Participant Information Sheet

Title of the investigation:
CLOUDS Study - Cross-sectional investigation of burden of disease in newly operated stoma patients

Invitation

We would like to invite you to take part in a study. By 'study' we mean a research project where we would like you to take part in an online survey. The research will take place over a period of 6 months, between December 2021 and December 2022. Your participation in this study will last approximately one week.

Before you decide if you want to participate, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

The purpose of this study is to better understand the impact of living with a stoma on people who have had an ileostomy, or a colostomy.

Why have I been invited?

- You are invited because you have either an ileostomy or colostomy with liquid faecal (poo) output.
- You have had your stoma for less than twelve (12) months.
- In total, up to 200 participants with similar condition will be involved in the study
- The study is taking place in the United Kingdom.

Do I have to take part?

No, your participation is voluntary, and you can withdraw your consent for participation at anytime without giving a reason or explanation. If you decide to withdraw from the study this will NOT have consequences for your clinical care in the future.

What will happen to me if I decide to take part?

- If you decide to take part, we will arrange a phone call to help you understand more about the study. We will explain in detail about what your participation involves, and you will be able to ask any questions you may have. You are welcome to bring a family member or a friend to this meeting. If you choose to participate in the investigation, we will then ask you to sign a consent form, in which you agree to participate in the study as described in this information sheet.

- During the study you will be invited for a virtual meeting with a member of the research team who will ask you a series of questions about your experience of living with a stoma and some personal information.

- Virtual calls: All meetings will be planned to be virtual using Microsoft Teams, Skype or Face Time, if technically possible. If a virtual visit is not possible, a face-to-face meeting will be scheduled, either at your home or at the hospital site.

- You will also be asked to fill in two (2) surveys. The surveys will be sent to you via a link in an email or SMS (text).

  The first survey will ask you questions on your personal experience of living with a stoma.

  The second survey is sent out at the end of the study so that you can feed back your experience of taking part in research. This is a way of demonstrating that your contribution is valued, and to help improve the way research studies are designed and delivered, now and in the future.

- We will ask you to keep information about the study confidential, meaning that you are welcome to discuss the trial with your loved ones and of course also your GP/stoma nurse if there should be a need for this, but we must ask you not to share information about the study in a larger forum, such as on social media.

Summary of the study

The study will be conducted from December 2021 to December 2022. Once enrolled your involvement will be for approximately one (1) week.

Initial meeting – Study meeting 0 (enrolment/inclusion) – approximately 30 minutes

To ensure that you receive proper information to help you decide if you would like to participate, you will be invited to an initial meeting (meeting 0), which will be conducted as a phone call or as a virtual meeting. During this meeting, the study will be thoroughly explained to you, and you will have an opportunity to ask as many questions as you like. Once all of your questions have been answered, and you are fully satisfied, you can then decide whether you would like to participate. If you agree to participate, you and the member of the research team will sign the consent form. You and the researcher will then schedule the date for your next call (study meeting 1). However, the screening and the first test meeting can be on the same day, if possible and preferred by you.

Interview – Study meeting one – approximately one hour

At this meeting some personal information will be recorded such as your medication, age, information about your stoma, current leakage, output and your ability to use a smartphone and apps etc. You will also be shown how to log on to the online survey questionnaires that will be sent out to you via email or SMS (text) and you will answer a few of the survey questions under the supervision of the researcher so that you know what to do.

Online Study Survey – approximately one hour
You will be sent a link to the online survey via email or SMS (text) and you will be asked to complete this within two (2) days of study meeting one. This survey will ask you questions about your experience of living with a stoma.

Patient Research Experience Survey – approximately 15 minutes
After you have completed the online study survey, you will be asked to complete Participant Research Experience Survey. It is important to give people who take part in health research the chance to tell us what it is like. We value your support and want to make your research experience as positive as possible. These surveys are entirely voluntary and anonymous. No-one has to take part and no matter what they tell us, it will not affect their treatment or stop them from taking part in health research in the future.

Are there any medical / clinical reasons why I may not be able to take part?

If you have any of the following conditions, unfortunately you will not be able to participate in the study:

1) If you are currently receiving or have within the past 30 days received topical (e.g. lotion or spray) steroid treatment in the area around your stoma
2) If you have a complicated stoma
3) If you have more than one stoma
4) If you have stage 4 cancer
5) If you have a urostomy, or colostomy with firm stool/poo

Note: If you take contraceptive medication, you can still participate in the research.

Are there any other reasons I may not be able to take part?

Please inform the researcher if you are participating in any other research at the same time to ensure that there is no conflict.

Are there any possible disadvantages or risks from taking part?

There are no risks associated to this study since the study will not test any products.

What are the possible benefits of taking part?

There are no direct benefits associated to the participation in this study, other than contributing to the understating of how a stoma impacts on the lives of those people who have had an ileostomy, or a colostomy.

Will I be reimbursed for taking part?

- You will receive £25 for attending Interview - Study Meeting 1 and £25 for the completed Online Study Survey. This is GBP £50 in total to cover time spent and inconvenience caused by your participation in the study.
- The total allowance of £50 is taxable and the payments will be made as a gift voucher after each activity. Depending on your personal circumstances, part of this payment may be taxable if it exceeds the allowance threshold set by HMRC. Participants are reminded that they are responsible for their own tax affairs. If you are receiving benefits you should check with your benefits provider whether payments from clinical trials will affect them.
- You will also be compensated for transportation costs, if any. Please let the researcher know about all your expenses and you will be reimbursed.

Will my General Practitioner (GP) / family doctor be informed of my participation?

Your general practitioner will be informed of your participation in this study.

Who is organising and funding this study?

Coloplast UK & Ireland, Nene Hall, Peterborough Business Park, Peterborough, PE2 6FX, United Kingdom is sponsoring this study, and will cover salary to researcher(s), costs of study surveys, materials, and data analysis.

How will we use information about you? / Will my taking part in the study be kept confidential?

Your participation in the study will be kept confidential, and we have taken all measures to ensure the security of the data collected during the study.

In the UK we follow the General Data Protection Regulations (GDPR) rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules. Please see this link from the NIHR (National Institute for Health Research) for further information: https://www.ibdbioresource.nihr.ac.uk/wp-content/uploads/2020/02/My_data_and_research.pdf

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments or try to better understand a disease area, they need to be able to prove that they need to use patient data for the research. In legal terms this means that they have a 'legitimate interest' in using patient data.

If they could do the research without using patient data, they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

Data collected in this study will be stored outside the UK. The Sponsor is taking appropriate safeguards to make sure that your personal information is protected.

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.

Additional information
We understand that GDPR and data can be a complex area – so if you have questions or queries regarding Coloplast's handling of personal information, please contact Coloplast's Data Protection Officer at dataprotectionoffice@coloplast.com.

If you are not happy with the Sponsor's response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) in the UK (www.ico.org.uk or 0303 123 1113).

For additional information on how we process your data in Coloplast, in general and in this study, please visit this link:
https://www.coloplast.com/global/privacy-notice/

Who has reviewed the study?

All research like this is considered carefully by an independent group of people, called a Research Ethics Committee, to protect participants' interests. The ethics of the study has been reviewed and approved by the *Insert name* Committee.

What will happen if I don't want to carry on with the study?

- Your participation is entirely voluntary, and you can withdraw your participation at any time without having to give a reason or explanation.
- If you decide to withdraw from the study, this will NOT have consequences for your clinical care in the future.
- If at any point after you withdraw the study you experience problems that you believe are related to your participation or the products used, we will ask you to contact the researcher immediately.
- Coloplast will stop collecting data, but data collected up until the point of withdrawal of consent will be stored and included into the study analysis. All your data will be handled confidentially following the applicable regulations explained before.

What will happen to the results of the study?

Collected data in the study will be analysed and the results will be written in a final report and/or scientific publication. The results of the study, positive as well as negative and/or nonconclusive, will be published at a public webpage (e.g. the public database www.isrctn.com) as per current regulations.

It will not be possible to identify you in any report or publication.

What if there is a problem?

For any complaints or questions during the study, you are more than welcome to contact:

CHIEF INVESTIGATOR
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The Newcastle upon Tyne Hospitals NHS Foundation Trust
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UK
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Thank you for taking your time to read this participant information sheets

We hope that the Participant Information Sheet has given you sufficient information in what participation in this study involves, and that you feel informed enough to decide whether you would like to participate or not. We recommend that you keep this Participant Information Sheet in case you want to remind yourself about this study.

Consent Form to participate in the study

Participant identification number:

IRAS Project number: 301896

REC: XXXXX

Title of Project: Cross-sectional investigation of burden of disease in newly operated stoma patients

Study Number: **CIPUK01**

Site Number: **UK001**

Name of the researcher:

Participant declaration:

If you agree, please initial box

I confirm that I have read the information sheet dated DATE (version 2.0) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary, and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by representatives of Coloplast and from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I hereby give consent for Coloplast or its representants to use my data to further develop and improve Coloplast's products and services, and/or for education purposes.	
I agree to my General Practitioner being informed of my participation in the study.	
I agree to take part in this study.	

_____ _____ _____

Name of Participant (Capital letters) *Date* *Signature*

_____ _____ _____

Name of Person taking consent (Capital letters) *Date* *Signature*

When completed: 1 copy for participant and 1 copy for site file.