Ulster University

Nutrition Innovation Centre for Food and Health (NICHE)

Participant Information Sheet

Dietary advice and ileostomy– the experiences of people living with an ileostomy and health care professionals.

You are being invited to take part in a research study exploring the experiences of health care professionals in relation to providing dietary advice to those living with an ileostomy. Before you decide whether or not to take part, it is important that you understand the purpose of the study and what you will be asked to do. Please read the following information and do not hesitate to ask any questions about anything that might not be clear to you. Make sure that you are happy before you decide what to do.

Thank you for your time.

What is the purpose of the study?
Ileostomy formation can have a major impact on an individual's diet and therefore nutritional status. Dietary advice may be provided by health care professionals (HCPs; stoma nurse, dietitian, surgeon), social media outlets, charity organisations or peers. A low fibre diet is typically advised for the first 6-8 weeks following surgery, and you may be instructed to avoid certain foods and / or drinks to aid stoma management. Often, these dietary changes are sustained many months, and even years, after surgery.

The purpose of this study is to explore your role in providing dietary advice to people living with an ileostomy; how, when and where is dietary advice provided and what challenges (if any) have you, your colleagues or your clients faced.

Why have I been chosen?
You have been chosen because you meet the inclusion criteria of being a registered Stoma Care Nurse or dietitian (regularly working with people living with an ileostomy) and are able to attend one of the virtual / in-person interviews in your area.

Do I have to take part?
It is up to you to decide if you would like to take part in this study. If you decide to participate, you are free to withdraw from the study at any time without giving a reason. Any information that may have already been taken before your decision to withdraw from the study may be used for the purposes of this study unless you inform us that you do not wish for this to happen. If you decide to take part, you will be asked to hold on to this information sheet and you will also be asked to sign a study consent form.

What will happen to me if I take part?
If you decide to take part in the study, you will be asked to take part in a 1-1 interview, where a trained researcher will take you through a guided discussion to explore your experience of providing dietary advice to people living with an ileostomy. The interview take place either online (via Microsoft Teams) or in person, depending on your availability. The discussion is expected to last 20-25 minutes. Please note that all views and opinions are valid, and there are no right or wrong answers.

If you would like to check your connectivity with the online interview platforms (i.e., Microsoft Teams) we will offer you a "test run" ahead of the actual interview.

Some socio-demographic variables and information your job role will also be collected.

All discussions will also be video/audio recorded to enable us to make best use of all information gathered for analysis purposes. Electronic recordings and transcriptions will be anonymous – any identifying information (e.g., names, date of birth) will be censored. Recordings and transcriptions will be held securely for a maximum of 10 years, after which time they will be deleted. The chief investigator of the study will act as custodian for this data.

What are the possible disadvantages to taking part?
There are no known risks or disadvantages to taking part in this exercise.

Are there any possible benefits in taking part?
There is no intended benefit to you as a volunteer from taking part in the study.

What if new information becomes available?
If new information becomes available during the study, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your researcher will make arrangements for you to terminate your participation in the study. If you decide to continue in the study, you will be asked to sign an updated consent form.

Also, on receiving new information your researcher might consider it to be in your best interests to withdraw you from the study. They will explain the reasons and arrange for your care to continue.

What happens when the study ends?
At the end of the study, the data from the interviews will be transcribed (typed out) word-for-word and analysed for common themes. Personal details/information will be removed from any written data records so you will not be identifiable. Video recordings will only be used by the researchers to help understand any important non-verbal cues during discussions and to help with analysis.

What if something goes wrong?
It is extremely unlikely that something will go wrong during this study. However, you should know that the University has procedures in place for reporting, investigating, recording, and handling adverse events and complaints from study volunteers. The University is insured for its staff and students to carry out research involving people. The University knows about this research project and has approved it. Further details on the Complaints Procedure can be found in the University's Research Ethics and Governance" webpage (Internet address *http://research.ulster.ac.uk/rg/0208ResearchVolunteerComplaintsProcedure.pdf)*

Any complaint should be made, in the first instance, to the Chief Investigator (Dr Chris Gill, contact details at end of document) identified for this particular study. Any complaint you make will be treated seriously and reported to the appropriate authority. You can contact the Clinical Trails Manager (Dr Ruth Price) of the Human Intervention Suite at Ulster University by telephone +442870123878 or email rk.price@ulster.ac.uk to assist you in this process, if you consider contacting the Chief Investigator (Dr Chris Gill) unsuitable.

Confidentiality

All information you provide will be treated with the strictest confidence. You will be assigned a unique study ID which will ensure all files and data collected as part of this study are kept

anonymous. Electronic data files will be kept on a password protected computer server, and any hard copy data files will be kept securely under lock and key. Your personal details (for example, name, address, date of birth) will not be released to any other organisations or body. Only those researchers listed on the Ethical Approval for this study will be granted access to data relating to this study. Study records and data may also be looked at by people from regulatory authorities to check that the study is being carried out correctly.

The data you provide may be used in future research studies depending on the level of consent you provide (one of two options selected on the study consent form). This will be fully explained to you by the researcher taking your consent, and you will be given time to make your decision.

All data collected as part of this research study will be stored appropriately for 10 years after the study is complete. All records will be disposed of as required by the Data Protection Act. It should be noted that Freedom of Information legislation will allow access to certain non-personal or generalised data.

Privacy notice and sponsor compliance with GDPR and the Data Protection Act 2018

Ulster University is the managing organisation for this study, and we will use information gathered from you and/or your records to carry it out.

We will act as the data controller, which means that we are responsible for looking after your information and using it properly, as stipulated in GDPR and the Data Protection Act 2018.

Ulster University will keep identifiable information about you for 10 years after the study has finished.

You can find out more about how we look after your information at:

https://www.ulster.ac.uk/about/governance/compliance/gdpr

As a University we use personal identifying information to conduct research to review and improve people's health, wellbeing and care, the services they use and our understanding of the world in which we live. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personal identifying information from people who have agreed to take part in research. This means that when you agree to take part in a study, we will use your data to conduct the research and analyse the information and findings.

We need to manage your information in specific ways in order for the research to be reliable and accurate and therefore your rights to access, change or move your information are limited.

You should note that 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 personal identifying information possible.

Health, care and other human 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 University and appropriate UK policies and codes of practice.

The only people in the University who will have access to your personal identifying information will be those who need to contact you for the study or to carry out audits of the research. Any identifiers will be removed prior to publication as required under Data Protection Legislation.

Freedom of Information Legislation will allow access to certain non-personal or generalised data.
Additional information on GDPR is provided in the privacy note you have been provided with.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. 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).

Our Data Protection Officer is Eoin Coyle; you can contact him at e.coyle2@ulster.ac.uk

What will happen to the results of the study?
It is expected that the results will be used in publication of academic papers; you will not be identified in any publication as required under Data Protection legislation; it is likely that papers will be published within 2 years of completion of the study.

Who is organising and funding the research?
This research has been organised and funded by Ulster University.

Who has reviewed this study?
This study has been reviewed by the Ethical Filer Committee in the School of Biomedical Sciences at Ulster University.

Contact for further information:

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Thank you for your interest in this study and for taking the time to read this information sheet.