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Oxford University Hospitals   
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## **KOALA study (Kids with Occlusion therapy for AmbLyopia)**

### **INFORMATION SHEET FOR PARENTS / GUARDIANS OF CHILDREN WITH AMBLYOPIA**

We would like to invite your child to take part in a research project. We hope that you would like your child to take part, but before you decide, it is important that you understand the study. Please read this information sheet carefully and discuss it with your child. If there is anything you do not understand, or if you would like more information, please email the study team: [koalastudy@ndcn.ox.ac.uk](mailto:koalastudy@ndcn.ox.ac.uk)

#### ***What is the purpose of the study?***

Amblyopia (also called 'lazy eye') is the most common cause of vision loss in children. It is a condition in which the brain detects less information from one 'lazy' eye than from the other eye.

Amblyopia is commonly treated using Occlusion Therapy (also called 'patching'). This involves covering one eye with a patch to increase brain signals from the 'lazy' eye. This treatment cures the condition in many children but is ineffective for others. Currently, it is not well understood how Occlusion Therapy changes the brain and why it is more effective in some children than others.

We are investigating how Occlusion Therapy changes signals in the brain to understand how the treatment works. We hope that these findings will lead to better treatment for Amblyopia in the future.

More information about the project is available on our website: [koalastudy.wordpress.com](http://koalastudy.wordpress.com).

#### ***Why has my child been invited to be involved in this research?***

We are inviting your child to take part because they are a young person, aged 5-8 years with Amblyopia and have been recommended standard NHS Occlusion Therapy.

We will recruit 35 children with Amblyopia and 35 children without Amblyopia.

Your child must:

- Have sufficient understanding of spoken English to understand a simple explanation of the study and follow simple instructions
- Have a parent or guardian with sufficient understanding of spoken English to provide informed consent for their child's participation.
- Have Amblyopia, and no other eye condition
- Not have undergone recent surgery/ not have surgery planned within the next 7 months
- Not have certain types of metallic implants in their body
- Not suffer from severe claustrophobia
- Not have a neurological condition

If your child wants to participate, we will arrange a screening phone call with you to check they can take part based on these criteria.

Information Sheet for Parents/Guardians of Children with Amblyopia  
KOALA study (Kids with Occlusion therapy for AmbLyopia)  
Professor Holly Bridge

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### ***Does my child have to be involved?***

No. You can ask questions about the research before you decide whether to allow your child to participate. If you do agree to take part, you may withdraw your child, without giving a reason at any point. A decision not to take part, or to withdraw from the study, will have no effect on your child's care or their legal rights.

Your child can stop being part of the study at any time, without giving a reason, but we will keep the data that has already been collected.

### ***When can my child take part?***

Our recruitment is ongoing. Your child's first visit will need to be just before they start Occlusion Therapy and while they are aged between 5 and 8 years. We can only accept new participants up until 01/03/2026, and until enough participants have been identified.

Visits will be arranged flexibly to fit around your schedule so that your child will not need to miss any school or other commitments.

### ***What will happen if my child takes part?***

#### Screening Phone Call

Once you send us an email to express your interest, a researcher will contact you to:

- Go over the information sheet for parents/guardians (this is the sheet you are reading right now) and explain what is involved for participants
- Go through a screening form with you to check whether your child can participate. This will include asking you some questions about your child's medical history
- Send you an electronic Orthoptic Pre-Screening consent form to sign and send back to the researcher.
  - This form gives your consent for the orthoptist to check your child's eyes and for the researchers to access the NHS notes relating to your child's orthoptic assessment.
  - Signing the pre-screening consent form does not mean that you are consenting to take part in the full study. It is only the first step to establish eligibility to take part.

If you decide that you would like to take part in the study with your child and you sign the pre-screening consent form, we will arrange your Orthoptic Pre-Screening Visit (Visit 1). We will inform your child's GP that your child is taking part in the study.

#### Orthoptic Pre-screening Visit (Visit 1)

The Orthoptic Pre-screening Visit will take place at the Oxford Eye Hospital, John Radcliffe Hospital, Headington, Oxford and will last up to 30 minutes.

The research orthoptist will use some eye-tests to investigate:

- The function of each of your child's eyes separately
- How their eyes work together (binocular vision)
- How their eyes are aligned (ocular deviation)

The research orthoptist will also take an image of your child's retinae (the back of their eye) using an 'Optical Coherence Tomography' machine (as shown in *figure 1*). This is safe, non-invasive and painless.



**Figure 1.** An orthoptist taking an image of a child's retina using an Optical Coherence Tomography Machine.

Your child will not need any eye drops.

The orthoptist will share this assessment with the researchers so that we can assess whether your child is eligible to take part.

### Arranging Study Visits

After the pre-screening, a researcher will contact you.

If your child is eligible to take part, we will invite you to take part in the study and schedule your study visits (Visit 2 and Visit 3). Visit 2 and visit 3 will be 6 months apart. Both visits will either take place in the FMRIB (Functional MRI of the Brain) Building on the John Radcliffe Hospital site, Oxford, or OHBA (Oxford Centre for Human Brain Activity) on the Warneford Hospital site, Oxford.

### MRI Brain Scan and Eye Test Visits (Visits 2 and 3)

Visit 2 and Visit 3 will last up to 3 hours each, during which time:

- We will help your child settle in and remind them what the visit involves.
- Your child will have an MRI scan. This is a safe and non-invasive series of brain scans.
  - It will last 45 minutes.
  - Your child will watch a cartoon film while in the scanner.
  - Your child will need to lie very still during each 5–8-minute scan. They will be given a short break between each scan when we will talk to them. We will provide materials to help you to prepare your child for what to expect before the session.
- Your child will do some eye tests so that we can understand how their vision works.
  - Eye tests will take place in a testing room in the same building as the MRI scan.
  - The eye tests will last about 20 minutes.
  - Your child will sit at a desk and look at a screen on which we will show them some images. We will record your child's eye movements and ask them to tell us what they can see.
- We have included lots of time for breaks and questions.
- You or your child can ask to pause or stop the research activities at any time if necessary.

You are encouraged to stay with your child throughout both sessions:

- During the eye tests, we will ask you to sit in the same room as your child.
- During the MRI scan, you may remain in the scanning room with your child.
  - To ensure you are safe to enter the scanning room, we must ask you the same safety screening questions about yourself which we asked you about your child; this includes asking you about your medical history. You may only enter the scanning room if approved

- to do so by the radiographer.
- If you are unable or would prefer not to enter the scanning room with your child, a member of the study team can remain with them in the scanning room.

### Between MRI Brain Scan and Eye Test Visits (Visits 2 and 3)

Your child will begin their NHS Occlusion Therapy shortly after visit 2. The research will have no impact on their standard treatment. As part of the research, your child will be asked to wear an 'Occlusion Dose Monitor' on their patch; this is a small device worn on a patch which records the length of time for which the patch is worn. The Orthoptist will explain how this device works during the Orthoptic Pre-Screening. You will be asked to return the Occlusion Dose Monitor at the last study visit.

We will get back in touch with you before Visit 3 to remind you of your appointment and complete MRI safety screening again to check whether your child's medical history has changed.

### Extra Information

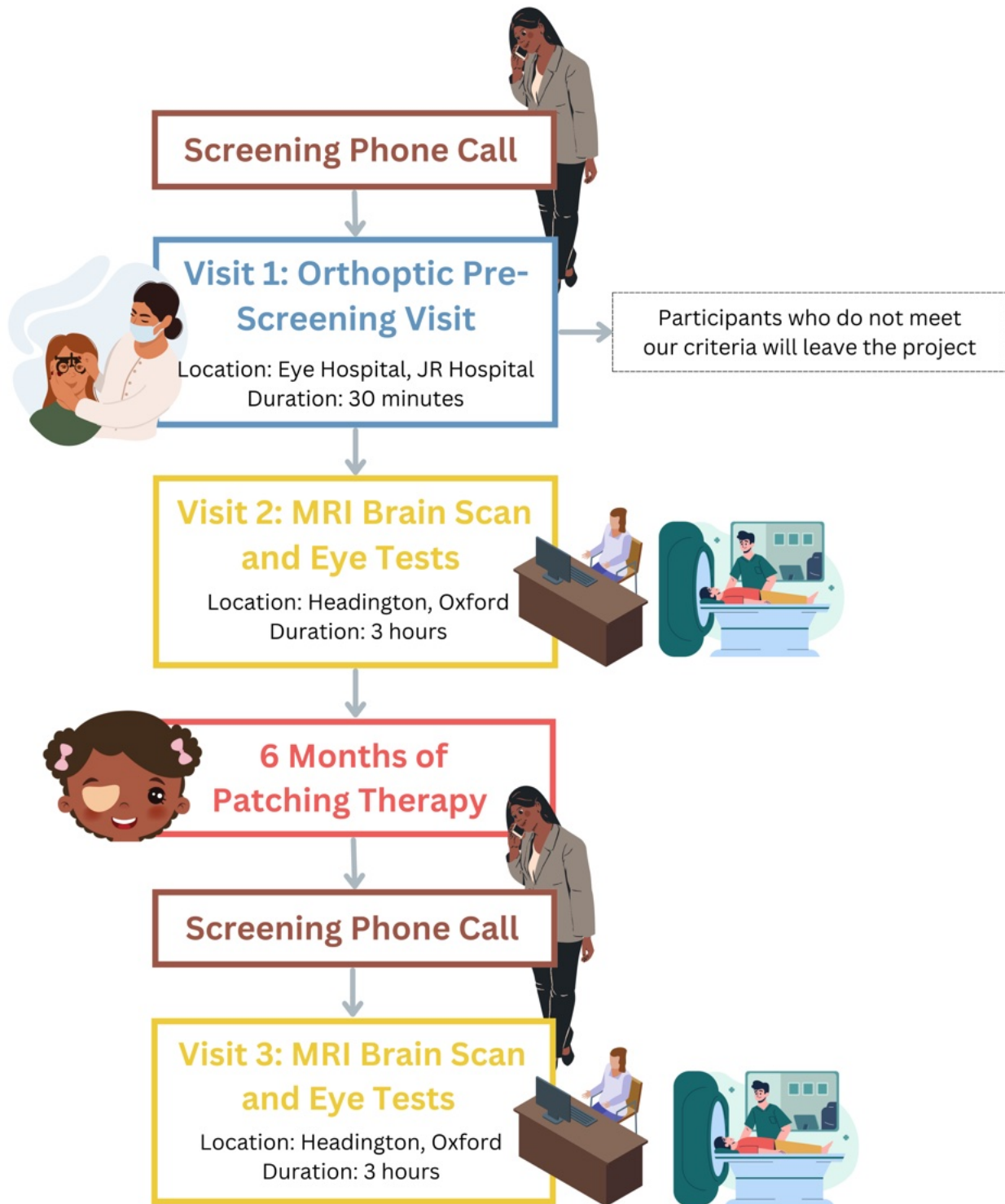
Please make sure that your child does not have any caffeine and sugary drinks on the day of study visits. This would affect the data we collect about your child's brain.

Please bring your child's usual glasses to all study visits.

Your child will have a second Optical Coherence Tomography scan during their NHS Orthoptic visit six months after beginning occlusion therapy.

All our researchers have enhanced Disclosure and Barring Service (DBS) clearance for working with children.

## Summary Flowchart



### ***What are the possible implications of the Orthoptic assessment?***

You and your child will have the opportunity to ask the Orthoptist any ophthalmic questions you may have about your child's eyes. If the Orthoptist detects an incidental finding during the screening tests this will be explained to you and your child, along with management advice the Orthoptist feels is appropriate. In the event of detecting an ocular abnormality during screening that the Orthoptist feels is an emergency, the Orthoptist will liaise with the Doctors in Eye Casualty. If your child is referred to Eye Casualty then a copy of the pre-screening report will be filed in your child's NHS notes.

## ***What are the possible disadvantages and risks in taking part?***

### *Disadvantages and Risks for your child*

MRI is safe and non-invasive and does not involve any ionising radiation (x-rays). It works through the use of a large magnet and is therefore not suitable for everybody. Before you consent to your child's participation, a researcher will arrange a screening phone call with you to ask you some MRI safety screening questions and determine whether your child can take part.

When entering the MRI scanning room, it is important that your child has no metal on their person. Just before your child enters the scanning room, we will ask your child to change into their own metal free pyjamas. In addition to the pyjamas, they may keep underwear and socks on. Please ensure that their pyjamas, underwear and socks do not contain any:

- Metal (including metal clips, zips and fasteners)
- Fabrics which contain metallic threads or have been silver impregnated (these are often marketed as 'anti-microbial/bacterial' or 'anti-odour/ stink')
- Labels
- Transfer prints
- Sequins

All metal jewellery, including body piercings, must be removed. Eye shadow and mascara must also be avoided, since some types contain materials that can interact with the magnetic field. If your child wishes to wear eye makeup to their scan we can provide makeup removal wipes but you are advised to bring your own makeup to reapply.

Your child will be introduced carefully to the scanner and allowed to leave at any stage. The scan will not begin until your child is comfortable. They will need to lie very still for short periods of time (5-8 mins) while each scan takes place to make sure the images are clear. We will provide cushions and a blanket to ensure they are comfortable and will give them regular breaks to rest. The scanner is noisy, so we will give your child earplugs to protect their hearing.

A screen above your child's head will display the cartoon film for them to watch. Your child cannot wear their own glasses in the scanner; prescription goggles will be provided so that they can clearly see the screen. Whilst in the scanner, your child will have a call button which they can press if they need to stop the scan or speak with the person operating the scanner.

It is important to note that we do not carry out scans for diagnostic purposes, only for research. Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor's appointment. In our experience with scanning children for research studies in Oxford, we see unexpected findings in about 4% of the children we scan. In such cases, we would ask a doctor to review the scan and determine whether it was thought to be medically important. You would be contacted directly and further investigations, such as a hospital (NHS) diagnostic scan might be recommended. Not all findings have implications for your child's current or future health.

Once anonymised, your child will not be identifiable from their data. They will not be identifiable from the research output.

### *Parents/ Guardians (only applicable if you enter the MRI scanning room with your child)*

To make sure you can safely enter the scanning room, you will be asked some safety questions before the day of the visit, and at the start of each visit.

We would need more information before you enter the scanning room if you have a heart pacemaker or stent, mechanical heart valve, mechanical implants such as an aneurysm clip, joint replacement (e.g., hip/knee), or if you carry other pieces of metal that have accidentally entered your body.

While there is no evidence that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit. We do not test for pregnancy as routine so if you think you may be pregnant you should not enter the scanning room.

If you have a new tattoo, you should not enter the scanning room until 48 hours after receiving the tattoo.

Before going into the scanning room, all metal jewelry (including body piercings) must be removed. You will be asked to empty your pockets, take off your shoes, and remove any other metal from your person (such as belts). We also recommend that you do not wear an underwired bra; an unwired bra may be worn. Lockers are provided to secure your personal belongings.

For your and your child's safety, you may only enter the scanning room if approved to do so by the radiographer.

Some of the scans are noisy, so we will give you earplugs to make this quieter for you. It is important that these are fitted correctly, as they are designed to protect your hearing.

*Please note: If you are unable or do not want to enter the MRI scanning room and would like someone in the room with your child, a member of the research team can stay in the room next to your child to reassure them.*

### ***Are there any benefits in taking part?***

There will be no direct benefit for you or your child in taking part in this study. However, by taking part you and your child would contribute to the understanding of how the brain is shaped by Amblyopia and Occlusion Therapy. We hope this understanding will lead to developments in treatment for the condition in the future.

### ***Expenses and payments***

You will be paid £10 in total if your child attends the 30-minute Orthoptist visit and is not eligible to complete the main study visits. You will be paid £45 for each complete visit to the MRI-Centre, which includes the brain scan and a vision test and can last up to 3-h. Thus, total payment will be £100 if your child completes the Orthoptist visit and all elements in the two MRI visits. Payment will be partial if visits are partially completed.

Appreciation tokens will also be given to your child for taking part in the study. This includes a toy and a certificate of completion.

You will be reimbursed for reasonable local public transport expenses or parking tickets incurred on all your study visits when submitted with a receipt. We cannot reimburse your travel costs without a receipt.

Payments and reimbursements are made through the Oxford University finance service to your personal bank account and need at least 3 weeks to come through.

### ***How have patients and the public been involved in this study?***

Parents of potential participants were involved in reviewing the study design and participant documentation. Changes were made based on their feedback to make the study clearer and easier to participate in.

### ***Will my child's taking part in the study be kept confidential?***

Yes. All study records and samples will be identified only by a code. We will only use names where this is necessary to contact you, on your consent form, and to link your child's MRI screening and Orthoptic Assessment records to your child. Information that can identify you or your child will only be held securely by Dr Betina Ip for the purposes of the study.

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you, your child or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

Responsible members of the University of Oxford, and regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

### ***What will happen to my/ my child's data?***

United Kingdom data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

We will be using information from you, your child and your child's Orthoptic Assessment records in order to undertake this study and will use the minimum personally-identifiable information possible.

This information will include your contact details, bank details, MRI safety screening forms, Orthoptic assessments, consent forms, assent form, Occlusion dose monitor data, MRI data and eye test data. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

We will store any research documents with personal information securely at the University of Oxford for 25 years after the end of the study as part of the research record, with the exception of your bank details (stored for 7 years), MRI safety screening forms (stored for 5 years), and contact details if you agree to your details being held to contact you about future research (stored indefinitely with a copy of the consent form). Data protection regulation provides you with control over your personal data and how it is used.

When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your information by contacting Dr Betina Ip ([betina.ip@ndcn.ox.ac.uk](mailto:betina.ip@ndcn.ox.ac.uk)) or the study team ([koalastudy@ndcn.ox.ac.uk](mailto:koalastudy@ndcn.ox.ac.uk)).

### Open Science

With your consent, we will put your child's de-identified retinal image, MRI images, eye movement data and behavioural response data in an online scientific data sharing repository such as 'Zenodo'. Facial features, direct identifiers (such as name, address and telephone number) and participant IDs will be removed from retinal and MRI images before being shared. Access to data will only be granted to individuals who: have a verified Institutional email or an ORCID, have a project researcher approved plan to use the data and sign a data usage agreement (which includes a commitment to not make any attempt to identify individuals from the data). The de-identification process and restricted use for legitimate research purposes ensures that your child's data are protected in accordance with GDPR.



### ***What if there is a problem?***

If you have a concern about any aspect of this study, please speak with the study team ([koalastudy@ndcn.ox.ac.uk](mailto:koalastudy@ndcn.ox.ac.uk)) or Dr Betina Ip ([betina.ip@ndcn.ox.ac.uk](mailto:betina.ip@ndcn.ox.ac.uk)). They will do their best to answer your questions.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you or your child suffer any harm as a direct consequence of your participation in this study.

NHS indemnity operates in respect of the clinical treatment provided.

If you wish to complain about any aspect of the way in which you or your child have been approached or treated, or how your or your child's information is handled during the course of this study, contact Dr Betina Ip University Tel: 01865 610472, University email: [betina.ip@ndcn.ox.ac.uk](mailto:betina.ip@ndcn.ox.ac.uk), or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) on 01865 616480, or the director of RGEA at [rgea.complaints@admin.ox.ac.uk](mailto:rgea.complaints@admin.ox.ac.uk).

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 221473, [PALS@ouh.nhs.uk](mailto:PALS@ouh.nhs.uk).

### ***Will the research be published? Could my child be identified from any publications or other research outputs?***

The findings from the research will be written up as academic publications with open access. The research will also contribute to the fulfilment of a doctoral thesis. It will not be possible to identify your child from these outputs.

At the end of the study, a summary of our findings will be published on the study website ([koalastudy.wordpress.com](http://koalastudy.wordpress.com)).

### ***Who has reviewed this research?***

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by West Midlands – South Birmingham Research Ethics Committee.

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

The University of Oxford is sponsoring this study.

The research is organised by Dr Betina Ip, a researcher at the University of Oxford. It is funded by a Royal Society Dorothy Hodgkin Fellowship to Dr Ip and a Medical Research Council research grant to Professor Holly Bridge and Dr Ip.

### **Participation in future research**

With your consent we will store your (parent/guardian) contact information indefinitely to contact you about future research. All contact will come from the research team of this study in the first instance. Agreeing to be contacted does not oblige you to take part in future research. You can be removed from this register at any time you wish by contacting the research team ([koalastudy@ndcn.ox.ac.uk](mailto:koalastudy@ndcn.ox.ac.uk)) or Dr Betina Ip ([betina.ip@ndcn.ox.ac.uk](mailto:betina.ip@ndcn.ox.ac.uk)).

***What should I do next?***

If you have any questions, would like to find out more, or are interested in participating in our study, then please get in touch using the following email: [koalastudy@ndcn.ox.ac.uk](mailto:koalastudy@ndcn.ox.ac.uk)

Please remember that you may withdraw your child at any time, without affecting their care and without giving a reason, by notifying the researcher.

***Further Information and Contact Details***

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please email the study team: [koalastudy@ndcn.ox.ac.uk](mailto:koalastudy@ndcn.ox.ac.uk)

***Thank you for taking the time to read this information sheet and for considering taking part in this study.***