

The 'Our Health' Study: Participant information booklet of measures

Introduction

Thank you for participating in the University of Melbourne's 'Our Health' study. The following document provides an overview and further detail of the study assessments you may be asked to complete.

Your study participation will happen over 3 phases:

Phase 1 - Pre-visit questions:

You will be asked to complete some questionnaires and information at home in the lead-up to your study appointment at the Participant Assessment Centre (PAC) in Carlton. **(1 hour, approx.)**

Phase 2 - On-site measures:

You will be invited to complete a series of assessments; give samples; and complete some questionnaires/provide some information during your study visit at the PAC. **(4 hours, approx.)**

Phase 3 - At home measures:

A two-week monitoring phase following your study visit to the PAC, which includes some assessments for you to complete at home. **(2.5 hours, approx., over 2 weeks)**

You might be asked to complete some, or all, of the listed assessments. The assessments may be completed in a different order than listed below. It is possible that certain assessments won't be available to you (e.g., owing to time constraints; if we have operational or equipment issues; or if a particular activity is not safe or relevant for you). We will discuss any changes to your study participation plan with you.

You are encouraged to contact our research team if you have questions about any of the assessments listed in this document. Our contact details can be found at the end of this information book.

Contents

Phase 1 - Pre-Visit Measures:	3
Questionnaires	3
1. Lifestyle, Environment and General Health History Questions.....	3
2. Medication Log.....	3
3. Personal and Family History	4
App downloads	4
Phase 2 – Study Visit and Onsite Measures	5
Preparing for your visit:	5
During your visit:.....	6
Biological Samples	6
Blood	6
Saliva	7
Urine.....	7
Plaque	7
Physical Measures.....	8
Dental health	8
Body Measure Station	8
DXA – Dual Energy X-ray Absorptiometry	9
Strength Station	10
1. Hand-grip strength	10
2. Sit-to-stand Assessment.....	10
Heart health	10
1. Blood Pressure	10
2. Electrocardiogram (ECG)	10
3. Carotid Artery Intima-media thickness (IMT) measurements	11
Measurement of liver stiffness (elastography)	11
Lung function and breathing	11
Eye health and vision	12
Ear health and hearing.....	12
Questionnaires (on-site) – Trauma, relationships, cognition, mental illness, and related wellbeing outcomes	13
Cognitive Assessment	13

Phase 3 - At home assessments	14
1. Faecal sample	14
2. On your smartphone	14
3. Passive phone use (Ksana EARS)	15
4. Wearable devices	16
Fitbit 'Charge 6'	16
Participant feedback	16
Return of Information	17
Contact Us	17

Phase 1 - Pre-Visit Measures:

These are the study components you will be asked to complete before your in-person visit.

Questionnaires

2 – 3 weeks before your study appointment, you will be invited to complete some online questionnaires on a Smart Device (computer/tablet/smart phone). You will receive an email with instructions and a link. The questionnaires are expected to take a total of 1 hour (approx.) and will cover topics including:

1. Lifestyle, Environment and General Health History Questions

We will ask some questions about your early life, background, education, living arrangements, surgical history, diet, daily activities, social connectedness and quality of life. This information gives us good context to your overall health, wellbeing, and your experience of illness. For example, some diet and lifestyle factors may impact a person's energy levels, mood, and digestion – and over time, their experience of chronic disease, bone health, and brain function. Early life events – such as the circumstances of your birth - can also play a significant role in your heart, digestive, respiratory, and immune system health throughout your life.

2. Medication Log

The medications that a person takes can also offer good information about their general health. You will be asked to fill in a 'Medication Log' before your on-site visit, including details of any recent:

- A. Prescribed medications
- B. Over-the-counter medications
- C. Supplements/vitamins



This log is best filled out before your study visit, in the comfort of your home, with access to your prescriptions and medication bottles as a point of reference.

3. Personal and Family History

We would like to gain an understanding of your overall health history by asking about any specific conditions or illnesses with which you may have been diagnosed. If you are able and willing, we also invite you to tell us some details about the medical histories of each of your first-degree biological relatives (any full siblings that you have, and your biological parents).

App downloads

- We will request that you download 2 separate apps prior to attending for your study visit
- We will also ask that you create a Google account, if you do not already have one
- Detailed instructions will be emailed to you in the week leading up to your visit, with further information outlined in the coming pages.

Phase 2 – Study Visit and Onsite Measures

Preparing for your visit:

For 12 hours before your study visit:

- **Please do not brush your teeth**
- **Please do not consume caffeine (coffee, tea, chocolate, energy drinks)**
- **Please avoid strenuous exercise**
- **Please do not consume nicotine (cigarettes, vapes, patches, other tobacco sources)**

For 4 hours before your study visit:

- **Please drink plenty of plain, unflavoured water (up until your arrival at the PAC)**
- **Please do not eat or drink anything else**

When attending your visit, we recommend that you wear:

- **Comfortable, non-restrictive clothing (allows you to move and bend freely)**
- **A two-piece outfit (i.e., separate top and bottom)**
- **Short sleeves, or sleeves that can be easily removed/rolled up above the elbow**
- **A wire-free bra (if applicable)**
- **Glasses (if applicable), rather than contact lenses, for ease of removal**

During your visit:

When you come to the PAC for your visit, the study team will invite you to complete a series of assessments and sample collections. We will ask you to stop drinking water as you arrive. We will complete any sample collections and assessments that need to be performed ‘fasted’ at the beginning of your visit – we will then offer you something to eat and drink (and the opportunity to brush your teeth!).

Biological Samples

Your bodily fluids and substances reflect valuable information about your body’s health, inner workings and functions, and also give good context to the results from your other study assessments. During your study visit, you will be invited to give samples of your blood, urine, dental plaque, and saliva – and to complete a faecal (poo) sample at home. You can read more below about how each sample will be collected.

Your samples will be assigned unique, random study codes, meaning that your identifying information is removed from your samples. They can then be transported, processed and stored without being directly linkable to you. Your samples will be prepared onsite for transportation to our accredited Australian partner laboratories for processing and testing, including:

1. The Royal Melbourne Hospital
 2. The Murdoch Children’s Research Institute
 3. The Bio21 Institute
 4. Other appropriate partner laboratories (as approved by our ethics committee)
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Blood

Reminder - for 4 hours before your study visit:

- **Please drink plenty of plain, unflavoured water**

(Being well hydrated assists with an easier, more comfortable blood collection)

Blood tests can provide information about your genetic makeup, your body’s health, and the function of your different cells. A researcher (who is either a senior registered nurse or an experienced phlebotomist) will collect a blood sample from your inner arm. We will collect around 2.5 tablespoons of blood.

Saliva

Saliva samples can be used to examine your own genetics; the genetics, numbers and types of the microscopic ‘bugs’ living in our mouths; and the other, various molecules produced by our bodies in response to the food, drink, and medications that we consume.

To collect your saliva, the study team may use one or both of the following techniques:

- Ask you to chew or move your tongue around and allow the saliva to ‘pool’ in your mouth, before drooling it gently down a straw into a collection tube (this may take a few minutes to collect enough saliva).
- Ask you to ‘swirl’ sterile water around your mouth for around 1 minute, before expelling the contents of your mouth into a collection tube.

Urine

Urine samples can be used to look at your kidney/bladder health and functions. The study team will provide you with a sample cup and instructions and direct you to our bathrooms at the start of your study visit where you will collect the sample in private. If you arrive early, please avoid using the toilet until you have spoken with a researcher.

Plaque

Reminder - for 12 hours before your study visit:

- **Please do not brush your teeth**

(This ensures there is some dental plaque in your mouth to collect!)

Dental plaque on our teeth houses a diverse range of microscopic ‘bug’ colonies. We can extract information from these colonies to learn more about your oral health, including markers of tooth decay and gum disease. Plaque sampling will typically occur during your dental check up with our dental or oral health practitioner. We will use a cotton swab to gently wipe away some plaque from your teeth. You should not feel any pain.

Physical Measures

Dental health

Dental concerns can affect different aspects of a person's self-image and wellbeing and play a notable role in determining overall health. Dental cavities and gum disease can result in significant pain and sensitivity. This can lead to an avoidance of certain foods, or incomplete chewing, which in turn can lead to digestive health problems and a diet lacking in key nutrients. Tooth decay may also give bacteria in the mouth the opportunity to enter the bloodstream, leading to serious infection or inflammation of the heart and lungs.

During your study visit, a researcher (who is either a registered dentist or oral health professional) will conduct a gentle check-up of your teeth and gums to assess your oral health. They will examine for dental decay, tooth wear and gum health (this won't involve any cleaning or 'scraping' of your teeth). Typically, your plaque sample (as described above) will also be collected during this assessment.

Body Measure Station

A person's body composition (the ratios and makeup of their body's lean muscle mass, water content, adiposity, and bone density) may reflect a variety of different individual factors, including their genetics, environment, age, nutritional status, and hormonal fluctuations.

To look at body composition, we will collect some body measurements (height and weight) using a standing automatic device. We will also take measurements of your waist, hip, and neck circumferences using a tape measure. You will be asked to take off your shoes, bulky clothing, and may be asked to temporarily adjust any (non-religious or non-medical) headwear or hairstyles so that an accurate measure of your height can be taken.

DXA – Dual Energy X-ray Absorptiometry

Please inform a member of the study team if:

- **You are pregnant (or pregnancy is a possibility)**
- **You have had any CT scans, X-rays, medical imaging with contrast, or nuclear medicine scans in the last month – we will assess your suitability for having a DXA scan**

DXA (Dual Energy X-ray Absorptiometry) is a non-invasive test which can assess both bone mineral density/strength and body composition (different ratios of a body's lean muscle mass, fat, water, and bone content). DXA (pronounced "dexa") scans are highly accurate and pain-free. The procedure involves exposure to a small amount of x-ray radiation to produce images of your different body tissues. This is less than the amount of radiation from a routine x-ray (e.g., for a broken bone), and is more like the amount of background radiation you would be exposed to at altitude on a flight from Melbourne to Bali.

For this test we will ask you to wear light clothing that does not have any metal zips, buttons or clips (alternatively, we can provide you with medical gown/medical scrubs to change into). We will ask you to remove all jewellery, glasses and hearing aids. We will ask you to lie flat and still on the padded DXA bed for the duration of the DXA scans.

We will take scans at two different body sites to measure your bone mass, strength and density. These results may indicate your likelihood of having or developing osteoporosis. We will take an additional scan to assess your overall body tissue composition, which may give good information about your metabolic function. The three DXA scans will take around 20 minutes in total – a researcher will remain in the room with you during the scans to instruct you on the different body positions and when you are able to move.

Please note:

- Although the amount of radiation is small, **we will not conduct DXA scans on any participants who are pregnant**
- **If you are (or might be) pregnant, it is important to let the study team know.**
- **If you might be pregnant,** we will discuss performing a urinary pregnancy screen with you before a DXA scan is performed
- Breastfeeding participants do not need to avoid having a DXA scan, unless there is another reason why they should not complete this assessment.

Strength Station

As we age, our bodies tend to see a natural reduction in strength, functionality, and resilience to stress and sickness over time. A gradual decline in our lean muscle mass may impact on strength, energy levels, balance, and the capacity for both physical exercise and recovery from injury or illness. Hand-grip strength and ‘sit-to-stand capacity’ can indicate whether an individual’s strength-related function is above, below, or meeting the standard considered ‘normal’ for their age.

1. Hand-grip strength

Hand-grip strength is assessed using a special grip tool called a ‘dynamometer’. A member of the research team will ask you to squeeze the grip tool as hard as possible for around three seconds to measure your ‘peak’ grip strength. You will be asked to repeat the grip squeeze three times on each hand.

2. Sit-to-stand Assessment

The ‘five times Sit-to-Stand Test’ measures lower limb movement, strength, balance and function. You will be asked to move from a sitting to standing position (and back again) 5 times in quick succession. A researcher will record the time this takes to complete.

Heart health

Your heart and blood vessels make up your cardiovascular system, which delivers oxygen and vital nutrients to the organs and tissues around your body. We will measure your blood pressure, take an electrocardiogram (ECG), and collecting some ultrasound-based measurements of the inner layers of the carotid arteries in each side of your neck. These measures, coupled with your blood results and other assessments, help us gain greater insight into your cardiovascular health and function.

1. Blood Pressure

Your blood pressure will be measured with a blood pressure cuff, like you may experience at a routine medical appointment. The cuff is inflated ‘tight’ for a short period of time to give a blood pressure reading. Blood pressure will be measured three times while seated or lying down, and twice after transitioning to a standing position.

2. Electrocardiogram (ECG)

An ECG is a painless test that takes a detailed reading of the electrical activity and rhythm of the heart. For this test you will be lying down, with adhesive (sticky) electrode dots connecting the ECG leads to your chest (we will use a blanket or a sheet to maximise your privacy during this test). If you have never seen or had an ECG test before, our team will explain the process to you beforehand.

For female participants, we will ensure a female researcher is available for this test at your request. We may need to shave a small section of chest hair on some participants to ensure the sticky electrode dots make good contact with the underlying skin.

3. Carotid Artery Intima-media thickness (IMT) measurements

An ultrasound is a non-invasive, painless scan that uses ultrasonic waves and a special transducer to assess the health, blood flow, structure and function of different body parts. After a period of rest, we will apply an ultrasound probe with water soluble gel to the side of your neck., We will take some specific research measurements of the blood flow and the thickness of the innermost layers of the carotid arteries (the main blood vessels supplying oxygen to the brain and head). We will then repeat this process on the other side of your neck. This assessment will take approximately 5-10 minutes. You may feel some mild pressure from the ultrasound probe. The researcher will ensure you are as comfortable as possible during this assessment.

Measurement of liver stiffness (elastography)

We will also perform an ultrasound-based measurement of your liver's stiffness/flexibility (elastography). Again, we will use water soluble gel and an ultrasound probe to collect specific images of parts of your liver and elastography measurements from the right upper side of your abdomen. *We will not perform this specific test on pregnant participants, as pregnancy alters normal liver function and blood flow.*

Lung function and breathing

Reminder:

- **Please do not smoke, vape, or use any tobacco or nicotine products for 12 hours prior to your study visit**

We will assess your lung function and breathing capacity using a test called 'spirometry'. Spirometry results may reveal lung damage due to asthma, infection, diseases, or exposure to smoke or other harmful airborne particles. For this test, you will be asked to wear a special nose peg, and perform some high-effort breathing exercises through a special mouthpiece. The spirometer unit will measure the volume of air you can breathe in and out, and the rate at which you can 'fill' and 'empty' your lungs. This exercise might be repeated up to six times to get an accurate picture of your current lung health.

Eye health and vision

Reminder:

- **Please wear glasses, not contact lenses, to your study visit (if applicable)**

Eye health is important to general wellbeing and may reveal information about other areas of health. For example, the presence of high blood pressure or early diabetes may be reflected in the function and behaviour of the tiny blood vessels inside the eyes.

During your study visit, we will conduct a series of short tests that measure eye function and general eye health. You may have similar assessments during an eye test with your optometrist. The eye assessments will take 10-15 minutes, and will include:

- Reading letters of different sizes on a chart, with one eye covered (a 'visual acuity' test)
- A specialised photograph of your eyes, which measures how light enters and travels through your eyes (an 'auto-refraction' test)
- A series of close-up images of your eyes and retinas from different angles, showing the individual structure of your eyes (an 'OCT' test)
- Using a handheld device and special, light-weight probe (which will make slight contact with your cornea to measure rebound pressure) to perform an 'eye pressure' test

Some of the eye images can take a few minutes to complete and will require you to sit with your face positioned on a chin rest, focusing on a light beam. The researcher will provide you with instructions on how to do this and will work with you to make the experience as comfortable as possible. The eye pressure test takes around 5 seconds for each eye. Some people describe the sensation of this test as 'mildly irritating', like something touching their eyelashes. We can provide you with eye drops if you experience 'dry eyes'.

We will ask you to remove your glasses (if applicable) for these tests. If you do wish to wear your contact lenses to your visit, please remember to bring an appropriate storage case and any relevant supplies along with you.

Ear health and hearing

Hearing loss is a common condition that affects many Australians. While it is more common with aging, other factors such as occupational exposure to loud noises, untreated ear disease, certain illnesses and genetics can result in hearing loss at any age. Some cases of hearing loss are preventable.

To screen your hearing and your middle ear health during your visit, we will:

- Look inside your ear canal for signs of infection, inflammation, or other damage - using a device called an 'otoscope' (commonly used by GPs)

- Play a series of tones of different frequencies ('high' or 'low' notes) and volumes to you through a headset. You'll be asked to indicate when you can hear a tone (a test called 'audiometry').
- Insert a small, rubber-tipped probe (a 'tympanometer') into your ear, sending small pulses of varying air pressure and sound to assess the eardrum's function and flexibility.

These tests are pain-free and well-tolerated by most participants. A slight change in pressure inside the ear may be experienced during the tympanometry assessment.

Questionnaires (on-site) – Trauma, relationships, cognition, mental illness, and related wellbeing outcomes

Around 1 in 4 Australian adults live with a mental illness (most commonly depression, anxiety, and substance abuse disorders). As we age, we also become more prone to declining brain function, memory, concentration, and judgement – factors which may significantly affect our relationships, wellbeing, and quality of life. Family relationships – including any experiences of parenting or fertility issues – and experiences of trauma can impact health throughout the rest of a person's life.

To give better context to your health information and the outcomes of your study assessments, you will be asked to complete some further surveys on an iPad during your visit. These will cover a range of potentially sensitive, health-related topics including:

- Your fertility, reproductive and sexual health history
- Any use of recreational drugs and alcohol
- Your brain function, mood, mental health and wellbeing
- Your early life experiences
- Any childhood or later-life traumas
- Any history of sexual assault

Staff will be available if you require support, should these questions cause you any distress. You will have the option of selecting 'prefer not to answer' as a response.

Cognitive Assessment

A 15-minute cognitive (brain function) test will be conducted on an iPad or computer. This test will assess various aspects of your cognition such as memory, attention, and decision making.

Phase 3 - At home assessments

Following your on-site study visit, you will undergo a 2-week period involving some home-based assessments, as detailed below:

1. Faecal sample

Gut microbes, the tiny ‘bug’ colonies that live inside our digestive systems, play a key role in digestion and nutrient absorption; aid the immune system; and influence metabolism. Gut health can also contribute to determining body composition; may influence autoimmune diseases; and can affect mental health outcomes.

To learn more about your individual gut microbe and its potential impacts on your wellbeing, we will request that you provide a faecal (poo) sample – collected at your home – in the days following your study visit. A researcher will provide you with a sample collection kit to take home with you following your study visit. The kit will contain everything you need to collect your sample, including instructions, collection tubes, and a pre-paid Express Post envelope to return the sample to our lab.

We kindly request that:

- You collect your sample as soon as possible (preferably within four days) following your study visit
- You return the sample via post as soon as possible following collection

2. On your smartphone

Our on-site assessments collect some retrospective (i.e., in the recent past) measures of physical and mental health. However, by monitoring behaviours in ‘real time’, we can develop a more accurate understanding of contributors and outcomes of health. For this part of the study, you may be asked to download some phone apps. These are discussed below.

3. Passive phone use (Ksana EARS)

With your permission, the Ksana EARS smartphone app works may be used to collect the following types of data:

Keyboard inputs

Ksana EARS will passively collect words typed into your phone's keyboard over the 2-week monitoring period. This information allows us to examine whether relationships exist between patterns of text-based language use, behaviours, and health. This data may include text message inputs, social media activity, internet searches, and emails. This may involve the installation of a temporary, specialised keyboard on your phone.

Please note:

- Text entered into encrypted fields (i.e. passwords; credit card details) are **NOT** collected
- Text data will be automatically processed by computer algorithms – not viewed by people
- Text data will be organised and stored based on the types of words used
- Text data will not be linked to your identifying information
- Keyboard input information is stored as exact keystrokes, and will include time, date and timezone data
- Your data will be stored anonymously in an encrypted cloud

Location

Ksana EARS collects geographic location data to examine how the environments that we spend time in are related to our health and related behaviours (e.g. time outside, in the city/country, near services, etc).

Phone Usage

Ksana EARS may collect information about phone usage, including interaction patterns with apps; call frequency and duration; music media consumption; and walking habits. If you use an android device, the app will estimate overall phone screen use.

Everyday mood

Ksana EARS may prompt you to complete a brief (~2 minute) daily survey about your mood over the 2-week monitoring period. The survey will ask you to rate your general mood, physical activity level, and diet quality over the last 24 hours.

Important:

- To allow to consistent collection of data, we ask that you open the Ksana EARS app each day during your 2-week monitoring period

4. Wearable devices

Fitbit ‘Charge 6’

The research team will provide you with a Fitbit device at the end of your study visit, and will assist you with setting up the device and linking to the Fitbit app installed on your phone (you will need to use a Google account to access this app – we can assist you to set one up if you don’t already have one).

The Fitbit Charge 6 provides real-time data relating to the wearer’s heart rate, exercise intensity, daily step counts and sleep cycles to add further context to the study health data already collected from you. Through the Fitbit smartphone app, you will also be able to view and access all collected Fitbit data.

Study information collected via the Fitbit app will be stored and managed by a third party ‘Fitabase’, including your age, gender, height and weight. Data collected by Fitabase is stored securely and privately and will only be made available to the study team.

You may choose to delete this Fitbit account at completion of the study monitoring period. We ask that you wear the Fitbit at all times over the 2 weeks, including during showering and sleep, except when charging the device (or if you go scuba diving!). We will provide you with a pre-paid, Express Post envelope to return the Fitbit and charger to us at the completion of the 2-week monitoring period.

Participant feedback

We want to hear from you about your participation experience! After completing our study, you will receive a link to an online form where you can tell us what we did well, and what we can do better to improve the study for participants like you. All feedback is valued and welcomed.

Return of Information

You will have the option of having a ‘Personalised Bespoke Report’ (PBR) sent to you following your study participation. The PBR will outline general results of some of the assessments completed during your study participation (e.g., your hearing screen results). You can choose what you will receive out of the results that are available. The PBR will outline whether certain results fall outside of normal/acceptable ranges, along with any relevant recommendation(s) for appropriate follow-up health care.

Please see the [Patient Information and Consent Form](#) for further information regarding the return of the PBR, and some considerations that may be relevant for you.

Contact Us

If you have any questions after reading this participant information booklet, we invite you to visit our [website](#), or view or download our participant resources:

- [Participant Information and Consent Form](#)
- [Participant Journey Map](#)
- [Health, Lifestyle and Crisis Services Information Sheet](#)
- [Return of Urgent or Critical Results](#)
- [Privacy and Data Security Policies](#)

We invite you to email us at ourhealth-study@unimelb.edu.au with any further queries. Please note, this inbox is staffed during office hours only and is not an emergency contact.

[In a medical emergency or mental health crisis, please dial 000.](#)