

PARTICIPANT INFORMATION SHEET: Pregnant Volunteers

Name of Investigator:	Jacqueline Wallace
Name of Study:	Flavour

You are invited to take part in a research study. Before you decide whether to volunteer, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Please do not hesitate to contact us (see below) if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

Infant taste preferences develop early in development and may be influenced by the mothers diet during pregnancy or while breastfeeding. We want to test whether increasing maternal intake of fruit and vegetables in late pregnancy, in women who normally struggle to achieve their 5-a-day, increases the diversity of fetal flavour exposure and makes infants more likely to accept a wide variety of fruit and vegetables in childhood. We have developed a range of innovative presentation formats for a variety of our most pungent fruit and vegetables. These include soups, sauces, crispbreads, muffins and smoothies that incorporate vegetables and /or fruits often perceived as tasting bitter or sour and thus less preferred. Before testing this hypothesis, we need to establish the general acceptance and taste profile of the different fruit and vegetable containing foods we intend to offer to mothers.

The foods to be tasted will not contain any food product that is not advised in pregnancy.

Why have I been invited?

You have volunteered to take part in this taste and palatability trial because you have an interest in participating in this piece of research and you are >16 and <32 weeks pregnant and have no major health issues.

The **exclusion** criteria for this study are listed below:

- Males
- Anyone with food allergies or intolerances
- Smokers
- Vegetarians or vegans
- Anyone using medication that they believe influences their ability to taste
- Anyone with a hormone imbalance or metabolic disease that impacts their ability to taste.
- Anyone with a history of an eating disorder.
- Pregnant women with a history of recurrent miscarriage or a diagnosis of hyperemesis gravidarium (severe nausea and vomiting), gestational diabetes or gestational

- hypertension or any other major pregnancy complication.
- Anyone who is unable to provide informed consent

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. However, even after you have done this you are still free to withdraw at any time and without giving any reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard treatment you receive. Any data collected to the point of withdrawal will not be used further.

What will happen to me if I take part?

The study will involve three visits to the Human Nutrition Unit (HNU) at the Rowett Institute building at Foresterhill. Prior to the first visit, you will be asked to complete a health questionnaire and food allergy screening form to confirm you have no major health issues or known food allergies/food intolerances. Providing this is the case you will be invited to attend HNU at times convenient to you. On each occasion you will be asked to refrain from eating, drinking or chewing gum for one hour prior to arrival.

Visit 1 (~60 minutes):

At the first visit the high level aims of the main research study and the current palatability trial will be explained by the researcher / research assistant and any questions answered. If you are happy to continue you will receive a paper version of this information sheet and asked to complete a consent form. A further questionnaire will assess how frequently you eat fruit and vegetables, and your general attitudes, format and individual preferences with respect to fruit and vegetable consumption. Additional questions will relate to age, physical activity, weight/height, and ethnicity as these may influence your taste preferences. We will also ask about any experience of nausea/vomiting and food cravings while pregnant.

You will be asked to collect your own cheek cells using a sterile swab and the analysis of this sample will tell us if you are likely to be supertaster, medium taster or non-taster. You will then be given instruction on how to complete a 7- day food diary.

Visits 2 and 3 (~90 minutes each):

8-10 days after visit 1, you will be asked to return to HNU for the first of two identical food-tasting sessions (up to 10 food products per session). The interval between the second and third visit may range from 1-10 days to suit your availability. Before starting each taste session you will be asked to collect cells by swabbing your tongue with a sterile swab. This will allow us to measure the different cells that allow you to taste food. You will then be offered food products containing vegetables and or fruit and you will be asked to rate for aspects of (a) appearance and smell before tasting, (b) texture, flavour, pleasantness while eating (c) aftertaste and (d) likelihood of being incorporated in diet at specified level/frequency, and overall acceptability on a 9 point scale. You will also be asked if you can identify the main ingredients/flavours in the individual food product from a total list of all possible ingredients.

If you have any adverse reactions to the food provided we will advise your GP.

After completing the food diary and both taste sessions you will have the option of receiving

some brief feedback on the adequacy of your diet and a recipe leaflet covering the preparation of the test foods offered.

What will happen to the samples I give?

The cheek and tongue swabs will be taken to the laboratory and processed to extract the cells before being stored at -70oC in a secure freezer. The cheek and tongue cells will then be used to measure the genes and receptors involved in your sense of taste. Your samples will be stored for a maximum of 5 years, after which they will be destroyed.

Expenses and payments

Participants will be given a gratuity of £30 sterling after the third study visit as a thank you for taking part and to cover any travel expenses.

What are the possible benefits of taking part in the study?

This study will probably not help you personally but it will help in the subsequent design of a study to determine if increasing maternal fruit and vegetable intake influences an infant's taste preferences at weaning.

What are the possible disadvantages of taking part in the study?

You may not like the taste of individual food products but we are only asking you to try a small amount (e.g. a spoonful) and you will have the option of spitting it out.
You may experience mild discomfort while using the swabs to collect your own cheek or tongue cells but you will have the option of assistance from a team member if you prefer.

What if there is a problem?

If you have any complaint about the way you have been dealt with during the study or any possible harm you might suffer, please get in contact with the study investigator (Dr. Jacqueline Wallace) as soon as possible and she will try to immediately address the problem.

Alternatively, you can make a complaint to the Chair of the Human Studies Management Committee, Dr. Baukje de Roos, University of Aberdeen, Rowett Institute, Foresterhill, Aberdeen AB25 2ZD (01224 438636, b.deroos@abdn.ac.uk).

Who has reviewed this study?

This study has been reviewed and approved by the Human Studies Management Committee of the Rowett Institute and the North of Scotland Research Ethics Service.

Who is organising and funding the research?

Funded by the Scottish Governments Rural and Environmental Science and Analytical Services Division as part of its Strategic Research Program

Will my taking part be kept confidential?

Your anonymity will be guaranteed in any publication from this study. Only your consent form will have a record of your name; the rest of the documents will be given a code to anonymise your data and will be stored separately from your consent form. All of the data will be held in locked cabinets, in locked offices and/or on password protected computers/memory sticks. All data will be stored for a maximum of 5 years, after which they will be destroyed.

CONTACTS FOR STUDY

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