Quality of Life After Transplant

Participant Information Sheet for Transplant Recipients

This Participant Information Sheet will help you to decide whether you would like to take part in the *Quality of Life After Transplant* study. Taking part in this study is entirely **optional**, you are under no obligation to take part.

To help you to decide whether you would like to participate, it is important that you understand why the research is being carried out and what it will involve for you. Please take the time to read the following information carefully and discuss it with others if you wish. Please contact the study team at ODT.experiences@newcastle.ac.uk if there is anything that is not clear or if you would like more information.

You can access the surveys on the website: Quality of life after transplant surveys pilot test

This study is being conducted by Ben Rimmer and Daisy Robinson, who are researchers at Newcastle University.

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1. What is the purpose of this study?

Organ transplantation saves lives. But life after transplant surgery is not always easy and can result in physical, mental, and social challenges. This study follows on from the 'Experiences of Life After Transplant' study, which explored the quality of life experiences of solid organ transplant recipients. Those findings were used to inform the development of Patient-reported Outcome Measures (PROMs) to measure quality of life and symptoms in transplant recipients. PROMs are surveys that allow people to answer questions about their quality of life, health and wellbeing.

We are now testing the surveys and would like to invite people who **live in the United Kingdom**, **aged 18 years or older** and have **received a solid organ transplant 12 months ago or more** to fill them in online to help us understand how the surveys work in practice.

We hope the information gathered from this pilot test will help us to refine and validate the surveys and address any issues with their completion. Speaking to people from a variety of backgrounds will help to reflect the wide range of experiences and views there may be across the population of transplant recipients in the UK.

It is hoped that surveys exploring quality of life and symptoms for transplant recipients will have multiple uses, for example, to identify potential support needs, stimulate discussion at follow-up appointments, or track changes in quality of life over time.

2. Why have I been given this information sheet?

You have been given this information sheet because you have expressed an interest in hearing more about this study. This could have been through seeing the recruitment advert, finding out about the study from someone you know, or a conversation with someone from the study team. It may also be that you expressed an interest in taking part in the 'Experiences of Life After Transplant' study and indicated that you were happy to be contacted about future opportunities. If you feel you have received this information sheet in error, please let us know – if you do not wish to be contacted again, we will respect this request.

3. Do I have to take part?

No. It is up to you to decide whether to complete one or both of the surveys. You can take some time to think over the contents of this information sheet and talk to others about it if you wish before you decide if taking part is right for you. Please feel free to contact the study team if you have any questions: ODT.experiences@newcastle.ac.uk

4. What will happen if I take part?

If you are happy to take part, please find the links to each survey on the website: Quality of life after transplant surveys pilot test

We know some people may prefer or need to fill in the survey on paper. In this pilot test we are only using an online survey, though we intend to add a paper option for the survey in future.

You will first complete the 'consent' section of the survey. This is to show you understand and agree to take part. You will then fill in the survey online. We think most people will need about 10-15 minutes to complete each survey. You can decide whether you complete one or both of the surveys.

At the end, you have the option to share what you thought about the survey. You are also asked a bit about your background, such as your age and gender, so we can understand the different groups of people who have tested the surveys. You do not have to give this information if you do not want to. Your answers will be anonymised and only accessed by members of the research team.

We also ask if people will fill in the surveys again two weeks later in a **repeat test**. The survey is the same both times as we are checking to see if the questions work as we expect. If you want to take part in the **repeat test**, we will ask for your email address. This is so we can send a link to the second survey. We will **only** use this email address to **contact you about the repeat test** and link your answers. Once the pilot test is complete, we will delete your email address from our records and your answers will remain anonymised.

5. What will happen if I do not want to take part, or I change my mind?

If you decide you do not want to take part, we completely understand. When you submit your answers to the survey, they are automatically recorded. It will not be possible to remove your answers after they are submitted. If you have given your email address and then change your mind about the Repeat Test, you can contact the research team at ODT.experiences@newcastle.ac.uk to have your email address deleted from the study records. Your first set of anonymised answers will remain in the records. You do not have to give a reason for changing your mind about the Repeat Test.

6. What are the possible disadvantages and risks of taking part in this study?

You may find answering questions about your quality of life and symptoms upsetting. You do not have to complete the surveys if you do not want to. If you do become upset at any time you can choose to pause or stop completing the survey immediately. You can discuss mental health concerns with a healthcare professional such as a GP.

7. Are there any possible benefits to taking part?

There are no direct benefits for you from taking part in this study, but it will help us to ensure that the surveys work as well as possible. We hope that the surveys will be used to positively impact quality of life after transplant for transplant recipients in the future.

8. How will my information be used?

We will keep all information about you safe and secure, stored at Newcastle University. We are bound by a strict code of confidentiality. Storage and deletion of all personal or identifiable data, such as your email address, will comply with data protection legislation, such as GDPR, and local guidelines. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a study ID number instead. We will destroy your personal details at the end of the study. If you have previously requested to receive a short summary of the results and/or have stated that you would be happy to be contacted about future related work, we will keep your details to fulfil these requests before destroying them.

The information that the study team will use for analysis will all be anonymised, such as the survey response. We will collect all the answers together and test how well the survey questions have worked. For example, we will check if any questions are often missed out. This could mean the question does not make sense to people. If you provide your email address to be part of the Repeat Test, we will only use this to contact you with a personal link to complete the survey a second time two weeks later. If you do not respond, a further email will be sent after another week. After this, or completion of the Repeat Test, your email address will be deleted. When we link the answers from the two different times in the Repeat Test, we can see if the answers are very different. This could mean it is not clear to people what the question is asking about. We can then change the wording or layout of the survey before we use it in future.

9. What will happen to the results of the study?

The results from this study will be published in scientific journals where the quality of the results will be assessed. In addition, results will be presented at national and international academic and research meetings. The results will also be reported to the Funder. We will write our reports in a way that no-one can work out that you took part in the study.

Fully anonymised survey data may also be made available to research students associated with the research team to help inform other studies. **Your identity will always be protected**.

10. Who is organising and funding this study?

This work is part of the research taking place in the Newcastle and Cambridge Blood and Transplant Research Unit in Organ Donation and Transplantation. The Research Unit is

funded by the National Institute for Health and Care Research and backed by NHS Blood and Transplant. You can find more information on the Unit's website: http://odt.btru.nihr.ac.uk/theme-6/.

This study is being led by Catherine Exley, Professor of Qualitative Health Research and Dean of Population Health Sciences Institute, Faculty of Medical Sciences, Newcastle University. The researchers who are conducting the study work directly with Catherine Exley at Newcastle University.

11. Who has reviewed this study?

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This Committee includes members who are internal to the Faculty. This study was reviewed by members of the Committee, who must provide impartial advice and avoid significant conflicts of interests. Reference number 3072/58662.

12. What if there is a problem?

We do not expect anything to go wrong as a result of you taking part. If you have a concern about this study or the behaviour of one of the researchers, you can seek advice from someone who is not working on this study by contacting sponsorship@newcastle.ac.uk and quoting the reference number 3072/58662 in your email.

If you have any concerns that you wish to discuss with Catherine Exley, the lead for this study, she can be contacted using the details below:

Catherine Exley
Professor of Qualitative Health Research
Dean of Population Health Sciences Institute
Faculty of Medical Sciences
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NE2 4HH
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Thank you for taking the time to read this information sheet.