

Official title of the study: Oral Processing Behavior of Gluten-free and Gluten-containing Breads

NCT ID: not yet assigned

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## INFORMATION SHEET AND DECLARATION OF CONSENT TO THE TRIAL IN THE CASE OF ADULT AND CAPABLE VOLUNTEERS

Title of the experiment and protocol number: Research on chewing behavior of bread

### Introduction

Dear Sir / Madam,

You are invited to take part in a research study on chewing behavior of breads. Participation is voluntary and requires your written consent. Before deciding if you want to participate in this study, you will be given an explanation about the study. Please read this information carefully and ask the researcher for an explanation if you have any doubts or questions.

### INFORMATION SHEET

- What does this study propose?

Our oral behavior (food oral processing) influences the way we perceive and appreciate food. Everyone has their own distinctive way of eating, which adapts to the type of food being eaten.

The impact of ingredient composition on food oral processing and, consequently, on food perception and preference is not fully understood. Therefore, this study aims to characterize the oral behavior during the consumption of different types of bread. This will be done through video recording of our participants as they consume different types of commercial bread. The result of this study will provide new insights into oral bread processing and provide the foundation for the development of healthier food products.

- What investigations will you be subjected to during the study?

When you participate in this study, you will have to go to the Food Chemistry and Technology Section of the Department of Agriculture, Environmental and Animal Sciences (Di4A) of Udine University. Overall, participation in this study will take a total of 1 hour divided into two test sessions.

### Trial sessions

Particular attention will be given to the procedures necessary to avoid the spread of the coronavirus:

- Sessions will be designed for a single participant
- Upon arrival in the sensory room you will be asked to wash or disinfect your hands

- Both the researcher and the subject will wear gloves and face masks. He will be authorized to remove the mask only during the analysis of the samples
- At least a distance of 1 meter will be maintained between participant and researcher
- At the end of each session, all surfaces will be disinfected

Each of the trial sessions will take approximately 30 minutes and will be scheduled on working days. During the session, you will receive some pieces of bread and will be asked to consume them in a natural way while keeping her head straight towards a camera placed in front of you. You will be video recorded throughout the session. These videos will only be used to acquire information on your chewing behavior and your personal data will undergo a pseudonymisation process.

After consuming the bread, you will be asked to evaluate some sensory attributes of the bread. All products are commercial samples suitable for consumption. Therefore, there are no risks or inconveniences related to your participation in the research.

- What are the risks of participating in the study for the patient?

No particular health risks are anticipated in this study.

- When can the study be stopped?

We inform you that you can withdraw from the study at any time without having to give any explanation. Furthermore, we inform you that even doctors may at any time interrupt your collaboration in the trial and that in any case, they will provide you with the reasons.

- Is personal data protected and confidential?

Pursuant to the General Data Protection Regulation (EU Regulation 2016/679), we inform you that your personal data will be collected and stored electronically and will be used exclusively for scientific research purposes. Any information collected during the trial, and in particular your personal data, will be considered strictly confidential.

For further information, please refer to the information attached to this document and available online at <https://www.uniud.it/it/pagine-speciali/materiale-gdpr/informative/informativa-art-13-gdpr-food.pdf>.

#### Use of video recordings

For this study, it is necessary to make and use video recordings and to collect personal data relating to your person essential for conducting the research. The videos will be given a code and its name will not be mentioned. However, by their nature, the videos cannot be considered completely anonymous as you will be partially recognizable based on the captured image. However, the videos will not be published or shared with people not involved in the study.

The video recordings will also be retained following the publication of the study results in order to allow further analysis of the collected data, again in the context of the overall objective of this study. In the informed consent form you can indicate whether or not you agree with this. After analyzing the videos and determining the eating behavior, the results will be used exclusively for research.

The contact information and codes that allow the identification of the data subjects will be deleted after three years.

#### Your data

All your data will remain confidential. Researchers are the only people who will know what code has been given. Only this code will be used in the study reports. Personal information will be stored in a document encrypted with a password.

If you sign the consent form, you consent to the collection, storage and access of your personal data. The researchers will keep your personal data for three years after the study results are published.

- Can information be obtained about the results of the study?

If you wish, at the end of the study, the results of the investigations concerning you will be communicated to you and illustrated by one of the research collaborators.

- Who can you contact if the patient has questions to ask during the trial?

For further information and communications during the study, the following staff will be at your disposal:

Prof. Nicoletta Pellegrini, associate professor [nicoletta.pellegrini@uniud.it](mailto:nicoletta.pellegrini@uniud.it) Tel: 0432-558183 (mobile 334 6575868)

Dr. Ana Carolina Mosca ([anacarolina.mosca@uniud.it](mailto:anacarolina.mosca@uniud.it)) Tel: 0432-558183 (mobile 3490539118)

### Informed consent form

- ☐ I have read the information sheet about the study. I was also able to ask questions. My questions were answered to my satisfaction. I had enough time to decide whether to participate.
- ☐ I know that participation is voluntary. I know that I could decide at any time not to participate or to withdraw from the study. I don't need to give a reason for this.
- ☐ I know that some people can access my data. These people are listed in this information sheet.
- ☐ I agree that my data will be used in the manner and for the purpose indicated in the package insert.
- ☐ I agree that my image will be used free of charge for scientific research and dissemination purposes pursuant to Law 633/1941.
- ☐ I want to participate in this study.

I hereby declare that I have been fully informed of the purpose of this study and, having read and understood all the information, I authorize the processing of my personal data.

Name:

Signature:

Data: \_\_ / \_\_ / \_\_

I hereby declare that I have been fully informed of the purpose of this study.

Name of researcher:

Signature:

Data: \_\_ / \_\_ / \_\_