Everyday social behaviour and mood in individuals with a family history of depression

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This study aims to investigate how serotonin influences social functioning in healthy adults with a first-degree family member diagnosed with MDD. The primary goal is to investigate the effect of an experimental increase in brain serotonin on...

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

Summary

ID

NL-OMON39507

Source
ToetsingOnline

Brief title
Serotonin and everyday 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: behavior, mood, Serotonin, social

Outcome measures

Primary outcome

Primary outcome is the level of quarrelsome behaviour measured using ecological momentary assessment.

Secondary outcome

Secondary outcome measures include levels of agreeable, dominant, and submissive behaviours, as well as affect, cognitions, and perceptions. Finally, polymorphisms of genes thought to be related to MDD may be determined.

Study description

Background summary

Poor social functioning may contribute to major depressive disorder (MDD). Low serotonin levels may also contribute to MDD. Recent research suggests that serotonin plays a role in regulating human social behaviour. Therefore it would be intriguing to investigate the effect of serotonin on the quality of everyday social interactions in a population at risk for MDD. Human social behaviour can be reliably assessed in everyday life using Ecological Momentary Assessment (EMA).

Study objective

This study aims to investigate how serotonin influences social functioning in healthy adults with a first-degree family member diagnosed with MDD. The primary goal is to investigate the effect of an experimental increase in brain serotonin on everyday social behaviour, measured using Ecological Momentary Assessment. This will be done using oral supplementation with tryptophan, the amino acid precursor of serotonin. Secondary goals are to determine how this manipulation influences people*s feelings and thoughts after negative and positive interpersonal events, as well as their perceptions of other*s social behaviour. An exploratory goal is to investigate if these effects are moderated

by genes thought to be involved in MDD.

Study design

A mixed design, with gender as between-subjects factor and intervention (tryptophan or placebo) as within-subjects factor.

Intervention

Participants take 1-gram tryptophan (2 capsules) and identical placebo capsules three times daily with meals (in total 3 x 2 = 6 capsules per day) for 14 days each in a randomized, counterbalanced order. The two intervention periods are separated by 1 week.

Study burden and risks

In general the risks associated with the present study are minimal and the burden is very low and to the opinion of the investigators justified by the potential value of the research.

Possible side-effects of tryptophan may be nausea, dizzyness and lightheadedness.

The burden per participant is estimated to be 12 hours.

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

• Age 18-65 years
• At least one first-degree family member with MDD
• Willingness to cooperate; to sign written informed consent

Exclusion criteria

• Any current or past MDD or other mood disorder as determined by the SCID-NP
• Any current anxiety disorder, psychotic disorder, substance use disorder, eating disorder, or somatoform disorder as determined by SCID-NP
• Any contraindication for the use of tryptophan, i.e. pregnancy, diabetes, cancer or a history of cancer, a history of any scleroderma-like condition, evidence of achlorhydria, upper bowel malabsorption, or irritation of the urinary bladder
• Current use of psychotropic medications including medications for psychiatric problems (e.g., antidepressants such as MAO inhibitors and fluoxetine) or migraines
• Not speaking Dutch fluently

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):	29-08-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-10-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-05-2013
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL38398.042.11