OCELOT STUDY

Help us find out what outcomes for OA/TOF are the most important to measure

We invite you to take part in an on-line research study

- We would like to invite you to take part in the OCELOT study
- Before you take part, it is important for you to understand why the study is being done and what taking part will involve.
- Please read this information sheet carefully.
- Please get in touch if something is unclear or if you would like more information.

Who can take part in the study?

We are looking for 4 groups of people to be included in the OCELOT study

- People who were born with OA/TOF (children, young people and adults)
- Family members of people born with OA/TOF
- Health professionals (who have experience of treating people with OA/TOF)
- Researchers (who will use the core outcomes in research)

We want as many people as possible from each of these groups, from all over the world to take part. The opinions of all these groups will be brought together to decide on what outcomes are the most important

This study is looking at all ages – right from birth through to old age. You can take part in this study if you are aged 8 years and older.

What is the aim of this study?

The OCELOT study needs your help to find out **what outcomes are so important** that they should **always** be measured in studies for OA/TOF. We call these **the core outcomes**. If all future studies on OA/TOF measure these core outcomes, the results of the studies can be easily compared and combined. This may help identify if treatments are effective or if one treatment choice is better than another. This would be helpful for planning treatments throughout life right from birth to old age.

What is an outcome?

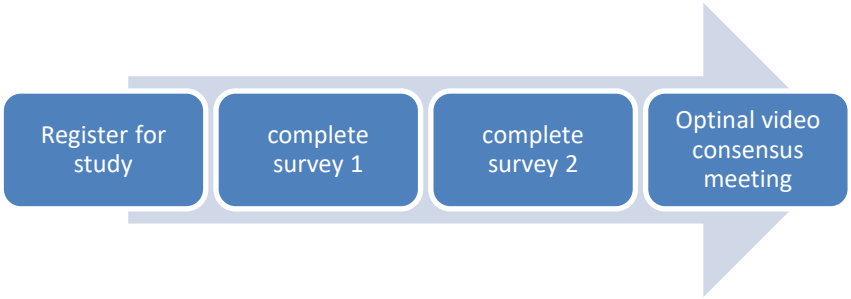
Currently, different studies that look at new treatments or treatments options for OA/TOF measure different outcomes. This makes it difficult to compare the results of different studies and means it is not possible to put the study results together. For example, one study for a common cold might measure "being able to breathe through your nose more easily" and another may measure "decrease in headaches experienced during a cold". The results of the treatments used in these studies can therefore not be compared to see which is best as they have measured different things – or different outcomes. This means that it is hard to know which treatment might be best for patients. When taking part in the OCELOT study – it is important to remember that we are interested in "what" outcomes should be measured. We want to know which outcomes are the most meaningful to you when considering being born with OA/TOF. There might be different ways to measure these outcomes, but we are interested in the outcome, and not in the way we find out that outcome.

More information on outcomes

This short [03:22] video explains a bit more about what core outcome sets are, why they are important and how patients and health professionals are involved in developing them. You can watch it here: https://youtu.be/AlLc2yN0pII

What does taking part in the study involve?

Taking part involves completing two online surveys, sent 4-8 weeks apart. These surveys are summarised below.



Are the surveys available in other languages?

The participant information sheet and surveys will be available in English language and Spanish. Unfortunately, these are not available in other languages.

Survey 1

Takes about 20-30 minutes to complete

In the survey, you will be shown a list of outcomes. For each outcome we want you to rate how important you personally think it is to measure that outcome in **all** future research of treatments/interventions for OA/TOF.

At the end of the survey, you can also suggest other important outcomes that you think are missing from the list.

The survey will be open for around 4 weeks from the 10th august 2022 If you register to take part but haven't completed the survey, we will send you a reminder email one week after you register and another a few days before the survey closes.

Once the deadline for completing the survey has passed, we will review everyone's responses. This usually takes around 2 weeks. We will then email you an invitation and instructions on how to take part in the second survey. We will send the second survey to the email address that you used when you registered to take part. Please let us know if your email address changes after you complete the first survey.

Survey 2

Takes about 30 minutes to complete

In the second survey, you will see the same list of outcomes from survey 1. You will also see a reminder of your own rating from round one along with a chart that shows you how the groups of people who took part in the first survey (people born with OA/TOF, family members, healthcare professionals and researchers) rated that outcome as well.

We would like you to rate the outcomes again. We would like you to think about how you and the other groups of people taking part in the first survey rated each outcome last time. This is a chance for you to **consider the opinions of others and to reflect on your own previous ratings**. We are trying to find out which outcomes patients, health professionals, and researchers can agree must always be measured. If you would like to change your ratings, please feel free to do so. On the other hand, it is completely fine if you would like to keep your ratings the same as before.

. **Your opinion in BOTH Survey 1 and 2 is extremely important in developing the core outcome set. It is very important that you complete BOTH surveys.**

Video meeting to discuss the results

Once everyone has answered both surveys, we will look at results. We will then invite a group of patients, family members, healthcare professionals and researchers to meet to discuss the results and agree the final core outcomes. This meeting will be held by video meeting.

You will be asked if you are interested in attending this video meeting at the end of the second survey. If you are interested in attending, we will send you more details including the date of the meeting and what to expect. You can then decide if you would like to take part in this final meeting.

How can I take part?

To register and take part in the online surveys please visit https://delphimanager.liv.ac.uk/ocelot/

What happens after the surveys and meeting?

By the end of the surveys and meeting we will have agreed all of the outcomes that should be measured. We will review this data and will publish this in a medical journal and present it at an international

conference. We will also write a report that explains the results of the study to people who are not medical. We will send you a copy of this if you have told us you would like this when you register for the study. The report will be sent by email and can be several months after the end of the study. We will also share the agreed core outcome set with relevant patient and professional organisations.

Will I be identified if I take part?

Only if you want to be! There is a question in the second survey that asks if you would like to be acknowledged for your contribution. If you answer yes, then your name will be included in the medical journal publication in a specific acknowledgements section. If your name appears there will be no way of knowing what you said and your own thoughts. All results

will be presented according to the different groups that took part (i.e. patients, healthcare professionals etc.). If you prefer not to be acknowledged/ identified, then just answer "no" and there will be no way of anyone identifying that you took part.

Will I get paid for taking part?

There is no payment for taking part in the study.

Are there any risks in taking part?

We do not expect there to be any major risks, although occasionally some people can find it upsetting thinking about outcomes related to their condition. If you do feel uncomfortable completing any part of the questionnaire or during the consensus meeting you can stop taking part at any time and, if you would like to, provide feedback on any areas of concern.

What if I am unhappy or if there is a problem?

We hope that you will not be unhappy but if you are unhappy or if there is a problem, please let us know by contacting the study team and we will try to help. If you remain unhappy or you would like to raise any concerns about the study with an independent person, please contact Alder Hey PALS team on 0151 282 4907 (option 4) or PALS@alderhey.nhs.uk

Where can I get more information?

If you have any questions about the OCELOT| study, please contact the study team: theocelotstudy@gmail.com