Informationbrochure

Bitter Study

WAGENINGEN
UNIVERSITY & RESEARCH

Contacts

Research Team:

Sophia Eijsman

Dr. John Hayes

Dr. Sanne Boesveldt

Contact person:

Sophia Eijsman

Department Human Nutrition and Health, Wageningen University

Sophia.eijsman@wur.nl

Post address:
t.a.v. *Sanne Boesveldt,* Wageningen University
Department Human Nutrition (bode 62)
Postbus 17
6700 AA Wageningen

Visitors address:

Helix (Building 124) Stippeneng 4
6708 WE Wageningen

Preface

This brochure contains information about the purpose and design of the Bitter study.

This brochure describes what we expect from you as a participant during the research and what you can expect from us as researchers. The research is being conducted by the Human Nutrition and Health department at Wageningen University. We request that you read this brochure carefully before you decide to participate in the study.

The research consists of 12 test days in which you come to the test location twice (Helix Building, 30 minutes per session). The research will take place in the period 01-04-2019 to 12-05-2019.

Thank you for your interest in our research; we hope to meet you during the study! If you still have questions after reading this brochure or if you are interested in the study, please do not hesitate to contact us.

Sincerely,

On behalf of the research team

Sophia Eijsman, Dr. John Hayes, and Dr. Sanne Boesveldt

The bitter study

Goal of the research

The purpose of the study is to determine the effect of caffeine on the pleasantness of bittersweet drinks.

Who can participate?

You can participate if you:

- Are a healthy male or female
- Are 18-55 years old
- Are not hypersensitive or allergic to fragrances and/or flavourings
- Are not pregnant, do not intend to become pregnant and do not breast-feed
- Drink coffee daily (at least 2-3 cups a day)
- Do not smoke
- Are not an employee of the Human Nutrition and Health department

To participate in the study, you have:

- No impaired sense of smell or taste
- Have not used any medication in the last 2 months (with the exception of the contraceptive pill and paracetamol)

Declaration of consent

If you meet the participation criteria, you will receive a consent form to sign. After you have signed the declaration consent, we will ask you to complete a number of short questions about personal data and eating behaviour. During the test sessions you will perform a number of simple tasks. The tasks are described in detail below.

Content of the research

Taste tests: on the first and last days of the study (days 1 and 12) you will come to the Helix building. You taste a number of bittersweet beverages and assess them on various aspects with a computer guided questionnaire. All beverages are water with added flavourings. All ingredients are suitable for consumption and are registered and approved by the Food and Consumer Product Safety Authority. Each taste test in the laboratory should take a maximum of 30 minutes.

In addition, you will be given various drinks at home – these may or may not contain caffeine. **You have to drink these beverages every morning at 08.30 am and complete an online questionnaire at 09.30 am**. This should take no more than 10 minutes each day. It is important that you drink these and complete the questionnaires at the assigned times, as we need to control this to get useful data**. We will send you a reminder for this every day, for 10 days, including weekend days.** You do not have to come to the university, except on the first and last day of the study.

There are three different starting days for the study:

1. Monday April 1 ending on Friday April 12 (lab visits on April 1 and 12)
2. Monday April 15 ending on Friday April 26 (lab visits on April 15 and 26)
3. Monday April 29 ending on Friday May 10 (lab visits on April 29 and May 10)

All test days start in the morning at 08.30 am, except for Monday April 1 (starts at 13.00) and will last approximately 30 minutes.

What else is expected from you

We ask you not to eat and drink anything that contains calories or caffeine (such as coffee, black tea, cola) the morning before drinking the bittersweet drinks at home. You can still drink water during this period. This only involves the at home testing in the mornings before 08.30 am. After 09.30 you can simply maintain your daily diet.

Possible advantages and disadvantages

Since the bitter study is a study in which you get foods that can be purchased in stores, there is no reason to believe that consuming these products entails a risk. The other investigation procedures also do not entail any risk.

You make an important contribution to scientific research. Participation in the study will not have any direct benefits for you.

If you do not want to participate in the research or want to stop prematurely

Participation in the research is on voluntary basis, so you decide whether you want to participate. If you do participate, you can always change your mind about stopping without having to give a reason for this. However, the data used up to that point will be used.

End of the research

Participations stops if:

- You have completed all 12 test days
- You choose to stop the investigation yourself
- The researcher thinks you should stop
- You become sick or pregnant
- The government or the evaluating medical ethics admission committee decides to stop the investigation

The entire research is completed when all participants are ready.

Independent doctor

An independent doctor is appointed for each scientific study. An independent doctor is a doctor who is not involved in conducting the study. The independent doctor can be consulted by the participants for questions that are related to the research and that the participant does not want to ask the researcher. For the studies of the Human Nutrition and Health department this is Dr. N. Muhsen, M.D., MFPM. Physician researcher in Utrecht. Dr. Muhsen can be reached during office hours on 06-16963517. If necessary, leave a message on the voicemail so that he can call you back. You can also ask questions by mail: nhmuhsen@hotmail.com.

Compensation

After completion of the study you will receive a financial reimbursement for participation of 30 euros. This amount can be paid in cash, on your account or via a VVV voucher. You also make an important contribution to scientific research.

What happens with your data

All data that we collect from you will be stored and handled with due care in accordance with the Personal Data Protection Act. This means, among other things, that personal data and research data are separated from each other and that all research data is stored under a number. All researchers directly involved in the investigation have signed a "Privacy Statement for Privacy Sensitive Data".

Results

Results of this research will be offered for publication in a scientific journal, whereby the information provided is not traceable to individuals. We cannot give you insight in your personal outcomes. The data will be kept for a period of 15 years after the results of the study have been published.

Approval by the medical ethics review committee

The research was positively assessed by the medical ethics committee of Wageningen University. Because there is no risk associated with the research, the medical ethics review committee of Wageningen University has granted exemption for the subject's insurance policy.

Declaration of consent

If you want to participate in the study, we ask you to sign a statement of consent. In this letter you indicate that you are sufficiently informed about the purpose and conduct of the research, that you know what is expected from you and that you give permission for participation.

Questions?

If you have any questions, please feel free to contact us.

Sophia Eijsman: Sophia.eijsman@wur.nl

Subject's consent form

- I have read the information letter. I could also ask questions. My questions have been answered sufficiently. I had enough time to decide if you would like to participate
- I know that participating is voluntary. I also know that I can decide at any time not to participate or to stop the research. I don't have to give a reason for that.
- I consent to the collection and use of my data to answer the research question in this study
- I give permission to keep my research data for answering the research question for 15 years after publication of the research.
- I know that some people may gain access to all my data for the purpose of checking the investigation. Those people are enlisted in this information letter. I give permission for inspection by those people.
- I want to participate in this study.

Name of the subject:

Signature: Date : __ / __ / __

I declare that I have sufficiently informed this subject about the aforementioned research.

If new information becomes known during the research that could influence the tests subject's consent, I will inform him/her in good time.

Name of the researcher (or representative):

Signature: Date: __ / __ / __

The test subject will receive a full information letter, together with a signed version of the consent form.