The effect of moderate alcohol consumption with a meal in different ambiances on postprandial mood, evaluated by subjective and objective responses.

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Primary objective:To determine whether moderate alcohol consumption with a meal in different ambiances affects postprandial mood, evaluated by subjective (POMS, B-BAES, PPW questionnaires) and physiological (ACTH, cortisol, TRP:LNAA ratio, ghrelin...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35204

Source
ToetsingOnline

Brief title
Effect of moderate alcohol consumption on postprandial mood

Condition

- Other condition
- Lifestyle issues

Synonym
mood fluctuations

Health condition

stemmingswisselingen

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Alcohol Research
Source(s) of monetary or material Support: Stichting alcohol research (SAR) en Ministerie van Economische Zaken;Landbouw & Innovatie (EL&I)

Intervention

Keyword: alcohol, mood, postprandial

Outcome measures

Primary outcome

Subjective response:

- POMS (extended with mood scales happiness and calmness)

- Brief BAES

- Postprandial wellness (PPW) questionnaire

Physiological response:

- Stress hormones (ACTH and cortisol)

- Serotonin system (Trp:LNAA ratio)

- Satiety hormone (ghrelin)

Secondary outcome

Physiological response:

- Endocannabinoids and N-acyl serotonins

- β-endorphin plasma levels

- dopamine plasma levels

- Satiety hormones (Insulin, CCK and GLP-1).

- Metabolites (FFA and glucose)

- Non-invasive measures (Heart rate, HRV and SCL)

Study description

Background summary

Food choice is influenced by postprandial mood; the feelings of well-being after a meal. Postprandial mood can be measured by subjective responses. Physiological responses may play an important role in the generation of postprandial mood. However, the relationship between subjective and physiological responses after a meal is not clear yet. To investigate this relationship, moderate alcohol consumption will be used as a mood modulator, because of its well-studied effects on mood. Postprandial mood depends on the current mood state. Therefore we will manipulate the current mood state by changing the ambiance to measure the influence of moderate alcohol consumption with a meal on postprandial mood in a pleasant or unpleasant ambiance.

Study objective

Primary objective:
To determine whether moderate alcohol consumption with a meal in different ambiances affects postprandial mood, evaluated by subjective (POMS, B-BAES, PPW questionnaires) and physiological (ACTH, cortisol, TRP:LNAA ratio, ghrelin blood concentration) parameters.

Secondary objective:
To investigate whether moderate alcohol consumption with a meal in different ambiances affects other physiological parameters related to mood, which are not part of the primary objective (endocannabinoids, N-acyl sertonins, β-endorphin, dopamine, insulin, CCK, GLP-1, FFA, glucose, heart rate, HRV and SCL).

Study design

Study design: Randomized, placebo-controlled, single-blind, cross-over trial

Intervention

4 times having dinner at TNO Zeist with either 3 glasses of white wine (~30g alcohol) or alcohol-free white wine in either a pleasant or unpleasant meal ambiance.

Study burden and risks

Subjects need to visit the study site six times, once for a screening, once for a familiarisation session and four times for a treatment day. During these visits blood will be collected five times. The total amount collected during the whole study will be less than 460 mL blood. The study will be performed in women, because women are suspected to have a different postprandial mood response than men, which might be due to female hormones. We will only include women taking oral contraceptives, because they have a reduced variation in female hormones over the menstrual cycle. A large number of women use oral contraceptives nowadays, therefore this group will reflect a large population of women. Women above 45 years will be excluded, because we will include only premenopausal women.

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

9.4 Inclusion criteria
1. Healthy as assessed by the health and lifestyle questionnaire, (P9334 F02; in Dutch).
2. Females aged 18-45 years at Day 01 of the study*
3. Taking a monophasic combined oral contraceptive pill at Day 01 of the study, with 21 days of taking pills with active ingredients followed by 7 days taking no pills or continuous intake of the oral contraceptive pill**.
4. Body Mass Index (BMI) of 18.5-27 kg/m2 *
5. Body weight between 57 and 80 kg
6. Normal Dutch eating habits as assessed by P9334 F02
7. Alcohol consumption >= 3 and <= 21 standard units/week*
8. Voluntary participation
9. Having given written informed consent
10. Willing to comply with the study procedures, including refrain from alcohol 24 h before the test days and refrain from caffeine during the afternoon of the test day.
11. Appropriate veins for blood sampling/cannula insertion according to TNO
12. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
13. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.;* Volunteers within the age of 25-45 years, a BMI of 20-25 and with an alcohol consumption between 3-14 standard glasses/week are preferred for inclusion.
** With the recruitment letter, a list with accepted brands of oral contraceptive pills for participation will be added.

Exclusion criteria

9.5 Exclusion criteria
Subjects with one or more of the following characteristics will be excluded from participation:
1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study.
2. Having a history of medical or surgical events or disease that may significantly affect the study outcome, particularly physiological disorders, or psychiatric, metabolic or endocrine disease and gastrointestinal disorders.
3. Use of medication that may affect the outcome of the study parameters (e.g. antidepressive drugs).
4. Having a family history of alcoholism
5. Having a history of alcohol or drug related problems
6. Smoking
7. Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening
8. Reported slimming or medically prescribed diet
9. Reported vegan, vegetarian or macrobiotic
10. Recent blood donation (<1 month prior to the start of the study)

11. Not willing to give up blood donation during the study.
12. Pregnant (to their own knowledge) or lactating or wishing to become pregnant in the period of the study
13. Personnel of TNO Zeist, their partner and their first and second degree relatives
14. Not having a general practitioner
15. Not willing to accept information-transfer concerning participation in the study, or information regarding her health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2011
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
ClinicalTrials.gov	NCT01426022
CCMO	NL38036.028.11