



THE RAINE 23 YEAR FOLLOW UP Sleep and Respiratory Study

INFORMATION FOR PARTICIPANTS

Please take time to read the following information carefully. If any part of the information is not clear to you, or if you would like more information please do not hesitate to ask us to explain it more fully.

Your decision to participate in this study is voluntary, and you are able to change your mind at any time during the study.

The two main focus areas of the Raine Study 22/23 year follow up are respiratory functioning (breathing and asthma) and sleep.

BRIEFLY WHAT WE WILL ASK YOU TO DO

We would like you to spend one night sleeping overnight in the UWA Centre for Sleep Science and undergo a sleep assessment. The Sleep Centre is a newly converted house, with comfortable facilities (sitting rooms, kitchen, showers, bathrooms). During your time in the Sleep Centre (while you are awake!) we would also like to test your lung function and see if you have any allergies. We will provide you with dinner and breakfast and snacks if you feel hungry.

Before you go to sleep we will

- Measure your height, weight, blood pressure etc
- Take a 3-D photograph of your head and face
- Take a photograph of the inside of your mouth
- Do a mole count on your arm, and take an impression of the skin on the back of your hand to assess sun damage to your skin
- Do some tests to measure your lung function (for research into asthma)
- Do an allergy test to see if have any allergies and take a nasal swab
- Do a back and leg muscle strength test and sensory perception test (pressure and cold sensation)
- Fit you with accelerometers to measure your activity level while you sleep (hip and wrist)
We would like you to keep the hip monitor on for the next week (it is small).
- Ask you to please complete a questionnaire about your usual sleep patterns and a diet questionnaire.
- Ask for urine sample (only if you are OK with this)
- Give you dinner
- When settled in bed, connect the sleep monitors to you to record your sleep patterns
- We may also ask you to complete some sleep questions while you are in bed

In the morning when you wake up, we will

- Take your blood pressure again
- Ask for a urine sample (only if you are OK with this)
- Take a blood sample (only if you are OK with this)
- Give you breakfast
- Do an asthma challenge test

INFORMATION

Raine Study 23 year follow up - Sleep and Respiratory Study

When you arrive at the UWA Centre for Sleep Science, we will ask you to please complete and sign a consent form and the Raine Study Staff will answer any questions you may have and explain the different tests and procedures. Anything you don't feel comfortable with, you don't have to do.

MEASURES AND TESTS WE WOULD LIKE YOU TO DO

In the evening, before you go to sleep we will ask you to complete some tests and measurements.

- The Raine Study Staff will measure your height, weight, waist, hip, skin folds, neck circumference, take your blood pressure and take a 3-D photograph of your head and face.
- We would like to take a photograph of the inside of your mouth to assess the position of your tongue and teeth etc. We believe that throat anatomy might predict whether you are more or less likely to have sleep apnea. For example, it might be that someone with a narrow throat, or large tonsils, or large tongue has more chance of the throat collapsing during sleep. We can measure the dimensions of these structures from photos of the back of your throat. For this reason we will ask you to open your mouth, poke out our tongue and let us take a photo of the inside of your mouth.
- We will count the number of moles that you may have on one arm, and take an impression from the skin on the back of your hand. We smooth a bit of dental plastic onto the skin, then lift it off. This gives a measure of sun damage to your skin.
- We will also measure how strong your back and leg muscles are.
- We will fit you with a small activity monitor (the size of a watch).
- We will also ask you to do the cog-state test. This is a quick on-line computer puzzle solving test that tests your memory and reasoning.

We will then ask you to do the first part of the respiratory and lung testing.

RESPIRATORY, LUNG FUNCTION AND ALLERGY TESTING

Lung Function Testing

Spirometry is a method of assessing lung function by measuring the volume of air that you breathe out. You will take a deep breath in and fill your lungs to capacity and then breathe out as hard and fast as possible into a tube, until there is no air left. You will need to do this three times for three different tests. Factors that can affect your lung function include asthma and smoking. The Research Assistant will be able to tell you how good your lung function is.

Assessment of Airway hyper-responsiveness (coughing reaction) test.

After you have slept the night doing the Sleep study, we would like to measure the responsiveness and how powerful your airways are. (If you are not doing the Sleep Study, this can be done after the Spirometry tests).

- Your airways contract and respond to various triggers, like dust or smoke, which causes you to cough.
- This contraction is called a bronchospasm and this is caused by the contraction of the small airways in your lungs.
- People with asthma or other lung disease have less powerful contractions of these airways
- We will ask you to breath in a substance called Mannitol that triggers a response in your airways, to make you cough, and then test your lung function using spirometry (as above).
- The substance will probably make you cough, and we will then collect a sputum sample from your cough. You may not cough, or you might not cough up any sputum, this is fine.

Coughing and diseases such as asthma can cause your air passages to become bruised and inflamed. We would like to test your air passages for inflammation. We do this by asking you to simply breathe deeply, and then breathe out into a machine.

Allergy Testing -Skin Prick Test

We would like to see if you have any allergic reaction to common substances.

- A Skin Prick Test for dust mite, cockroach, dog hair, mould, grass, fungus, milk, eggs.
- This involves putting a drop of these substances on the inside of your arm (in a specific pattern so we know which is what) and then making a slight prick in your skin.
- If you are allergic to any of these substances, you will develop a red area in that region. We will have cream to sooth any response you may have.
- If you are not allergic, then nothing will happen.

Nasal Swab

We will ask you to use a nasal swab (like a long cotton wool bud) to wipe around the inside of your nose. This is easy to do and is not uncomfortable. We will then place these in special storage containers and freeze them for later analysis. We will use this to look at which 'bugs' we find and whether or not these bugs are different in asthmatic individuals.

SLEEP STUDY

The only way to do a sophisticated sleep study is to stay overnight in a specialised facility. The UWA Centre for Sleep Science has 5 separate bedrooms designed to have you sleep overnight. A sleep study requires many different measurements to be obtained at the same time, but all are non-invasive - measuring devices are stuck to your skin or placed on your chest, abdomen, fingers or head.

You can bring anything that you normally prefer to sleep with (special pillow, teddy bear). It's best to wear pyjamas or something that has a separate top and bottom, but make sure that you

are comfortable sleeping in them. At least two Raine Study staff members will be there all night as well.

A sleep study records and evaluates breathing patterns, heart rate, oxygen levels and brain wave activity during the time you are asleep. To do this, wires and electrodes are attached to various part of your body and then connected to computers. The electrodes are measuring the electric impulses created by your body, your brain waves and your heart beat. They do not create any electricity.

Our Raine Study Research Assistant will hook you up with the following

- Six small electrodes and wires attached to your scalp with a medical paste (the electrodes and paste are easy to remove in the morning)
- One stick-on electrode behind each ear, one next to either eye, three under your chin and two on your upper chest
- A soft band around the chest and another around the abdomen to measure breathing
- Soft tape on one finger to measure oxygen saturation
- A soft wire and soft tubing under the nose with an airflow sensor to measure breathing.
- 2 electrodes on each leg to record leg movement
- A microphone to record sound
- A watch (accelerometer) on one wrist to measure body movement
- A video camera also records your movements while you are asleep. This is only turned on once you are settled in bed and it is dark. It is an infra red camera and does not record details.

All the wires etc go into one connection box that can easily be unhooked and taken with you should you want to get up during the night.

A Raine Research Assistant will be in the office next door to your bedroom. You will be able to communicate with this person through an intercom system next to your bed.

Most people think that they will find it difficult to sleep in a different place hooked up to machines, but generally almost everyone falls asleep.

In the morning, we will be able to give you results of your sleep patterns and quality of sleep.

BLOOD SAMPLE

As before, we are asking if you could please provide a fasting blood sample. Our Raine study phlebotomist will be at the Sleep Centre in morning, and its OK with you, take a morning fasting blood sample while you are still lying in bed.

We will then give you breakfast.

Again, we would also do the regular blood tests looking at fats, glucose, insulin, coeliac disease antibodies, iron levels.

We will send you these blood test results. As the blood is batch tested, this will be two to three months after the sample has been taken.

Previously at both the 17 and 20 year follow ups, we asked your permission to use your blood sample to extract a sample of your DNA to use for genetic analysis of risk factors associated with the development of childhood and adult health and disease. If you have previously provided a DNA

sample, or if you have previously said that you did not want to do this, then we will not ask you again.

If however, you have not provided a blood sample before, or the DNA sample we have from you previously was not of high quality, then we will ask your permission again to do this, and give you a separate information sheet and consent form to fill in.

URINE SAMPLE

We will also ask you for a urine sample, before you have your dinner and when you wake up in the morning.

The urine will be used to analyse urinary sodium and potassium levels which provides a good indication of your food intake. Taking a urine sample both in the evening and the morning will provide an overall indication of your diet in the past day. Again, if you don't want to do this, you don't have to.

ACCELEROMETER

You will be asked to **wear an activity monitor on a soft belt** for 7 days and complete a brief log each day stating your sleep and work times. The monitor is water resistant so can be worn in the shower or when surface swimming (but not when diving below 1 meter). However it is better to take it off when showering or swimming, as the belt gets wet and is uncomfortable. After the 7 days we ask you to please post the activity monitor, belt and logbook back to the Raine Study Office in a pre-paid envelope provided.

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QUESTIONNAIRES

We will ask you to please complete some questionnaires for us. We will post out a the general Raine Study Questionnaire and Medical questionnaire for you to fill out at home. If you don't manage to do this, you can complete it while at the Centre for Sleep Science. While you are at the Centre, we will ask to fill out a short questionnaire about your diet, and a questionnaire specifically about your sleeping habits. These are quick to complete.

Work Loss Confidentiality Questionnaire.

The Raine Study would like to record the amount of work or university days that people cannot attend due to ill health, or the amount of days that you do go to work when you are feeling ill and don't function properly. We will ask you this question in the questionnaire, which will be the first time, then again in three months time, then the next three months until we have information from a full year. We will send you a text message in 3 months time, if you have not missed any days, you simply text back NO. If you have missed days, you will be sent a link to a short questionnaire to complete online.

Please Contact us at the Raine Study if you have any questions (tel 9489 7792 or 9489 7794 or 0447863944).

Confidentiality

All information we collect is strictly confidential.

Your participation in this study does not prejudice any right to compensation, which you may have under statute or common law.

Approval to conduct this research has been provided by the University of Western Australia (RA/4/1/5202), in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time.

In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Research Ethics Office at the University of Western Australia on (08) 6488 1610 or by emailing to hreo-research@uwa.edu.au

All research participants are entitled to retain a copy of any Participant Information and Participant Consent Form relating to this research project."

This Study has been approved by the Curtin University Human Research Ethics Committee (Approval number HR 23/2013). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.