpoints:
Primary outcome is empathic accuracy measured with an empathic accuracy task (EAT). 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 Scales (VAS). Finally, polymorphisms of genes thought to be related to MDD are analysed.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
There is no direct benefit to the participants. The greatest potential risk to the participants involves the possibility of transient occurrence of mild symptoms of depression, especially in those with a family history of depression. In the past this possible occurrence of depressive symptoms 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 needle stitch bruising.

Recruiting countries: The Netherlands.

Study objective

The present study will investigate how serotonin (manipulation via ATD) modulates psychological and physiological reactions to interpersonal stimuli in individuals at risk for MDD. This is relevant for several reasons:
1. The onset, severity, and duration of MDD are influenced by interpersonal factors, but little knowledge is available about the underlying neurobiological processes;
2. Considering that MDD is more common in FH+ than in FH- individuals, it is important to understand why FH+ individuals are more susceptible to mood worsening following ATD than FH- individuals;
3. Serotonin may have, in addition to a direct effect on mood, an indirect effect on mood by influencing social behaviour;
4. MDD is a risk factor for CVD, and it is important to investigate whether and how ATD affects HRV in a social context, especially in FH+ individuals.

Study design

The present study comprises 1 first screening and visit and subsequently two separate test days.

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.

Contacts

Public
University of Groningen, Experimental Psychopathology
Grote Kruisstraat 2/1
K. Hogenelst

Groningen 9712 TS
The Netherlands
Scientific
University of Groningen, Experimental Psychopathology
Grote Kruisstraat 2/1
K. Hogenelst
Groningen 9712 TS
The Netherlands

Eligibility criteria

Inclusion criteria

1. Age 18-65 yrs;
2. At least one first-degree family member with MDD (FH+) or no first- and second-degree family members with MDD (FH-);
3. Willingness to cooperate; to sign written informed consent;
4. Declared healthy after medical interview.

Exclusion criteria

1. Any current or past DSM-IV Axis I disorder;
2. Any contraindicated medical condition as determined by history;
3. Not speaking Dutch fluently;
4. Current or past use of neuroleptics, sedative drugs, antidepressants etc;
5. Current or past alcohol and/or substance abuse or dependence;
6. On test days positive urine test for drugs of abuse;
7. Women: Pregnancy (urine test) or initiation of hormonal treatments ≤ 3 months of screening.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 36285
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2505
NTR-old	NTR2623
CCMO	NL34731.042.10
OMON	NL-OMON36285

Study results

Summary results
N/A