PARTICIPANT INFORMATION SHEET

Name of Investigator: Jacqueline Wallace

Name of Study: Womb to Wean: Weaning and Exploring Acceptance of New tastes

You and your unborn baby are invited to take part in a postgraduate (PhD) 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 life and may be influenced by the Mother’s diet during pregnancy or while breastfeeding. We want to test whether increasing the variety of fruits and vegetables consumed in late pregnancy will increase the flavour exposure to infants and make them more likely to accept a wide variety of fruits and vegetables in childhood. If this proves to be correct this will help inform dietary guidelines for pregnant women and benefit the health of the future population.

Who can take part?
We are looking for pregnant women in, or near, their 3rd trimester (27 weeks onwards) aged 20+

The exclusion criteria for this study are listed below:

- Women with a history of late miscarriage/still birth or a diagnosis of gestational diabetes, pre-eclampsia or any other major pregnancy complication
- Women with a history of severe food allergies
- Women currently experiencing, or with a history of, severe anxiety or depression
- Women with a history of an eating disorder
- Smokers
- Vegans
- Twin/multiples pregnancies
- Anyone without email access
- Anyone without access to a freezer
- Anyone who is unable to provide informed consent
- Women < 20 years old
- Women who intend to exclusively use a baby led weaning approach
- Women who live >50 miles from the Rowett Institute Aberdeen
Do we 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 of treatment you receive.

What will happen to us if we take part?

This study has two main phases:

- **The intervention** phase takes place for 24 days during your 3rd trimester of pregnancy. It will involve you eating a variety of foods (1 per day), such as soups and snacks, with a high fruit and vegetable content.
- **The taste-acceptance test** phase takes place when your baby is ready to begin weaning (around 6 months old). It will involve you feeding your baby a variety of fruit and vegetable purees at home and filming it so we can see their reactions to the new flavours as well as weighing the food so we know how much they have eaten.

The study will also involve you periodically telling us about your habitual fruit and vegetable consumption and your baby’s diet in terms of milk feeding and new foods they are introduced to when weaning.

If you express an interest in taking part in the study, you will be asked to complete a health-screening checklist to ensure you are eligible to participate. Once this has been confirmed, we will arrange a time which is convenient for you to visit the Rowett Institute, or alternatively, we can come to your home. During the visit, you will be able to ask any questions you may have about the study, and we will ask you to sign a consent form to say you are happy to take part. After this, we will find out about the fruits and vegetables you like/dislike and how much you usually consume by asking you to complete two online questionnaires – either during the visit or soon afterwards, depending on your preference. This can be done at any time up until your 30th week of pregnancy.

**Intervention phase**

The intervention phase will begin when you are at, or around, 30 weeks pregnant. We will provide you with a range of foods to be consumed on a daily basis. The foods will not contain any product that is not advised in pregnancy. These foods have been developed on site at the Rowett Institute by a team of dieticians/nutritionists and have been prepared in the Rowett Human Nutrition Unit Kitchen by trained staff following strict hygiene and food safety policies and procedures. The foods will be frozen and portioned for convenience and you can pick them up from the Rowett Institute or we can drop them off at your home. Depending on how much freezer space you have available, we may need to arrange pick-up/drop-off more than once.

Twenty-four light meals of soup/pasta sauce and 8 snacks will be provided in total. You are not required to eat all of the foods (although you can finish them once the intervention phase is over if you wish) however giving you more than you need will allow you some choice in what you are eating as pregnancy can often be a time when food aversions arise. We will ask you to eat a light meal on 2 consecutive days and a snack on the 3rd day, repeated 8 times – i.e. for 24 days total. As it is recommended that women in their 3rd trimester of pregnancy should consume an extra 191 kcal per day, the addition of these relatively low-calorie foods to your diet should not have a
negative impact on your weight status. You will be asked to keep a note of the intervention foods you eat and to rate your enjoyment of them. You are not required to alter your fruit and vegetable consumption, or diet in general, in any other way before, during or after the intervention phase.

After the intervention phase we will ask you to complete the online questionnaire (24-hour diet recall) a further 3 times: at around week 35 of pregnancy, 3 months postnatal and 6 months postnatal. This is so we can collect information on the flavours your baby may be exposed to out with the intervention phase. This takes about 20 minutes to complete. We will also ask you to keep a monthly milk feeding diary once your baby is born so we can find out about the type of milk they are drinking (i.e. breastmilk, formula milk, or both) and how often. This will involve you noting down their feeds for 1 day of the month and telling us whether this was typical of the rest of the month. We would like you to do this until they are 6 months old. We would also like to collect stool samples from your baby’s nappies at various points throughout the study. This is so we can see how your baby’s gut microbiota is influenced by their diet, both before and after weaning. The nappies can either be picked up from your home or dropped off at the Rowett Institute, depending which is more convenient for you. It would also be really helpful if we could collect a single stool sample from you, the Mother, so that we can compare your gut microbiota with your baby’s. This would add to the knowledge base hugely as there is currently a lack of research in this area. Should you agree to this, we will provide you with a sample collection kit to be used at home and returned to the Rowett using the prepaid return envelope. We would like to collect this sample after the intervention phase and before your baby is born (i.e. around 35 weeks pregnancy).

**Taste-acceptance test phase**

Once your baby is ready to begin weaning onto solids foods, we will ask you to film them as you introduce them to new flavours. The timing of this phase is completely flexible to fit around your baby’s development and when you wish to begin weaning – although we would encourage you to wait until they are 6 months old as recommended by the NHS. Once you have expressed the intention to begin weaning, we will arrange a home visit at a time that is convenient for you, so that we can explain the tests in detail and drop off all the resources you will need. Prior to this, we will ask you to complete an “attitudes to weaning” questionnaire that will ask you about any previous experiences you may have with weaning as well as your intended method of weaning your new baby. The questionnaire will also address signs of readiness for weaning for those who may be unsure whether their baby is ready. We will send you an information pack ahead of the home visit which will provide detailed instructions about the tests. It is not essential that you read this before the visit as we will go over everything with you, but it may help you generate questions and make the visit more efficient. We would like to collect cheek cell samples at the home visit, from both you and your baby, which would involve you rubbing a swab, similar to a cotton bud, against the inside of your cheeks. This is so we can look at the genetic make-up of your taste receptors as this has been shown to influence taste preferences. Your DNA will be used for this purpose only.

The taste acceptance tests will compare the amount your baby eats of a plain potato puree and then each of 3 test purees: apple and potato (fruit flavour), broccoli and potato (vegetable flavour), and spinach and potato (strong vegetable flavour). We will also ask for the feeding sessions to be video recorded so we can observe your baby’s reactions to the different flavours. As this will be your baby’s first experience of eating, we will ask you to familiarise them with eating by offering them the plain potato puree for a couple of days before the first test. To keep
this phase as short as possible, you will be asked to send us a short clip of them eating the potato puree the second time they try it so that we can see if they are ready to move on to the tests. Once your baby is eating well, we will ask you to do a trial test with the potato puree following the step-by-step instructions so that you can become familiar with the method. If after this you are happy to move on to the real tests, you will be asked to do the first three tests on three consecutive days, starting with plain potato puree. After the test with the plain food, half of the babies taking part in the study will try the fruit flavoured test food first, and then the vegetable; and the other half will try the vegetable flavoured test food first and then the fruit. This randomisation helps us to account for other factors that may influence the outcome of the tests.

If you wish to introduce your baby to finger foods during this phase of the tests, we would ask that they take the form of relatively bland foods that do not have a strong flavour, such as sliced avocado, sliced boiled potato and cucumber sticks.

The fourth test with the spinach and potato should be carried out four days after the first three. This is so we can see your baby’s reaction to the strong vegetable flavour once they have had some more practice at eating. It is likely that you will want to introduce your baby to some new flavours between the 3rd and 4th tests, so we will provide you with a weaning diary to record any foods your baby tries during this time - as well as any bland finger foods previously introduced. This will allow us to see if your baby’s reactions to the purees have been influenced by exposure to other flavours. We would like you to continue to complete the weaning diary monthly for a further 3 months so that we can find out if the intervention has had a short-term impact on your baby’s acceptance of new foods. Once the taste acceptance tests are complete, we will make another brief visit to your home to pick up the equipment. Lastly, we will ask you to submit your weaning and milk feeding diaries along with a copy of your baby’s growth measurements from their “red book”. This is the book which your health visitor uses to record your baby’s length and weight. This will allow us to interpret the results of the taste tests in relation to your baby’s growth.
What will happen to the video recordings?
The video footage of the flavour acceptance tests will allow us to observe the facial expressions your baby makes when eating the foods. You will need to upload your videos via ZendTo, directly from your recording device, using a unique access code which we will send to you by email. ZendTo stores files securely on the Aberdeen University network drive and can only be accessed via a secure login. Any video footage you send us will be anonymously coded, and will only be accessible by the research team. All images will be destroyed once fully analysed.

How secure is ZendTo?
All files which are transferred across the network are securely encrypted. ZendTo is in no way a "cloud" service. Everything is stored on equipment directly owned by the University and managed by its own IT staff. All access to data is very tightly and strictly controlled by the University. All accesses to data on ZendTo are logged and can be easily checked if you are ever concerned that a 3rd party might have gained access to your data. Uploaded data is only held on ZendTo for a maximum of 14 days, after which time it is automatically deleted. There is no "undelete" facility available at all. No backups are taken of the uploaded data (it’s only a transitory stopping point), so no uploaded data ever moves off ZendTo itself onto other equipment or media such as backup tapes. After an uploaded file has been deleted, there is no way of recovering the file. Retrieval of a transferred file by a recipient can only be done with both the participants’ Claim ID and Passcode. This information will only be provided to the person who requested the file transfer, i.e. a member of the research team.

Expenses and payments
All of the resources required (except recording device and highchair) will be provided by the Rowett, therefore there will be no costs to participants. If volunteers choose to attend the Rowett for the first visit, their travel expenses will be reimbursed. Once the volunteers’ participation has ended, they will receive a gift for their baby, such as a bath toy, as a thank you for taking part.

What are the possible benefits of taking part in the study?
All of the foods provided for the intervention contain a lot of fruits and vegetables, therefore – depending on your usual consumption – taking part in the intervention may increase the volume and/or variety of fruits and vegetables you eat. This may have a positive impact on you and your baby’s health. The volunteers that took part in the pilot study of the taste acceptance tests, especially first time Mums, found it useful having extra support throughout the weaning process.

What are the possible disadvantages of taking part in the study?
We will ask that you do not introduce your baby to any foods before the second phase of the study begins, however we understand that this will not always be possible due to the, sometimes rapid, progression at this developmental stage. If you wish to introduce your baby to solids sooner than anticipated, and/or you would like to introduce finger foods, we would ask that these take the form of bland foods, such as plain cereal, potato (not sweet potato), cucumber sticks and sliced avocado and that no other flavours are introduced. Please note that this will not have any negative effects on your baby’s health or development and is in line with
British Dietetic Association/NHS guidelines. We will stay in touch throughout the study so that any changes to the timing at which weaning will begin can be communicated and the start date adjusted according to you and your baby’s needs.

Weaning is often the time when food allergies first become evident. All the foods used in the study are considered non-allergenic and are recommended as suitable first foods for weaning by the British Dietetic Association. Irrespective we will make you aware of the signs and symptoms of food allergies and what to do if they occur.

Please be assured that all images you send us will be uploaded securely and will be inaccessible to anyone other than the research team.

**What will happen to the samples I provide?**

Cheek cell DNA samples:
Genotyping will be performed to identify taste receptor variants (single nucleotide polymorphisms or SNPs) that influence taste perception. DNA extraction will be carried out in laboratories at the Rowett Institute. Extracted samples will be stored in a locked freezer suite with access limited by electronic card entry to the study management and analytical team only. Samples may be stored in this way for up to 5 years in the same location in case analytical data suggest further analyses are required. The genotyping will be carried out by an external company (LGCgenomics). Samples held by LGCgenomics will then be destroyed in accordance with the Human Tissue Authority's Code of Practice.

Faecal samples:
Faecal (stool) samples will be processed in two ways in laboratories at the Rowett Institute: DNA will be extracted and sequenced to profile the microbial community living in the gut and samples will be derivatised and used to measure the amounts of the most common short chain fatty acids produced in the gut and involved in keeping it healthy. Sample storage and security as above.

All samples provided by you, and the data associated with it, will be exclusively used for the purposes of this study. Due to the sensitive nature of this data, your samples will only be associated with your participant ID number and never with your identity.

**What if there is a problem?**

If you have any concerns about any aspect of the study please get in contact with the study investigator (Dr. Jacqueline Wallace) as soon as possible and she will try to immediately address the problem.
If you remain unhappy and wish to make a formal complaint, you can do this by contacting the Chair of the Human Studies Management Committee, Professor Baukje de Roos, University of Aberdeen, Rowett Institute, Foresterhill, Aberdeen AB25 2ZD (01224 438636, b.deroos@abdn.ac.uk).

There is absolutely no reason to believe that eating extra vegetables or fruit in the third trimester of pregnancy has any potential to harm or injure your unborn baby in any way. However volunteers need to be aware that the terms and conditions of the insurance policy held by the University of Aberdeen and covering this study state that no claim can be made in connection with any incidence of birth defect, injury or death.
Who has reviewed this study?
This study has been reviewed and approved by the Human Studies Management Committee of the Rowett Institute and the East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Aberdeen and NHS Grampian, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Who is organising and funding the research?
This study is funded by the Scottish Governments Rural and Environmental Science and Analytical Services Division as part of its Strategic Research Program

What will happen to the results of the research study?
The results will be used for a PhD thesis which may be published after its completion in January 2021. You will not be identified in any report/publication.

Will my taking part be kept confidential?
Your anonymity will be guaranteed in any internal report or conference presentation relating to this study. A confidential participant log will record details of names and addresses of participants to enable dropping-off of foods, etc. In all documentation (except the consent form) the participant will be identified by a code allocated to them in the participant log. All of the data will be held in locked cabinets, in locked offices and/or on password protected computers. All data will be stored for a maximum of 5 years, after which they will be destroyed. Your GP will be informed of your participation in the study, and in the case of an adverse reaction to any of the foods at either the pregnancy or weaning stage.

General Data Protection Regulation
The University of Aberdeen is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen will keep identifiable information about you until 2023. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information http://www.abdn.ac.uk/privacyand/or by contacting Iain Gray, University Data Protection Officer.
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