

Participant Information Sheet for: ostomates who are invited to the “Ostomate’s quality of life” survey

Study Title: Re-Designing the Ostomy Bag

Invitation

I am Ivana Lobet, a student of the Msc Healthcare and Design from Imperial College London. I am conducting a research project inviting ostomates to talk about their daily experience living with an ostomy bag.

Before you decide if you want to participate in this survey it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

In the UK, 1 out of 500 people currently live with a stoma. A stoma is a hole in the abdomen that diverts the flow of faeces and/or urine, this waste is then collected in a stoma bag. The reason why they have a stoma can be because they suffer from bowel disease or bowel cancer among other reasons. Ostomates are those who live with ostomy bags. Ostomy bags and stomas still nowadays a taboo topic, up to one in four ostomates experience psychological symptoms including angst, fear, social isolation and depression. Innovation in this area is needed.

This project aims to look at how we can improve the quality of life of ostomates by redesigning the ostomy bag. To do so, we want to better understand the challenges and journeys of people living with ostomy bags.

This project will involve your participation in a survey.

You will be asked to answer about 20 questions.

Why have I been chosen?

You are being invited to take part in this research to provide your perspective and experiences in relation to living with an ostomy bag. In this survey you will be asked about some questions regarding your quality of life, you will need to think about your daily challenges.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep.

What will happen to me if I take part?

The survey is done using the software Qualtrics, you can answer it at a time that works for you at a place that is convenient for you.

The survey can take from 5 to 30min to complete, depending on the level of detail you want to give.

What do I have to do?

We will not ask you to do or change anything about your life in order to be part of this project. If you agree to participate in this study, you will be expected to answer the questions from the survey.

What are the possible disadvantages and risks of taking part?

You may decide to share some personal information when answering some of the questions, or you may also feel uncomfortable answering questions about some of the topics.

You do not have to answer any questions if you don't wish to do so. However, we do not wish for this to happen, you do not have to give us any reason for not responding to any question.

What are the possible benefits of taking part?

Your participation in this project will help provide perspective from ostomates on an important healthcare issue. It will also help to understand if surveys such as these create more tailored, more useful solutions for innovating in this area.

The survey will hopefully give you an opportunity to see your own view on your quality of life as an ostomate.

We cannot promise this study will help you, but the answers may provide information that will eventually improve the healthcare of ostomates and their daily life.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator Dr Jamie Murphy at jamie.murphy@ic.ac.uk. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

Will my taking part in this study be kept confidential?

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep identifiable information about you.

- *10 years after the study has finished in relation to data subject consent forms.*
- *10 years after the study has completed in relation to primary research data.*

Further information on Imperial College London's retention periods may be found at <https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf>.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Dr Jamie Murphy at jamie.murphy@ic.ac.uk

Imperial College will collect information from you for this research study in accordance with our instructions.

Imperial College will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Imperial College and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in Imperial College who will have access to information that identifies you will be people who need to contact you for purposes of the project or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. We will keep identifiable information about you from this study for 10 years after the study has finished.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

We are fully GDPR compliant. You can find more information about the GDPR in here: <https://www.imperial.ac.uk/admin-services/secretariat/information-governance/data-protection/internal-guidance/guide-3---introduction-to-gdpr/>

INTERNATIONAL TRANSFERS

Although it is very unlikely to happen in this particular project, there may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

CONTACT US

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Imperial College will collect information for this research study in accordance with our instructions.

Imperial University College will keep your name and contact details confidential and will not pass this information on. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

What will happen to the results of the research study?

If participants wish, they will receive a summary of the project once it is complete in October 2019. This will be shared electronically via email, if they provide these contact details.

Who has reviewed the study?

Head of department and the Joint Research Compliance Office have reviewed this study.

Contact for Further Information

If you have any questions, do not hesitate to contact me. You can ask them now or later. You can contact me at any time to the following:

Ivana Llobet

Email: ivana.llobet17@imperial.ac.uk

Tel: +44(0)7568967871

By clicking “next”:

- I confirm that I have read and understand the participant information sheet dated 26/07/2019 version 10.0 for the above study and have had the opportunity to ask questions which have been answered fully.
- I understand that my participation is voluntary, and I am free to withdraw the survey at any time, without giving any reason and without my legal rights being affected.
- I consent to take part in this study.

Thank you for taking part in this study.