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**YOUNG PARTICIPANT INFORMATION SHEET- OPIA STUDY**

**Oral Peanut Immunotherapy with dietary starch adjuvant for peanut allergy**

**HREC number:**

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 **Information for young people 10 - 14 years**

**What is the study about?**

At the moment, there is no cure for peanut allergy. People with peanut allergy have to avoid eating any food which might contain peanut. This is not always easy and can be a worry, especially when away from home. You have been invited to take part because you have peanut allergy.

In the OPIA study, we are looking at a new way of treating peanut allergy, called oral immunotherapy (OIT). We want to see how successful OIT is and whether eating a special fibre along with the peanut will help.

**What is Oral Immunotherapy (OIT) or desensitisation**

In OIT, we give small and increasing doses of peanut to eat every day, over months, to teach your body not to react to peanut. These doses are given very carefully, to keep you safe. Whenever we go up on the dose, this is done in our hospital allergy center. Most people (but not all) are then able to eat some peanut without having a reaction.

**What’s different about this study?**

Other studies have used roasted peanut for OIT alone. In OPIA we will be adding in a type of special fibre which has been developed by the CSIRO to help with allergies.

**What will I have to do if I take part?**

If you take part in this study, you will come to our allergy center at the hospital, where a nurse or doctor will check your allergies and make sure you can join the study. We have to ask your parent or legal guardian to agree (consent) to the study, but we want to be sure you are happy to take part too. We will do some allergy tests, many of which you’ve probably had before:

**Skin prick tests**: You’ve probably had this test before - we put some drops on to the skin on your arm and then prick the skin, a bit like being pressed with a sharp pencil. This doesn’t usually hurt, but might cause itchy red bumps for a short time. We’ll repeat the skin tests three times, during the 14 months of the study.

**Breathing test (Lung Function test)** – where you breathe into a tube connected to a computer, to tell us how much ‘puff’ you have.

**Paper quiz/questionnaire** – to tell us about the effect your allergies have on what you eat and when you are out with your friends. Your parents will also fill in their own questionnaire.

**Food challenge test** – for this test, we will give you a tiny amount of peanut to eat, then bigger amounts every 30 minutes. This is to see how much peanut you need to eat before you start to have a reaction. We do this slowly, with the doctor and nurse checking you carefully, to keep you safe and give you treatment if needed. The first food challenge will involve 2 visits to our allergy center, each taking 6-7 hours. On one occasion, you will eat peanut, on the other, you will eat a ‘dummy’ food. Some people are nervous during the test and this can mimic an allergic reaction, so we need to make sure that neither you nor the doctor/nurse know which one you’re eating. The challenges do take the whole day, so bring some things with you to keep you busy!

We need to do a **blood test** to measure your allergy and help us learn in whom OIT might work best in. To do this, we will insert a needle and plastic tube (cannula) into a vein in your arm. This can hurt so we can give you numbing cream or “cold spray” which will help a lot. We do this during the food challenge, and leave the cannula in until you go home, so that we can give you treatment easily and take blood from it without having a use another needle.

We will also ask that you collect your **stool** and bring it in to us. You will be provided with a special container and instructions on how to do this. You can’t see through the container and we will give you a plastic bag to put it into.

**What then happens?**

If you are allergic to peanut at the food challenge, then you can take part in the rest of the study. Some people will start the OIT immediately, while others have to wait a year before starting. This is decided at random, using a computer – a bit like tossing a coin. We need to do this to prove that the OIT works, as some people naturally grow out of their allergy.

If you begin OIT immediately (ACTIVE GROUP), then you will start to eat small amounts of peanut every day. You will also eat a small amount of a fibre supplement which will come in a sachet or a small tub. It can be mixed in with any other food. Half of the children will get a special CSIRO fibre and half of the children will get a normal fibre supplement.

Neither you, your parents nor the research staff or your doctor will know which type of fibre you are getting until the end of the study. Every 2-3 weeks, you’ll need to come to our research unit in hospital for 1-2 hours, so that we can increase the dose of peanut and check that you’re ok. We will also repeat some of the allergy tests. After 12 months, if you have been taking the peanut and the fibre you will stop both of these for 6 weeks. After 6 weeks we’ll repeat the peanut challenge tests, to see how well the OIT has worked and work out how often you need to eat peanut to maintain this.

If you start off in the CONTROL GROUP, then for the first 12 months you’ll need to carry on avoiding all peanut, as you’ll still be allergic to peanut. We will regularly call your parents to see how you are going and if you have had any accidental peanuts and, if so, if you had an allergic reaction. After 12 months, we will repeat the peanut challenge test and then you can start the OIT treatment.

**What will I need to do at home?**

You will need to eat a dose of peanuts every day. Your parent(s) will check that you are ok before each dose, so tell them if you aren’t feeling well. You will need to avoid running around or doing sport for 2 hours after taking the peanut. You will also take the fibre every day at home, at a different time to the peanut. You can mix the fibre into any food or drink and don’t need to avoid any activity with the fibre.

We will teach you and your parents how to look out for any reaction to the peanut, and what to do if they occur. This includes learning how to use an adrenaline injector ‘pen’. You will be able to call us at any time to ask for our advice, for example if you become itchy after taking a dose.

**Do I have to take part?**

You don’t have to take part. It is up to you to decide and you can say no without any problems. Even if you take part at the beginning and change your mind later on and don’t want to be a part of the study that is okay as well. All you need to do is tell us that you don’t want to take part anymore.

If you don’t want to take part, your normal clinic team will look after you and your allergies, exactly the same as they do now.

**Is there anything that might make me upset if I take part in the research?**

Taking part in the research means that you will have many of the same allergy tests as everyone else coming to hospital with peanut allergy. Some children can get itchy or have other funny feelings with the skin tests, but these can happen whether you take part in the research or not.

We expect the food challenge tests will cause you to have an allergic reaction, which can be unpleasant. Because we do these tests slowly and carefully, these reactions are usually mild e.g. itchy skin, or feeling sick. If this happens, we will give you medicine to help you feel better. Occasionally, you might have a more significant reaction e.g. cough, wheeze. This is why we are only doing the challenge test in hospital, where our staff (who do these tests regularly) know how to manage reactions safely.

You may experience mild symptoms when eating the daily doses of peanut at home – if this happens your family can give you treatment, and we may change the dose to stop this happening.

**What are the possible benefits of taking part?**

We hope that the OIT will increase the amount of roasted peanut you are able to eat without having an allergic reaction. At the end of the study you may be able to eat foods that contain peanut. Hopefully, the results of this study can help us treat other people with peanut allergy in the future.

**Are there any people who cannot take part?**

If your peanut allergy is very mild, or alternatively you have had a very bad reaction to peanut resulting in a stay in hospital, you may not be able to take part – we will discuss this with you and your family if this is the case. If you have other illnesses or health issues, you may also not be able to participate.

**What will happen to the information I tell you?**

The results of your allergy tests and how you get on with OIT will only be used by us; no-one else will be allowed to use this information. We will add all the results from all the people in the study together so that we can tell other doctors about our research in reports or research papers. We will talk about the results for the whole group, and you will not be able to be identified in these reports or papers.

**Who is organising and funding the research?**

The study sponsor is Sydney Children’s Hospital’s Network and the study is funded by a grant from the National Medical Research Council of Australia (NHMRC).

**Other information**

If you have any concerns about the conduct of this study please do not hesitate to discuss them with Professor Dianne Campbell or Dr Melanie Wong (T 02 9845 3420) or with the research ethics manager (98453066), secretary of the Ethics Committee that has approved this project and quote HREC/16/SCHN/372.