WAGENINGEN UNIVERSITY
WAGENINGEN UR

2021

Information Brochure：

Study on oral burn

Information brochure for subject participation in scientific research

Study on oral burn

Introduction

Dear Sir/Madam,

You are asked to take part in a scientific study. Participation is voluntary. Participation requires your written consent. Before you decide whether you want to participate in this study, you will be given an explanation about what the study involves. Please read this information carefully and ask the researcher for an explanation if you have any questions. You may discuss this study with your partner, friends or family.

General information

This study is being carried out by the Division of Human Nutrition and Health and the chair group of Food Quality and Design of Wageningen University.

Aim of the study

The aim of this study is to quantify the effect of spicy food on the way people eat solid and liquid foods and on their perception of different sensory attributes.

What participation involves

When you participate in this study you will visit the Axis building at Wageningen University. The location details are described in Appendix A. You will be assigned to participate in either 2 or 4 sessions. During these sessions you will be expected to consume spicy tomato cream soup, beef burgers and curried rice. You may be video recorded during consumption. A breakdown of the possible sessions expected of you can be seen below:

- 1 rate-all-that-apply (RATA) attribute familiarization session (1.5 hr) + 1 RATA test session (1 hr) [2 sessions total, 2.5 hours total]
    - Reimbursement: €20 in VV vouchers
- 1 rate-all-that-apply (RATA) attribute familiarization session (1.5 hr) + 1 RATA test session + 2 food oral processing (FOP) parameters with tomato soup (1 hr each) [4 sessions total, 4.5 hours total]
    - Reimbursement: €40 in VV vouchers
- 1 rate-all-that-apply (RATA) attribute familiarization session (1.5 hr) + 1 RATA test session (1 hr) + 2 bolus properties sessions with burgers and rice (1 hr each) [4 sessions total, 4.5 hours total]
    - Reimbursement: €40 in VV vouchers

Overall, participating in this study will take you a total of 2.5-4.5 hours. The tests sessions will be spread out over approximately 8 weeks. You will be notified of which sessions you will need to attend after you return the necessary paperwork, and your eligibility is approved.

Screening participants

Firstly, you are provided with this information brochure, the eligibility questionnaire, and the informed consent form via email. You can ask questions by email about the information brochure and the researchers will do their best to answer and explain. After that, if you decide to participate you will complete the eligibility questionnaire and informed consent form and send these to the researchers.

The researchers will screen you based on the information you have provided. Within a few days you will be contacted by email or phone to inform you whether you are eligible to participate in the study. At this time, you will also be notified of which sessions you will attend.

Test sessions

For the test sessions you will visit the University (Axis: Building 118) 2 – 4 times across approximately 8 weeks. The familiarization session will take approximately 1.5 hours, the RATA test session, FOP parameter sessions and bolus properties sessions takes 1 hour each. The RATA test session, FOP parameter sessions and bolus properties sessions will be scheduled on working days between 8:00 to 17:00.

During the test sessions, the following will take place:

In the RATA familiarization session, you will be given all three foods (tomato cream soup, burger patty cubes and curried rice) and be introduced to sensory attributes of each food. You will also be familiarized with the range of spiciness of the foods you will eat. Finally, the survey software used in the RATA test session will be introduced to you.

In the RATA test session, you will perform the sensory test introduced to you in the familiarization session using small portions of each of the three foods of varying spice levels.

In the food oral processing (FOP) parameters test sessions, you will eat two soups per session. You will be recorded

while eating.

In the bolus properties test sessions, you will first be asked to spit saliva into a cup over the course of five minutes. You will then be asked to chew a series of burger pieces and rice and expectorate them into a dish.

Crackers and water will be used during these sessions to cleanse the palette eliminate burning sensations between samples.

Expectations and eligibility

You are eligible to participate in this study if you:

- Have complete dentition.
- Have no swallowing issues.
- Have normal smell and taste functions.
- Are a non-smoker.
- Have good general health.
- Have a BMI of 18.5-30 kg/m^2.
- Aged 18-60 years old.
- Have not followed an energy restricted diet during the last 2 months.
- Are willing to eat spicy foods.
- Are willing to do a PCR speed test prior to only the **bolus collection session**
- Do not have food allergies or intolerances to any of the food products used in this study: chili pepper, gluten, flour, beef, eggs, curry sauce, rice, mustard and peanuts.
- Are not pregnant, do not have the intention to become pregnant, or are not currently breastfeeding.
- Are not an employee of the Division of Human Nutrition or Health or Food Quality & Design (Wageningen University).
- Are not participating in another medical study.

The study instructions require that you:

- Keep appointments for visits for the test sessions.
- Do not eat, smoke, or drink coffee in the 3~4 hours preceding the test sessions (you may drink water). You are permitted to eat and drink before the information session.

It is important that you contact the researcher:

- If you no longer wish to participate in the study.
- If your contact details change.
- If you are feeling ill before a test session.

Possible undesirable effects or discomforts

All food products are suitable for consumption; therefore, we do not expect any risks from your participation in the research. You might have a slight discomfort by the irritation of chili.

If you do not want to participate or want to stop participating in the study

It is up to you to decide whether to participate in the study. Participation is voluntary. If you do participate in the study, you can always change your mind and stop participation at any time. You do not have to say why you are stopping, but please tell the researcher immediately if you want to stop. If there is any new information about the study that is important for you, the researcher will let you know.

End of the study

Your participation in the study ends when:

- You have completed all the test sessions as described.
- You choose to stop.
- The researcher considers it best for you to stop.
- The Medical Research Ethics Committee decides to stop the study.

The study will conclude once all the participants have completed the study. After processing the data, the researcher will inform you about the most important results of the study. This will happen about a year after your participation.

Usage and storage of your data

All your data will remain confidential. You are assigned a participant code to mask your personal information from your study data. The researchers are the only people who will know which code you have. In the reports about the study only this code will be used. Personal information will be filed in a document encrypted with a password.

People who may access your medical and personal data are the research team listed in Appendix A. They will keep your data secret. If you sign the consent form, you consent to your medical and personal data being collected, stored, and accessed by the research team.

Researchers will keep your personal data 15 years after the results of the study are published. Note that publishing will not follow immediately after the concluding of the study, but after all processing and analysis of the data.

Study subject insurance

This study will be performed with commercially available products that can be bought in supermarkets in The Netherlands. As this study is not associated with any risks for you, no insurance is provided.

Compensation for participation

When participating in the entire study you will receive a financial compensation of €25 to €50 paid as VVV vouchers. If you stop before completing all three test sessions, you will receive a smaller amount equivalent just to the test sessions attended.

Any questions?

If you have any questions, please contact all the following in the email:
lauren.geary@wur.nl
anne1.hendriks@wur.nl
cong.lyu@wur.nl

Thank you for your attention.

Appendices to this information

A) Contact details
B) Informed Consent Form

Appendix A: Contact details

Research team

Lauren Geary, MSc.
Anne Hendriks, MSc.
Cong Lyu, MSc.
Prof. Markus Stieger

Contact person(s)

Lauren Geary: lauren.geary@wur.nl
Division of Food Quality & Design, Wageningen University

Anne Hendriks: anne1.hendriks@wur.nl
Division of Food Quality & Design, Wageningen University

Cong Lyu: cong.lyu@wur.nl
Division of Human Nutrition and Health, Wageningen University

Study locations

Axis (Building 118)
Bornse Weilanden 9
6708 WG Wageningen

Appendix B: Subject consent form food spiciness study

I have read the subject information brochure. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.

I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.

I know that some people can access my data. These people are listed in the information brochure.

I consent to my data being used in the way and for the purpose stated in the information brochure.

I consent to my data being stored at the research location for another 15 years after this study.

I want to participate in this study.

☐ Yes

☐ No

Name of study subject:

Signature: Date: ___/___/ ___

I hereby declare that I have fully informed this study subject about this study.

If information comes to light during the course of the study that could affect the study subject's consent, I will inform him/her of this in a timely fashion.

Name of researcher (or his/her representative):

Signature: Date:___/___/ ___

The study subject will receive a copy of the signed consent form.